

Introduction to Management of Healthcare Organizations
HPM 510s Summer 1 Session
Syllabus 2015

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Office Hours: Office hours can be arranged. Please check daily schedule
on course website for availability

Text and Reading Materials:

No text requirement. Optional text follows:

- Longest BB, and Darr K. Managing Health Services Organizations and Systems, 6th ed. Baltimore: Health Professions Press, 2014.
- Rakich JS, Longest BB, Darr K. Cases in Health Services Management. Health Professions Press. Baltimore, MD. 2010 5th Edition
- Kovner AR and Neuhauser D. Health Services Management: Readings, Cases and Commentary, Health Administration Press, 2009.

Developing Countries and Resource Constrained Environments. Optional resources follow:

- World Health Organization. Making Health Systems Work Series.
<http://www.who.int/management/mhswork/en/index.html>
- Partners in Health. Program Management Guide.
<http://www.pih.org/library/pih-program-management-guide>

All other reading requirements listed with each class.

(Conway) Notes to be provided in class.
(Link) are online.

Course Outline:

This course provides an introduction to health management with a focus on four of the major tasks confronting managers of health care organizations. After an introduction to management and organizational theory, the course focuses on organizational strategy, the management of change and improvement, leadership development, and the management of human resources. This course makes use of case-based classroom

discussions, on-the-spot problem solving, guest lectures, and selected conceptual readings.

Course Learning Objectives:

By the end of the course, the student is expected to have enhanced skills and knowledge in their ability to:

1. Understand the key principles of management.
2. Describe, through content and illustrative case, how these are applied effectively in public health and health system organizations.
3. Present specific approaches to successfully drive for optimal results strategy, change, and improvement.
4. Successfully deal with the ongoing issues and challenge of managing human resources and careers of self and others.

Course Ground Rules:

In the first class, we will review and accept the ground rules that will guide each class. Each class will open with a review of these ground rules to optimize the educational environment and experience for students, guest faculty, teaching assistant, and teachers. As a draft, ground rules include:

- RESPECT: Nothing more important than RESPECT
 - Celebrate diversity
 - Challenge one another, but do so respectfully.
 - Do not interrupt one another.
 - If you are offended by what's said, acknowledge immediately or bring to attention of Professor or TA.
- ACTIVE: Listen actively and attentively.
- QUESTION: Ask for clarification if you are confused.
- IDEAS: Critique ideas, not people.
- BUILD: Build on one another's comments; work toward shared understanding.
- LEARNING COMMUNITY: Do not monopolize discussion.
- CONFIDENTIALITY: Consider anything said in class confidential.
- TIME: Begin and end on time with YOU!

Voices of Innovation, Transformation, Leadership, Management:

Each week around HSPH, Harvard and the Greater Boston and Cambridge community, there are opportunities to hear from great leaders. In the spirit of shared learning, at the start of each class, we'll discuss "Who'd you hear speak?" and "As a student of management what was a key take away?"

(Note that HSPH maintains a great video collection, Voices from the Field, of interviews with leaders, many of which focus on management.

<http://www.hsph.harvard.edu/policy-translation-leadership-development/decision-making-voices-from-the-field/archive-of-videos/>)

What worked and what could be improved?:

Each week the TA will ask you to complete an anonymous survey where we will ask you what worked for you and what was unclear or could be improved. This could be either

content or presentation. This data will be summarized for continuous improvement of the course and shared at the start of the subsequent class. Although results are anonymous, completion of these surveys will be part of your individual class participation grade.

Outcome Measures:

Assignments to measure the student's competence in the course objectives should be in the following format and are detailed below. **Each assignment should be added to the appropriate drop box on the course website, on or before the specified dates (23:59 EDT).** Please note: All papers must be typewritten, 1.5 line spacing, using Arial or Times New Roman font, and font size 12.

MANAGEMENT: JUST IN TIME (JIT). Conducted 5-6 times in semester.

- In the first class you will be put into groups of 5-6 which will be used for the semester
- On 5-6 occasions I will spring a "Just in Time" question/problem to you and you will be asked to identify 3-5 next steps.
 - You will meet as a group for 10 or more minutes to identify the steps. The more tangible the better. Citations/resources always helpful.
 - One member of the group will send the instructor an email immediately with your 3-5 next steps.
 - We will open it for class discussion for 10-15 minutes
 - Each group will receive a grade for their overall approach throughout the course.

MANAGEMENT: A PERSONAL ASSESSMENT. DUE EOD¹ CLASS 5

- Where are you on your management journey? You have plans. There are essential competencies to be acquired and grown over the life of a manager and leader.
- Using the approach of the Healthcare Leadership Alliance (or approved alternate), assess where you are as weighed against the role you want to have in 5 years. What are your strengths, and your opportunities for considerable growth (including weaknesses)?
- Given that assessment, what is your plan to close the gap in competencies?
- Maximum length is 5 pages. Use of tables is encouraged.

THE FINAL PAPER: SHOW ME THE MONEY. DUE EOD CLASS 15

Management to achieve vastly improved financial performance is the name of the game everywhere in healthcare. Consider that you have just been appointed chief of the division, a division that has been through a lot of instability and turmoil in the last few years. With some exceptions the staff is made up of strong individual contributors who are focused on their research and practice. There is not a collective sense of responsibility for the overall division. Clinicians and staff to date have been excluded out of management issues—the

¹ EOD End of Day

department administrator has worried about the negative implications of that exclusion. You took the position because you see a tremendous amount of potential in the group, a gap to be filled in the organization, a lot of need and emerging competition in the market, and it is a golden opportunity for you to show your stuff and make a significant contribution. In taking the position you specifically agreed to improving overall quality, service and satisfaction while achieving two financial targets: a 10% operating budget reduction in year one and a cumulative 20% operating budget reduction by the end of year two.

In four weeks you arrive on the job and will be meeting with leadership and staff. You're sitting at the beach excited and in near panic, "What am I doing and how did I ever agree to those targets?" While you look forward to working with them when you arrive, you know you need to have thought through a high level initial approach. Reflecting on what you learned in that HSPH Intro. to Management Course, outline your draft plan to include: your overall theory, organizational strategy, the management of change and improvement, leadership development, and the management of human resources. Your response should include citations to materials covered throughout this seminar and other course material.

Paper must be typewritten; limit is ten pages, not single spaced, using Arial or Times New Roman font, and font size 12.

Grading Criteria:

Your final class grade will be determined as follows: Homework assignments will include 50% of your final grade, JIT's 20%, and class participation 30%. Students will receive a letter grade for the course. You are expected to be an active participant in classroom discussions. This includes attending all classes, reading and analyzing the assignments ahead of class time, and being ready to offer your analyses and perceptions to the class. The following guidelines will be used to determine your grade on class participation:

- B:** Good attendance, clearly listening to the discussion, speaking up once or twice in response to a question by the professor.
- B+:** Conditions for B plus excellent attendance, with a greater number of contributions, regularly trying to be recognized.
- A-:** Conditions for B+, plus contributions that show creative thinking, willingness to take risks, thoughtful disagreement.
- A:** Conditions for A-, plus someone whose contributions show mastery of the facts of the readings/case/discussion, good analysis of the essential elements, and someone who regularly moves the discussion to a higher level.

Coaching, through office hours, is provided and should be used to ensure understanding and consistency with all requirements of the course.

Course Evaluations:

On the spot, mid course, and final evaluations are used in this course to determine what's working and what needs improvement. Completion of the final evaluation is a

requirement for this course. Your grade will not be available until you submit the evaluation.

Session 1 7/2/15 What is the Role of a Manager?

Objective: To provide an introduction to the course, and a broad overview of the functions of a manager.

Required Reading:

- Bloom N, Sadun R., & Van Reenen J. (2012). Does management really work? Harvard Business Review, 90(11), 76-82. [LINK](#)
- Drucker PF. 1999. Managing oneself. Harvard Business Review. Mar-Apr; 77(2): 64-74, 185. Reprint #R0501K. [LINK](#)
- Stefl M. Common competencies for all healthcare managers:The Healthcare Leadership Alliance Mode. J HealthcManag. 2008 Nov-Dec;53(6):360-73; discussion 374. [LINK](#)

Case: Dashman Company [LINK](#)

Study Questions:

1. Why do we have managers? Why not just have people do their work without the “waste” of employing managers?
2. How should managers judge their own success? How do they know when they have done a good job?
3. What should the manager in this case do?

Management “Just in Time” Exercise: NO

Guest Speaker: NO

Session 2 7/6/15 Studying Organizations

Objective: To provide an introduction to organization theory as a way to understand why organizations behave as they do.

Required Reading:

- Beer. Organizational behavior and development. Harvard Business School Working Paper, No. 98-115, 1998.
http://www.hbs.edu/faculty/Publication%20Files/98-115_2dcf4172-0442-416c-a6a9-2a6edf6c0d33.pdf
- Grenny J, Maxfield D, Shimberg A. (2008). How to have influence. MIT Sloan Management Review. October 1. [LINK](#)

Case : No

Study Questions:

1. What determines the power and influence of different groups in an organization?
2. What determines the views and values of the members of each group?
3. Under what circumstances can managers get subordinates to do what they want them to? What tools do they need to accomplish that?

Management “Just In Time” Exercise: Yes

Guest Speaker: No

Session 3 7/7/15 Group Power & Organizational Behavior

Objective: Using Pfeffer’s Power Decision Model, compare the organizational behavior of different types of healthcare settings as each addresses critical decisions such as the task of planning for future expansion.

Required Reading:

- Buckingham M. 2005. What great managers do. Harvard Business Review, March. Reprint R0503D. [LINK](#)
- Cross R, Baker W, Parker A. (2003) What creates energy in organizations? MIT Sloan Management Review. Reprint #4445. Summer, 2003 [LINK](#)

Case:

1. Jeannette Clough at Mt Auburn, HBS, Nov 3, 2005 [LINK](#)

Study Questions:

1. Who are the major groups whose views influence capital expansion decisions in this hospital?
2. For each group, identify:
 - a. Its source of power and influence.
 - b. Its beliefs and values (i.e., what did it want?).
3. For each specific group, what accounts for the variations across hospitals (Mt. Auburn and others you know) in both their beliefs and their power?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 4 7/8/15 Introduction to Strategy Setting

Objective: This session will concentrate on imparting an understanding of nomenclature, rationale, and general process of strategic planning.

Required Reading:

- Ducker PF. (1994). The theory of the business. Harvard Business Review, September-October. Reprint # 94506. [LINK](#)

- Porter ME. 1996. What is strategy? Harvard Business Review, November-December. Reprint # 96608. [LINK](#)

Case: No

Study Questions:

1. What do we mean by an organization's "strategy?" Is it always what its leaders say it is?
2. How can we judge whether a strategy is good or bad?
3. Why have an explicit strategy? What is its value to both managers and staff?

Management "Just In Time" Exercise: Yes

Guest Speaker: No

Session 5 7/9/15 Strategy in the Non-Profit Sector

Objective: To explore the problems of developing a strategy in the non-profit sector with conflicts between mission and external support

Required Reading:

- Levitt T. (1960, 2004). Marketing myopia. Harvard Business Review. [LINK](#)
- Porter ME, & Lee TH. (2015). Why strategy matters now. *New England Journal of Medicine*, 372(18), 1681-1684. [LINK](#)

Case:

1. Terry Ann Lunt and Greater Boston Rehabilitation Services: Rebuilding the Foundation **Course Website**

Study Questions:

1. What does Terry Ann Lunt have to do to ensure her organization survives?
2. Does she have to abandon her mission to achieve her goal?
3. What specific steps should she take now?

Management "Just In Time" Exercise: No

Guest Speaker: Terry Ann Lunt, currently Executive Director, Brazelton Touchpoints Center at Children's Hospital Boston

Assignment Due: A Personal Assessment

Session 6 7/10/15 Dealing with the External Environment

Objective: To understand how to rally support and deal with constituency groups.

Required Reading:

- Gebbie KM. Building a Constituency for Public Health.
- Crucetti JB. Building Constituencies to Promote Public Health.
- Partners in Health. Program Management Guide. Learning about the Local Environment. http://parthealth.3cdn.net/cec69bcc8792eb1d5a_ywm6bs28x.pdf

Case:

- Audry Simmons **Course Website**

Study Questions:

1. What has Audry done wrong up to now?
2. What approach should Audry do now?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 7 7/13/15 Business Planning

Objective: To explore approaches to business planning in the non-profit sector with a focus on effective execution to achieve results.

Required Reading:

- Cardamone M. 2004. Business planning: reasons, definitions, and elements. Journal of Healthcare Management, April. [LINK](#)
- Kaplan RS. Balanced scorecard and nonprofit organizations. Harvard Business Publishing Newsletters. Nov 15, 2002. Prod. #: B0211A-PDF-ENG [LINK](#)

Case Study: No

Study Questions:

1. What are some characteristics of well executed business plans?
2. What are some failures in business planning that you have seen?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 8 7/14/15 Introduction: Why Do People Work?

Objective: To introduce the basic of human resource management including work design and to provide an overview of the practical applications of these concepts.

Required Reading:

- Morse JJ, Lorsch JW. Beyond theory Y. (1970) Harvard Business Review 70307 [LINK](#)

Case/Notes:

1. The Challenge of Commitment [LINK](#)
2. A Note on High-Commitment Work Systems [LINK](#)

Study Questions:

1. Why do employees work hard?
2. What is the relationship between work motivation, job satisfaction, and organizational commitment?
3. What can managers do to improve employee performance?

Management “Just In Time” Exercise: Yes

Guest Speaker: No

Session 9 7/15/15 Dealing with Peers and Superiors

Objective: To explore what managers owe to their bosses and colleagues, and how to deal with them when they will not do what you want them to.

Required Reading:

- Gabarro JJ, Kotter JP. (2005) Managing your boss (HBR Classic) Publication date: Jan 01, 2005. Prod. #: R0501J-PDF-EN [LINK](#)
- Oncken W, Wass D. (1999) Revised. Management time: who’s got the monkey? Harvard Business Review. Reprint #99609. [LINK](#)
- Tabrizi B. Key to change is middle management. HBR.. October 27, 2014. <https://hbr.org/2014/10/the-key-to-change-is-middle-management>

Case: No

Study Questions:

1. What do managers owe their bosses?
2. What do bosses owe their managers, if anything?

Management “Just In Time” Exercise: Yes

Guest Speaker: No

Session 10 7/16/15 Performance Appraisal

Objective: To discuss problems with common approaches to employee performance feedback and annual reviews.

Required Reading:

- Ward AJ, et.al. Improving the performance of top management teams. MIT Sloan Management Review. Reprint # 48313. Spring 2007. [LINK](#)
- Partners in Health. Program Management Guide. Strengthening Human Resources. http://parthealth.3cdn.net/04ceee2b7795756213_t2m6bp3l3.pdf

Cases:

- Development and Promotion at North Atlantic Hospital. Boris Groysberg, Lisa Leffert, Kerry Herman, Libby Williams [LINK](#)

Study Questions:

1. What should the objectives be of a performance appraisal system?
2. What are the biggest challenges in performance appraisal today?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 11 7/17/15 Managing Resource Poor Environments

Objective: This session is set up for the students and instructors to probe the relevance of the content covered to date in developing countries and resource poor environments.

Required Reading:

- Towards better leadership and management in health: report on an international consultation on strengthening leadership and management in low-income countries 29 January - 1 February 2007 Accra, Ghana. http://www.who.int/management/working_paper_10_en_opt.pdf
- Mate KS, & Mehta NP. (2014). A two-way street: what the United States can learn from resource-limited countries to improve health care delivery and reduce costs. *Joint Commission Journal On Quality And Patient Safety/Joint Commission Resources*, 41(5), 236-239. [LINK](#)

Case: No

Study Questions:

1. What are the specific challenges and opportunities you have seen/heard of/learned about in resource constrained environments and/or developing countries?

Management “Just In Time” Exercise: No

Guest Speaker: Dr. Shaloo Puri, MBBS, DTCD, MPH, MPA, Visiting Scientist Global Health Systems Cluster, Harvard T. H. Chan School of Public Health; Research Fellow | CSRI Mossavar-Rahmani Center for Business & Government Harvard Kennedy School

Session 12 7/20/15 Nonperforming Employees

Objective: To develop some sense of why some employees perform poorly, and solutions to the problem.

Required Reading:

- Teal T. (1996). The human side of management. Harvard Business Review. (November-December 1996): 35-44. Reprint # 96610. [LINK](#)
- Kotter J. (2000). Leading change: why transformation efforts fail. Harvard Business Review, Feb 1. Reprint #95204. [LINK](#)

Case:

1. Kathryn McNeil (A)(P) [LINK](#)

Study Questions:

1. Why is McNeil not meeting her superior's expectations? Who is responsible for the current situation?
2. Who should do what now?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 13 7/21/15 Culture & Organizational Change

Objective: To acquire some understanding of what it takes for an organization to change successfully.

Required Reading:

- Garvin DA, Roberto MA. (2005). Change through persuasion. Harvard Business Review. Feb; 83(2): 104-12, 149. Reprint #R0502F. [LINK](#)
- Senge PM. (1990) The leader's new work: building learning organizations. MIT Sloan Management Review. Reprint # 3211. Fall, 1990. [LINK](#)
- Roth A, Lee T. Health Care Needs Less Innovation and More Innovation. HBR. November 19, 2014. <https://hbr.org/2014/11/health-care-needs-less-innovation-and-more-imitation>

Case:

1. Barbara Norris: Leading Change in the General Surgery Unit. Boris Groysberg, Nitin Nohria, Deborah Bell. Mar 13, 2009. [LINK](#)

Study Questions:

1. Most change fails on execution or over time—why? How did it show in the case with Barbara Norris?
2. What are the most important recommendations you have for the general surgery change?

Management “Just In Time” Exercise: No

Guest Speaker: No

Session 14 7/22/15 T-E-A-M, Yeah Team and Teamwork

Objective: To underscore the growing power of teamwork to achieve improving clinical, financial, service, and experience outcomes.

Required Reading:

- Bunnell CA, Gross AH, Weingart S, Kalfin MJ, Partridge A, Lane S, Burstein HJ et al. High performance teamwork training and systems redesign in outpatient oncology. *BMJ Quality & Safety*(2013). [LINK](#)
- Leonard M, Frankel A. Role of Effective Teamwork and Communication in Delivering Safe, High Quality Care. *Mount Sinai Journal of Medicine: A Journal of Translational and Personalized Medicine* 78, no. 6 (2011): 820-826. [LINK](#)
- Edmondson A., Bohmer R., & Pisano G. (2001). Speeding up team learning. *Harvard Business Review*, 79(9), 125-134. [LINK](#)

Case: No

Study Questions:

1. Perhaps in your professional experience, there have been occasions where the absence of teamwork jeopardized care or other outcomes. Think about how it could have been improved?
2. Think about a time where exceptional teamwork has produced spectacular results? Did you see any parallels between elements highlighted in the article by Bunnell et. al. and your personal example.

Management “Just In Time” Exercise: No

Guest Speaker: Pending

Session 15 7/23/15 Leadership for Excellence

Objective: To explore what makes a great leader and what is required of leaders to improve performance

Required Reading:

- Kotter J. (2001). What leaders really do. Harvard Business Review, December. Reprint R0111F0. [LINK](#)
- Bruch H, Ghoshal S. (2002). Beware the busy manager. Harvard Business Review. Feb; 80(2): 62-9, 128. Reprint #R0202D. [LINK](#)
- Goleman D. (1998). What makes a leader? Harvard Business Review. Nov-Dec; 76(6): 93-102. Reprint #R0401H. [LINK](#)
- Nelson WA. (2012). Healthcare management ethics-the ethics of avoiding nonbeneficial healthcare. *Healthcare Executive*, 27(6), 48. [LINK](#)

Case: No

Study Questions:

1. Think of leaders you have known. Try to find examples of a “coach”, “prophet”, “therapist” and “poet”

Management “Just In Time” Exercise: No

Guest Speaker: J. Conway.... 45 Years of Management Errors and Learning

Assignment Due: The Final Paper: Show Me the Money

Session 16 7/24/15 A Morning With Managers / Leaders

Guest Speakers: Alice Bonner, Secretary of MA Office of Elder Affairs (tentative), Anne Lang, Former Vice President for Human Resources and Legal Services at Winchester Hospital, William P. Macaux, Principal & Management Psychologist Generativity LLC.

A full and frank discussion with a panel of managers and leaders.

Study Questions:

1. What’s a question you always wanted to ask a senior manager / leader? Ask it!

Theme	Lec. #	Date	Class*	Lecture Title 2006
Introduction	1	7/31/2006	A	Introduction
Introduction	2	7/31/2006	B	Inpatient Clinical Information Systems
Introduction	3	8/1/2006	A	Outpatient Clinical Information Systems
Introduction	4	8/1/2006	B	Informatics Standards 101
Introduction	5	8/2/2006	A	Medication Informatics Standards and Knowledge-base
Introduction	6	8/2/2006	B	Clinical Documentation
Introduction	7	8/3/2006	A	Clinical Systems Decision Support
Introduction	8	8/3/2006	B	Methods of Evaluation 1
Introduction	9	8/4/2006	A	Methods of Evaluation 2
Applied Topics	10	8/4/2006	B	Measuring and Reporting on Quality
Applied Topics	11	8/7/2006	A	Computerized Guidelines/Knowledge Management
Applied Topics	12	8/7/2006	B	Quality Data Warehouse
Applied Topics	13	8/8/2006	A	Drugs, Lab, Radiology Clinical Systems Decision Support
Applied Topics	14	8/8/2006	B	Disease Management
	15	8/9/2006	A	initial student presentations
	16	8/9/2006	B	initial student presentations
Special Topics	17	8/10/2006	A	Privacy, Confidentiality, Security and HIPAA
Special Topics	18	8/10/2006	B	Interoperability
Special Topics	19	8/11/2006	A	Return in Investment of Clinical Information Systems
Special Topics	20	8/11/2006	B	Organizational Issues in Clinical Information Systems
Special Topics	21	8/14/2006	A	A Case Study in Responding to the Quality and Safety Imperative: The PHS Signature Initiatives
Special Topics	22	8/14/2006	B	Healthcare Policy Issues in Information Technology
Special Topics	23	8/15/2006	A	Patient Computing
Special Topics	24	8/15/2006	B	Machine Learning
Special Topics	25	8/16/2006	A	Genomics
Special Topics	26	8/16/2006	B	Biosurveillance
	27	8/17/2006	A	final student presentations
	28	8/17/2006	B	final student presentations
	29	8/18/2006	A	final student presentations
	30	8/18/2006	B	final student presentations

* Classes A 1:30-2:15pm, B 2:30-3:15pm

Other Important Dates

Lecture 3&4: Cyberday questions DUE

Lecture 5&6: What's wrong w/ a medical record? DUE

Lecture 11&12: Implementing a clinical guideline DUE

8/9/06 (after lecture 16): Computer Lab for analyzing CIS data (3:30-5pm)

Lecture 21&22: Analyzing CIS data DUE

8/25/06: grades DUE

Lecturer 2006
Bates
Middleton
Middleton
Blumenfeld
Broverman
Blumenfeld
Middleton
Bates
Bates
Bates
Hongsermeier
Einbinder
Gandhi
Einbinder
Einbinder
Middleton
Middleton
Einbinder
Meyer
Bates
Middleton
Ohno-Machado
Kohane
Mandl

HSPH Medical Informatics (HPM512) Schedule and Readings

Lecture #1

Monday, July 27, 2015

Introduction - Dr. Bates

1:30pm - 2:15pm

Assigned Reading:

- [Bates DW, Komaroff AL. A piece of my mind: a cyberday in the life. JAMA 1996; 275\(10\):753-4.](#)
- [Blumenthal D, Glaser JP. Information Technology Comes to Medicine. N Engl J Med 2007; 356\(24\):2527-2534.](#)

Optional Reading:

- [Greenes RA, Shortliffe EH. Medical informatics: an emerging academic discipline and institutional priority. JAMA 1990; 263\(8\): 1114-20.](#)
- [Collen MF. The origins of informatics. JAMIA 1994; 1: 91--107.](#)
- [Hersh W. The health informatics workforce: unanswered questions, needed answers. Stud Health Technol Inform. 2010;151:492-503.](#)

Lecture #2

Monday, July 27, 2015

Inpatient Clinical Information Systems - Dr. Einbinder

2:30pm - 3:15pm

Assigned Reading:

- [DesRoches CM, Charles D, Furukawa MF, Joshi MS, Kralovec P, Mostashari F, Worzala C, Jha JK. Adoption Of Electronic Health Records Grows Rapidly, But Fewer Than Half Of US Hospitals Had At Least A Basic System In 2012. Health Aff July 2013 10.1377/hlthaff](#)
- [Koppel R, Metlay JP, Cohen A, Abaluck B, Localio AR, Kimmel SE, Strom BL. Role of computerized physician order entry systems in facilitating medication errors. JAMA. 293\(10\):1197-203, 2005 Mar 9.](#)

Optional Reading:

- [Bates DW, Gawande AA. Improving safety with information technology. N Engl J Med. 2003 Jun 19;348\(25\):2526-34](#)
- [Institute of Medicine Committee on Data Standards for Patient Safety. Key Capabilities of an Electronic Health Record System. Letter Report 2003. <http://www.nap.edu/catalog/10781.html>](#)
- [Freudenheim M. The ups and downs of electronic medical records. New York Times: 10/8/2012 <http://www.nytimes.com/2012/10/09/health/the-ups-and-downs-of-electronic-medical-records-the-digital-doctor.html?pagewanted=all>](#)

Lecture #3

Tuesday, July 28, 2015

Outpatient Clinical Information Systems - Dr. Bates

1:30pm - 2:15pm

Assigned Reading:

- [Adler-Milstein J, Green CE, Bates DW. A survey analysis suggests that electronic health records will yield revenue gains for some practices and losses for many. Health Aff \(Millwood\). 2013 Mar;32\(3\):562-70. doi: 10.1377/hlthaff.2012.0306.](#)
- [Sinsky CA, Beasley JW, Simmons GE, Baron RJ. Electronic health records: design, implementation, and policy for higher-value primary care. Ann Intern Med. 2014 160\(10\):727-728. doi: 10.7326/M13-2589](#)

Optional Reading:

- [DesRoches CM, Campbell EG, Rao SR, Donelan K, Ferris TG, Jha A, Kaushal R, Levy DE, Rosenbaum S, Shields AE, Blumenthal D. Electronic health records in ambulatory care--a national survey of physicians. N Engl J Med. 2008 Jul 3;359\(1\):50-60.](#)
- [Baron R. What's Keeping Us So Busy in Primary Care? A Snapshot from One Practice. NEJM 2010; Volume 362:1632-1636.](#)

Lecture #4

Tuesday, July 28, 2015

Clinical Decision Support Systems - Dr. Bates

2:30pm - 3:15pm

Assigned Reading:

- [Bates DW, Kuperman GJ, Wang S, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. J Am Med Inform Assoc. 2003 Nov-Dec;10\(6\):523-30.](#)
- [Bright TJ, Wong A, Dhurjati R, Bristow E, Bastian L, Coeytaux RR, Samsa G, Hasselblad V, Williams JW, Musty MD, Wing L, Kendrick AS, Sanders GD, Lobach D. Effect of Clinical Decision-Support Systems: A Systematic Review. Ann Intern Med. 2012;157\(1\):29-43.](#)

Optional Reading:

- [Cebul RD, Love TE, Jain AK, et al. Electronic health records and quality of diabetes care. N Engl J Med 2011;365:825–33.](#)
- [Chaudhry B, Wang J, Wu S, Maglione M, Mojica W, Roth E, Morton SC, Shekelle PG. Systematic review: Impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med. 2006; 144:E-12-E-22.](#)

Lecture #5

Wednesday, July 29, 2015

Methods of Evaluation 1 - Dr. Bates

1:30pm - 2:15pm

Assigned Reading:

- Evaluation of Clinical Information Systems, in van Bemmel JH, Musen MA (eds): Handbook of Medical Informatics. Heidelberg, Springer-Verlag; 1997: 463-469. (*Course Packet*)
- [Randolph AG, Haynes RB, Wyatt JC, Cook DJ, Guyatt GH. Users' Guides to the Medical Literature: XVIII. How to use an article evaluating the clinical impact of a computer-based clinical decision support system. JAMA; 282\(1\):67-74.](#)

Optional Reading:

- [Sahota N, Lloyd R, Ramakrishna A, Mackay JA, Prorok JC, Weise-Kelly L, Navarro T, Wilczynski NL, Haynes RB; Computerized clinical decision support systems for acute care management: a decision-maker-researcher partnership systematic review of effects on p](#)
 - [Cusack CM, Poon EG. Evaluation Toolkit, Version 3. Agency for Healthcare Research and Quality, National Resource Center. Available from <http://healthit.ahrq.gov>. Accessed 7/28/13](#)
-

Lecture #6

Wednesday, July 29, 2015

Methods of Evaluation 2 - Dr. Bates

2:30pm - 3:15pm

Assigned Reading:

- Same as lecture #5

Optional Reading:

- Same as lecture #5
-

Lecture #7

Thursday, July 30, 2015

Knowledge Management and Computerized Guidelines - Dr. Rocha

2:30pm - 3:15pm

Assigned Reading:

- Rocha RA, Maviglia SM, Sordo M, Rocha BH. Clinical knowledge management program. In: Greenes RA, editor. Clinical Decision Support - The Road Ahead (Second Edition). Burlington: Academic Press. 2014 (Coursepacket)

Optional Reading:

- [Gooch P, Roudsari A. Computerization of workflows, guidelines, and care pathways: a review of implementation challenges for process-oriented health information systems. J Am Med Inform Assoc. 2011 Nov-Dec;18\(6\):738-48.](#)
 - [Damiani G, Pinnarelli L, Colosimo SC, Almiento R, Sicuro L, Galasso R, Sommella L, Ricciardi W. The effectiveness of computerized clinical guidelines in the process of care: a systematic review. BMC Health Serv Res. 2010 Jan 4;10:2.](#)
 - [de Clercq PA, Blom JA, Korsten HH, Hasman A. Approaches for creating computer-interpretable guidelines that facilitate decision support. Artif Intell Med. 2004 May;31\(1\):1-27.](#)
-

Lecture #8

Thursday, July 30, 2015

Meaningful Use and Clinical Informatics - Dr. Bates

2:30pm - 3:15pm

Assigned Reading:

- [Blumenthal, D., Tavenner, M. The "Meaningful Use" Regulation for Electronic Health Records, published on July 13, 2010, at NEJM.org. <http://healthcarereform.nejm.org/?p=3732>](#)
- [Classen DC, Bates DW. Finding the meaning in meaningful use. N Engl J Med. 2011 Sep 1;365\(9\):855-8.](#)
- [Wright A, Henkin S, Feblowitz J, McCoy AB, Bates DW, Sittig DF. Early results of the meaningful use program for electronic health records. N Engl J Med. 2013 Feb 21;368\(8\):779-80. doi: 10.1056/NEJMc1213481.](#)

Optional Reading:

- October 14, 2014 Meaningful Use Letter from American Medical Association
-

Lecture #9

Friday, July 31, 2015

Health Information Technology and Value - Dr. Einbinder

1:30 - 2:15 PM

Assigned Reading:

- [Wang SJ, Middleton B, Prosser LA, et al. A cost-benefit analysis of electronic medical records in primary care. Am J Med 2003; 114:397-403](#)
- [Adler-Milstein J, Green CE, Bates DW. A survey analysis suggests that electronic health records will yield revenue gains for some practices and losses for many. Health Aff \(Millwood\). 2013 Mar;32\(3\):562-70. doi: 10.1377/hlthaff.2012.0306. \[Also assigned in Lecture 3\]](#)

Optional Reading:

- [Hillestad R, Bigelow J, Bower A, Girosi F, et al. Can electronic medical record systems transform health care? Potential health benefits, savings, and costs. Health Affairs 2005; 24\(5\): 1103-1117.](#)
- [Kaushal R, Jha AK, Franz C, Glaser J, Shetty KD, Jaggi T, Middleton B, Kuperman GJ, Khorasani R, Tanasijevic M, Bates DW. Return on investment for a computerized physician order entry system. J Am Med Inform Assoc 2006;13:261-266.](#)

Lecture #10

Friday, July 31, 2015

Informatics Standards 101 - Dr. Einbinder

2:30pm - 3:15pm

Assigned Reading:

- [Hammond, EW. The making and adoption of health data standards. Health Affairs. Sep/Oct 2005;24\(5\): 1205-1213](#)

Optional Reading:

- [Cimino JJ. Desiderata for controlled Medical vocabularies in the twenty-first century. Methods Inf Med. 1998 Nov;37\(4-5\):394-403. Review.](#)

Lecture #11

Monday, August 03, 2015

Measuring and Reporting on Quality - Dr. Bates

1:30 - 2:15 PM

Assigned Reading:

- [Iezzoni LI. Assessing Quality Using Administrative Data. Ann Intern Med. 1997;127:666-674.](#)
- [Kern LM, Malhotra S, Barrón Y, Quaresimo J, Dhopeshwarkar R, Pichardo M, Edwards AM, Kaushal R. Accuracy of electronically reported "meaningful use" clinical quality measures: a cross-sectional study. Ann Intern Med. 2013 Jan 15;158\(2\):77-83. doi: 10.7326](#)

Optional Reading:

- [Berwick DM, James B, Coye MJ. Connections between quality measurement and improvement. Med Care 2003; 41 \(1 Suppl\):I30-8.](#)

Lecture #12

Monday, August 03, 2015

Clinical Documentation - Dr. Bates

2:30pm - 3:15pm

Assigned Reading:

- [Pollard SE, Neri PM, Wilcox AR, Volk LA, Williams DH, Schiff GD, Ramelson HZ, Bates DW. How physicians document outpatient visit notes in an electronic health record. Int J Med Inform. 2013 Jan;82\(1\):39-46. doi: 10.1016/j.ijmedinf.2012.04.002. Epub 2012 A](#)
- [Schiff GD, Bates DW. Can electronic clinical documentation help prevent diagnostic errors? N Engl J Med. 2010 Mar 25;362\(12\):1066-9. doi: 10.1056/NEJMp0911734.](#)

Optional Reading:

- [Tang PC, LaRosa MP, Gordon SM. Use of computer-based records, completeness of documentation, and appropriateness of documented clinical decisions. JAMIA 1999; 6: 245-251.](#)
- [Stetson, PD, Morrison, FP, Bakken, SH, Johnson, SB. Preliminary Development of the Physician Documentation Quality Instrument. JAMIA 2008; 15:534-541.](#)
- [Amarasingham R, Plantinga L, Diener-West M, Gaskin DJ, Powe NR. Clinical information technologies and inpatient outcomes. Arch Intern Med. 2009; 169\(9\):108-114.](#)
- [Linder JA, Schnipper JL, Middleton B. Method of electronic health record documentation and quality of primary care. J Am Med Inform Assoc 2012 doi:10.1136/amiajnl-2011-000788](#)

Lecture #13

Tuesday, August 04, 2015

Medications, Laboratory, and Radiology Testing - Dr. Bates

1:30 - 2:15 PM

Assigned Readings:

- [Bates DW, Leape LL, Cullen DJ, et al. Effect of computerized physician order entry and a team intervention on prevention of serious medication errors. JAMA 1998; 280\(15\):1311-1316.](#)
- [Chaudhry B, Wang J, Wu S, et al. Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care Ann Intern Med. 2006;144:E-12-E-22.](#)

Optional Reading:

- [Shah NR, Seger AC, Seger DL, Fiskio JM, Kuperman GJ, Blumenfeld B, Recklet EG, Bates DW, Gandhi TK. Improving acceptance of computerized prescribing alerts in ambulatory care. J Am Med Inform Assoc 2006; 13 \(1\); 5-11.](#)
- [Kuperman GJ, Teich JM, Tanasijevic MJ, et al. Improving response to critical laboratory results with automation: results of a randomized controlled trial. J Am Med Inform Assoc. 1999 Nov-Dec;6\(6\):512-522](#)
- [Evans RS, Pestotnik SL, Classen DC, Clemmer TP, Weaver LK, Orme JF Jr, Lloyd JF, Burke JP. A computer-assisted management program for antibiotics and other antiinfective agents. N Engl J Med. 1998 Jan 22;338\(4\):232-8.](#)
- [Boland WL, Thrall JH, Gazelle GS, Samir A, Rosenthal DI, Dreyer KJ, Alkasab TK. Decision Support for Radiologist Report Recommendations. Journal of the American College of Radiology; 8 \(12\): 819-823.](#)

Lecture #14

Tuesday, August 04, 2015

Population Management - Dr. Chaguturu

2:30pm - 3:15pm

Assigned Reading:

- [Zai AH, Grant RW, Estey G, Lester WT, Andrews CT, Yee R, Mort E, Chueh HC. Lessons from implementing a combined workflow-informatics system for diabetes management. J Am Med Inform Assoc. 2008 Jul-Aug;15\(4\):524-33. doi: 10.1197/jamia.M2598.](#)
- [Milford CE, Ferris TG. A Modified "Golden Rule" for Health Care Organizations. Mayo Clinic Proceedings. Volume 87, Issue 8, Pages 717-720, August 2012. \[http://www.mayoclinicproceedings.org/article/S0025-6196\\(12\\)00562-9/fulltext\]\(http://www.mayoclinicproceedings.org/article/S0025-6196\(12\)00562-9/fulltext\)](#)

Optional Reading:

- None

Lectures #15 & #16

Wednesday, August 05, 2015

Initial Student Presentations

1:30pm - 3:20pm

Computer Lab

3:30 - 5:00pm Kresge LL6

Computer Lab for Homework #3 "Analyzing clinical information system data"

Lecture #17

Thursday, August 06, 2015

Interoperability - Dr. Bates

1:30pm - 2:15pm

Assigned Reading:

- [Adler-Milstein J, Bates DW, Jha AK. A survey of health information exchange organizations in the United States: implications for meaningful use. Ann Intern Med. 2011 May 17;154\(10\):666-71. doi: 10.1059/0003-4819-154-10-201105170-00006.](#)
- [Rudin RS, Simon SR, Volk LA, Tripathi M, Bates D. Understanding the decisions and values of stakeholders in health information exchanges: experiences from Massachusetts. Am J Public Health. 2009 May;99\(5\):950-5. doi: 10.2105/AJPH.2008.144873.](#)

Optional Reading:

- [Kern LM, Wilcox A, Shapiro J, Dhopeswarkar RV, Kaushal R. Which components of health information technology will drive financial value? Am J Manag Care. 2012 Aug;18\(8\):438-45.](#)
- [Walker J, Pan E, Johnston D, Adler-Milstein J, Bates DW, Middleton B. The value of health care information exchange and interoperability. Health Aff \(Millwood\). 2005 Jan-Jun;Suppl Web Exclusives:W5-10-W5-18.](#)

- John D D'Amore, Joshua C Mandel, David A Kreda, Ashley Swain, George A Koromia, Sumesh Sundareswaran, Liora Alschuler, Robert H Dolin, Kenneth D Mandl, Isaac S Kohane, and Rachel B Ramoni. Are Meaningful Use Stage 2 certified EHRs ready for interoperability? Findings from the SMART C-CDA Collaborative. *J Am Med Inform Assoc.* 2014 Nov; 21(6): 1060–1068. Published online 2014 Jun 26. doi: 10.1136/amiajnl-2014-002883

Lecture #18

Thursday, August 06, 2015

Healthcare Analytics - Dr. Einbinder

2:30pm - 3:15pm

Assigned Reading:

- Adams J, Klein J. Business Intelligence and Analytics in Health Care - A Primer. The Advisory Board, August 2011. (Coursepacket)
- Bates DW, Saria S, Ohno-Machado L, Shah A, Escobar G. Big Data In Health Care: Using Analytics To Identify And Manage High-Risk And High-Cost Patients. *Health Aff* July 2014 vol. 33 no. 7 1123-1131. doi: 10.1377/hlthaff.2014.0041

Optional Reading:

- Einbinder JS. Case Study: A Data Warehouse for an Academic Medical Center. *Journal of Healthcare Information Management.* 2001;15(2):165-175 (*Course Packet*)
- [Hays CL. What Wal-Mart knows about customers' habits. *New York Times* 11/14/2004.](#)
- Davenport TH. Competing on Analytics. *Harvard Business Review.* January 2006.

Lecture #19

Friday, August 07, 2015

Privacy, Confidentiality, Security and HIPAA - Dr. Einbinder

1:30pm - 2:15pm

Assigned Reading:

- [Bova C, Drexler JD, Sullivan-Bolyai S. Reframing the influence of the Health Insurance Portability and Accountability Act on Research. *Chest.* 2012;141\(3\)782-786.](#)

Optional Reading:

- None

Lecture #20

Friday, August 07, 2015

Organizational Issues in Clinical Information Systems - Dr. Einbinder

2:30pm - 3:15pm

Assigned Reading:

- [Ash JS. Managing change: analysis of a hypothetical case. *JAMIA* 2000; 7:125-134.](#)
- Einbinder J. Implementation. In *Transforming Health Care Through Information*, Second Edition. Lorenzi N, Ash J, Einbinder J, McPhee W, Einbinder L, eds. Springer 2005. (pages 56-63) (*Course Packet*)

Optional Reading:

- [Lorenzi NM, Riley RT. Managing change: an overview. *JAMIA* 2000; 7:116-124.](#)
- [Massaro TA. Introducing physician order entry at a major academic medical center: I. Impact on organizational culture and behavior. *Acad Med.* 1993 Jan;68\(1\):20-5](#)
- [Massaro TA. Introducing physician order entry at a major academic medical center: II. Impact on medical education. *Acad Med.* 1993 Jan;68\(1\):25-30](#)
- [Ornstein C. Hospital heeds doctors, suspends use of software. *Los Angeles Times*, 1/22/2003.](#)
- [Kaplan B, Brennan PF, Dowling AF, Friedman CP, Peel V. Toward an informatics research agenda: Key people and organizational issues. *JAMIA* 2001: 235-241.](#)

Lecture #21

Monday, August 10, 2015

Biosurveillance - Dr. Mandl

1:30pm - 3:15pm

Assigned Reading:

- [Fine AM, Nizet V, Mandl K. Participatory medicine: a home score for streptococcal pharyngitis enabled by real-time biosurveillance. Ann Intern Med. 2013;159:577-583.](#)
- [Weitzman ER, Kelemen S, Quinn M, Eggleston EM, Mandl KD. Participatory surveillance of hypoglycemia and harms in an online social network. JAMA Intern Med. 2013 Mar 11;173\(5\):345-51. doi: 10.1001/jamainternmed.2013.2512.](#)
- [Mandl KD, Overhage JM, Wagner MM, et al. Implementing syndromic surveillance: a practical guide informed by the early experience. J Am Med Inform Assoc. 2004; 11: 141-150.](#)
- [Fine AM, VNizet V, Mandl KD. Improved Diagnostic Accuracy of Group A Streptococcal Pharyngitis With Use of Real-Time Biosurveillance. Ann Intern Med. 2011;155:345-352.](#)

Optional Reading:

- [Brownstein JS, Freifeld CC, Reis BY, Mandl KD. Surveillance Sans Frontieres: Internet-based emerging infectious disease intelligence and the HealthMap project. PLoS Med. Jul 8 2008;5\(7\):e151.](#)
- [Cassa CA, Chunara R, Mandl K, Brownstein JS. Twitter as a Sentinel in Emergency Situations: Lessons from the Boston Marathon Explosions. PLOS Currents Disasters. 2013 Jul 2 \[last modified: 2013 Jul 11\]. Edition 1. doi: 10.1371/currents.dis.ad70cd1c8bc585](#)

Lecture #22

Monday, August 10, 2015

Genomics - Dr. Kohane

2:30pm - 3:15pm

Assigned Reading:

- [Cancer Genome Atlas Research Network. Comprehensive genomic characterization defines human glioblastoma genes and core pathways. Nature. 2008 Oct 23;455\(7216\):1061-8. Epub 2008 Sep 4. PubMed PMID: 18772890; PubMed Central PMCID: PMC2671642.](#)
- [Paez JG, Jänne PA, Lee JC, Tracy S, Greulich H, Gabriel S, Herman P, Kaye FJ, Lindeman N, Boggon TJ, Naoki K, Sasaki H, Fujii Y, Eck MJ, Sellers WR, Johnson BE, Meyerson M. EGFR mutations in lung cancer: correlation with clinical response to gefitinib therapy. Science. 2004 Jun 4;304\(5676\):1497-500. Epub 2004 Apr 29. PubMed PMID: 15118125.](#)
- [Genome- and Phenome-Wide Analyses of Cardiac Conduction Identifies Markers of Arrhythmia Risk Circulation. 2013;127:1377-1385, published online before print March 5 2013](#)

Optional Reading:

- None

Lecture #23

Tuesday, August 11, 2015

Research Infrastructure and Instrumenting the Enterprise - Dr. Murphy

1:30pm - 2:15pm

Assigned Reading:

- None

Optional Reading:

- [Murphy SN, Weber G, Mendis M, Gainer V, Chueh HC, Churchill S, Kohane I. Serving the enterprise and beyond with informatics for integrating biology and the bedside \(i2b2\). J Am Med Inform Assoc 2010;17:124-130 doi:10.1136/jamia.2009.000893](#)

Lecture #24

Tuesday, August 11, 2015

Natural Language Processing - Dr. Zhou

2:30pm - 3:15pm

Assigned Reading:

- [Nadkarni PM, Ohno-Machado L, Chapman WW. Natural language processing: an introduction. J Am Med Inform Assoc. 2011;18\(5\):544-51.](#)
- [Friedman C, Rindflesch TC, Corn M. Natural language processing: State of the art and prospects for significant progress, a workshop sponsored by the National Library of Medicine. Journal of Biomedical Informatics. Available Online 25 June 2013. http://dx.doi.org/10.1016/j.jbi.2013.06.004](#)

Optional Reading:

- [Friedman C. A broad-coverage natural language processing system. Proc AMIA Symp. 2000:270-4. \(Columbia\) MedLEE: http://lucid.cpmc.columbia.edu/medlee/](#)

- Friedman C, Johnson SB. Natural language and text processing in biomedicine. In Shortliffe EH, Cimino JJ, eds. Biomedical Informatics: Computer Applications in Health Care and Biomedicine. Springer, NY, 2006 (Coursepacket).
- [Meystre SM, Savova GK, Kipper-Schuler KC, Hurdle JF. Extracting information from textual documents in the electronic health record: a review of recent research. Yearbook of medical informatics. 2008:128-44.](#)
- [Demner-Fushman D, Chapman WW, McDonald CJ. What can natural language processing do for clinical decision support? Journal of biomedical informatics. 2009;42\(5\):760-72.](#)
- [Alan Aronson. An overview of MetaMap: historical perspective and recent advances. JAMIA 2010;17:229-236. MetaMap. <http://metamap.nlm.nih.gov/>. \(NLM\)](#)
- [Savova G, Masanz J, Ogren P, Zheng J; Sohn S, Kipper-Schuler K, Chute C. 2010. Mayo Clinic Clinical Text Analysis and Knowledge Extraction System \(cTAKES\): architecture, component evaluation and applications. JAMIA 2010;17:507-513. cTAKES: <http://ctakes>](#)

Lecture #25

Wednesday, August 12, 2015

PHRs, Social, and Mobile - Dr. Bates

1:30pm - 2:15pm

Assigned Reading:

- [Verhoef LM, Van de Belt TH, Engelen LJ, Lisette Schoonhoven L, Kool RB. Social Media and Rating Sites as Tools to Understanding Quality of Care: A Scoping Review. J Med Internet Res. 2014 Feb; 16\(2\): e56. doi: 10.2196/jmir.3024](#)
- [Yamin CK, Emani S, Williams DH, Lipsitz SR, Karson AS, Wald JS, Bates DW. The digital divide in adoption and use of a personal health record. Arch Intern Med. 2011 Mar 28;171\(6\):568-74. doi: 10.1001/archinternmed.2011.34.](#)
- [Palen TE, Ross C, Powers JD, Xu S. Association of online patient access to clinicians and medical records with use of clinical services. JAMA. 2012 Nov 21;308\(19\):2012-9. doi: 10.1001/jama.2012.14126.](#)

Optional Reading:

- [Kaelber DC, Jha AK, Johnston D, Middleton B, Bates D. A research agenda for personal health records \(PHRs\). J Am Med Inform Assoc. 2008;15:729-736.](#)
- [Tang PC, Joan AS, Bates DW, Overhage JM, Sands DZ. Personal health records: definitions, benefits, and strategies for overcoming barriers to adoption. J Am Med Inform Assoc 2006;13\(2\):121-126.](#)

Lecture #26

Wednesday, August 12, 2015

Healthcare Policy Issues in Information Technology - Dr. Bates

2:30pm - 3:15pm

Assigned Reading:

- [Mongan J. J., Ferris T. G., Lee T. H. Options for Slowing the Growth of Health Care Costs N Engl J Med 2008; 358:1509-1514.](#)
- [Kushniruk AW, Bates DW, Bainbridge M, Househ MS, Borycki EM. National efforts to improve health information system safety in Canada, the United States of America and England. International Journal of Medical Informatics. Volume 82, Issue 5 , Pages e149-e1](#)

Optional Reading:

- [Kaushal R, Bates DW, Poon EG, Jha AK, Blumenthal D; Harvard Interfaculty Program for Health Systems Improvement NHIN Working Group. Functional gaps in attaining a national health information network. Health Aff \(Millwood\). 2005 Sep-Oct;24\(5\):1281-9.](#)
- [Audet AM, Squires D, Doty MM. Where Are We on the Diffusion Curve? Trends and Drivers of Primary Care Physicians' Use of Health Information Technology. Health Serv Res. 2014 Feb; 49\(1 Pt 2\): 347-360. doi: 10.1111/1475-6773.12139](#)

Lectures #27 & #28

Wednesday, August 12, 2015

Final Student Presentations

1:30pm - 3:20pm

Assignment due:

Final Presentation (presentations also take place on 8/14)

Lectures #29 & #30

Friday, August 14, 2015

Final Student Presentations

1:30pm - 3:20pm

Assignment due:

Paper due by 5pm (Sent via e-mail to: LPNEWMARK@PARTNERS.ORG)

Harvard School of Public Health
HPM512: Medical Informatics
Summer 2015

Faculty

David W. Bates, MD, MSc
Phone: 617-732-5650
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Jonathan S. Einbinder, MD, MPH
Tel: 781-416-8517
E-mail: jseinbinder@partners.org

Office Hours

The instructors hold office hours during lunch before class at the HSPH Cafeteria, additional time by appointment.

Course Coordinator

Lisa Newmark; E-mail: lpnewmark@partners.org

Course Website

tba

Class Time and Location

Summer Session 2: July 27 – August 14
Monday - Friday, 1:30-3:20pm
Classroom: Kresge G2

Course Description

Medical Informatics and health information technology (HIT) are increasingly critical for the delivery of safe, effective health care, and also for research and management. HIT will likely transform health care in the coming years, and the nation is adopting electronic health records at an unprecedented pace. Electronic health records are not only a vehicle for improving healthcare delivery but also represent a treasure trove of data for anyone interested in clinical effectiveness research. In this course we describe the core issues in the field of medical informatics, survey the methods used to perform clinical effectiveness research using clinical systems, give examples of healthcare improvement using HIT, and describe how to evaluate clinical systems interventions. Major topics include: the impact of clinical systems with a focus on clinical decision support, evaluation methods, obtaining information from clinical systems, and the role of informatics standards. Issues such as confidentiality and privacy, organizational factors, interoperability, and return on investment will also be covered. The relevance of informatics in disease management, genomics, natural language processing, patient computing, biosurveillance, and health care policy will also be highlighted. You do not need to be a programmer or have medical informatics as a primary interest to take this course.

We hope this course addresses your needs and interests. This will be the 15th year this course has been offered and we are continually working on improving it--for us to do this, your feedback will be especially important. We want to make the course as useful to you as possible. In particular, we would like to have the sessions be interactive, so ask questions as we go along.

Course Requirements

One project is required which involves an initial presentation, a final presentation, and a paper. Students may work on the project in groups. There will be three homework assignments. Required and suggested readings will be made available.

All assignments and projects should be submitted via e-mail to LPNEWMARK@partners.org. The homework assignments and presentation slides should be e-mailed before the start of class on the due date. The paper should be e-mailed by 5:00 PM on 8/14.

Important Dates

Wed. 7/29	Homework #1 Questions from Cyberday DUE
Wed. 8/5	3:30 – 5:00pm Computer Lab for Homework #3 “Analyzing clinical information system data”
Wed. 8/5	Initial Presentation DUE
Fri. 8/7	Homework #2 “Implementing a clinical guideline in a clinical information system” DUE
Mon. 8/10	Homework #3 DUE
Thurs. 8/13	Final Presentation DUE (presentations also are scheduled on 8/14)
Fri. 8/14	Paper DUE by 5pm

Quality and Safety in Health Care
HPM 516 – Spring 2, 2016
Tuesdays and Thursdays 1:30 – 3:20
3/22 – 5/12

Thomas Sequist MD, MPH

Associate Professor of Medicine and Health Care Policy, Harvard Medical School
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Amy Bulger RN, MPH

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Sarah Gordon, MS

Teaching Assistant
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Department of Health Services Research
Brown University
sarah.gordon@mail.harvard.edu
Office Hours: by appointment

Course Description

The quality and safety of health care is a national concern. This course addresses the conceptual basis for measuring and improving quality and safety, the effectiveness of methods used to improve health care, and the policies that influence the quality and safety of health care. Guest speakers emphasize recent developments and innovative initiatives and policies.

Course Objectives

At the conclusion of this course, you will be able to:

- Describe the nature and extent of problems with quality and safety in health care
- Describe the conceptual foundation for quality improvement
- Describe the application of the methods used to measure quality and safety in health care
- Describe practical approaches to improving quality and safety, including changes to policy, organizational strategy, team management, and individual behavior.

Outcome Measures

Classroom discussion/participation

Participation will be assessed based on in-class discussions and blog contributions.

- **In-class discussion:** You are expected to do all reading in advance of class and come prepared to contribute to the discussion through comments and questions. We value the quality of contributions over quantity.
- **Class blog (online discussion):** We ask that you submit blog posts for at least seven sessions over the course of the semester. We require three blog post submissions prior to the midpoint of the term. The blog posts may be either a question or a comment based on class readings or

slides and should be limited to 200 words. Blog posts must be submitted via the Discussion tab on Canvas by 8 pm the evening before the relevant session to count toward the seven-post requirement. This allows the lecturers time to review them in advance of class and address the issues raised.

Quiz

During class on **April 14th** we will administer a one-hour quiz to assess your understanding of foundational concepts in health care quality, as covered in the first seven sessions of the course. Quiz questions will be taken directly from the discussion questions for each lecture. When preparing for class, make sure to review not only readings, but also the discussion questions so that you stay up-to-date with the material that we will test for on the quiz.

Paper #1: Quality Problem

Paper 1 gives you the opportunity to apply what you are learning in the course to a real-world quality of care problem. You will describe a quality problem facing a specific health care service and in a specific setting and discuss the key barriers impeding improvement. This is a 2-page, double-spaced paper that is due on **April 21st**. Please refer to “Paper 1 Instructions” on the course website for additional details regarding this assignment. Note that Paper 1 sets the stage for the quality improvement project that you will outline in Paper 2. As such, give careful thought to the problem you want to focus on over the course of these two papers. We ask that you submit your proposed topic at least one week prior to the due date for approval before you start writing.

Paper #2: Quality Improvement Project

Paper 2 gives you the opportunity to describe a real-world quality improvement project that will change a specific health care service in a specific setting using concepts learned during the course. Paper 2 should build on the problem that you outlined in Paper 1. Please refer to “Paper 2 Instructions” on the course website for additional details on this assignment. This is a 4-page, double-spaced paper that is due on **May 10th**.

Grading Criteria

Grades are based on the following:

Assignment	Due Date	Percent of Grade
Classroom Discussion/Participation	Ongoing	30%
Quiz	April 14th	20%
Paper #1: Quality Problem	April 21st	25%
Paper #2: QI Project	May 10th	25%

Electronics Policy

The use of electronics—including phones, tablets, and laptops—is not permitted during class.

Course Evaluations

Completion of the evaluation is a requirement for all courses at Harvard Chan. Your final grade will not be available until you submit the evaluation.

Academic Accommodations

To request academic accommodations due to a disability, please contact the Office for Student Affairs by phone at 617-423-1542 or email Amy Wooldridge at awooldri@hsph.harvard.edu.

Quality and Safety in Health Care
HPM 516 – Spring 2, 2016
Tuesdays and Thursdays 1:30 – 3:20
3/22/16 – 5/12/16

Session	Date	Title	Leader
1	3/22	Introduction to Quality and Safety in Health Care	Tom Sequist
2	3/24	Overview of Patient Safety	Lucian Leape
3	3/29	Hospital Safety and Safety Culture	Allen Kachalia Karen Fiumara Christian Dankers
4	3/31	Patient Engagement and Experiences of Care	Susan Edgman-Levitan
5	4/5	Hospital Quality and Public Transparency	Ashish Jha
6	4/7	Ambulatory Quality and Safety	Tom Sequist
7	4/12	Financial Incentives and Health Care Value	Meredith Rosenthal
8	4/14	**** QUIZ **** Health Care Equity	Tom Sequist
9	4/19	Clinical Process Improvement	Joe Jacobson
10	4/21	**** Paper 1 Due **** Innovation and Adoption of New Practices	Eric Schneider
11	4/26	Electronic Health Records and Information Technology	Tom Sequist
12	4/28	Case Study: Organizational behavior meets operations management	Sara Singer
13	5/3	Quality of Care at the End of Life	Atul Gawande
14	5/5	ACOs and New Models of Care	Gregg Meyer
15	5/10	**** Paper 2 Due **** Quality and Safety in Post-Acute Care	David Grabowski
16	5/12	Discussion: Future Areas in Quality and Safety	Tom Sequist

Learning Objectives:

By the end of this session, you will be able to:

1. Understand the development of thinking on quality and safety in health care
2. Classify quality and safety problems
3. Define and describe the components of quality improvement

Read:

1. Vox video: if healthcare ran like an airline: <https://www.youtube.com/watch?v=5J67xJKpB6c>
2. Institute of Medicine (US). Committee on Quality of Health Care in America. Crossing the quality chasm: A new health system for the 21st century. National Academy Press; 2001. Chapters 1 and 2, pp. 23-60. <http://www.nap.edu/catalog/10027/crossing-the-quality-chasm-a-new-health-system-for-the>
3. Brook RH, McGlynn EA, Cleary PD. Quality of health care. Part 2: Measuring quality of care. *The Journal of Head Trauma Rehabilitation*. 1997;12(3):101-2. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM199609263351311>
4. McGlynn EA, Asch SM. Developing a clinical performance measure. *American Journal of Preventive Medicine*. 1998;14(3):14-21. <http://www.sciencedirect.com.ezp-prod1.hul.harvard.edu/science/article/pii/S0749379797000329>
5. Cassel CK, Conway PH, Delbanco SF, Jha AK, Saunders RS, Lee TH. Getting more performance from performance measurement. *New England Journal of Medicine*. 2014;371(23):2145-7. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1408345>

Be prepared to discuss:

1. How does Donabedian classify quality problems?
2. What are the strengths and weaknesses of structural or process measures compared with outcomes measures?
3. Why is developing good quality measures so hard?
4. What are the Six Worthy Aims for health care identified in “Crossing the Quality Chasm”?

Learning Objectives:

By the end of this session, you will be able to:

1. Understand the extent of error and preventable harm in health care
2. Explain how and why errors occur
3. Demonstrate how to prevent errors by application of human factors principles

Read:

1. Leape LL. Error in medicine. *JAMA*. 1994;;272(23):1851-7. <http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=384554>
2. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG, Newhouse JP, Weiler PC, Hiatt HH. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. *New England Journal of Medicine*. 1991;324(6):370-6. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM199102073240604>
3. Leape, L, Brennan, T, Laird, N, et al. The nature of adverse events in hospitalized patients. Results of the Harvard Medical Practice Study II. *N Engl J Med*, 1991;324: 377-84. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM199102073240605>

Additional reading:

1. Landrigan CP, Parry GJ, Bones CB, Hackbarth AD, Goldmann DA, Sharek PJ. Temporal trends in rates of patient harm resulting from medical care. *New England Journal of Medicine*. 2010;363(22):2124-34. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMsa1004404>
2. Institute of Medicine, 2000. *To Err is Human*. Washington, Nat Acad Press
3. Reason, J. 1990. *Human Error*. Cambridge: Cambridge University Press

Be prepared to discuss:

1. What are the defining characteristics of the automatic and problem-solving modes of cognition?
2. What is a “cognitive disposition to respond”? Why are they important?
3. What is a latent error (condition)?
4. What are human factors principles and how do they apply to the problem of health care errors?
5. What should hospitals do to reduce errors?

Learning Objectives:

By the end of this session, you will be able to:

1. Describe methods in which to engage hospital leadership in safety improvement efforts
2. Describe how you can build a robust safety culture and quality and safety infrastructure
3. Identify the leading causes of hospital safety concerns and approaches to address them

Read:

1. Weaver SJ, Lubomksi LH, Wilson RF, Pfoh ER, Martinez KA, Dy SM. Promoting a culture of safety as a patient safety strategy: a systematic review. *Annals of Internal Medicine*. 2013;158:369-74. <http://annals.org/article.aspx?articleid=1656428>
2. Kachalia A. Improving patient safety through transparency. *New England Journal of Medicine*. 2013;369(18):1677-9. <http://www.nejm.org/doi/full/10.1056/NEJMp1303960>
3. Chassin MR, Loeb JM. The ongoing quality improvement journey: next stop, high reliability. *Health Affairs*. 2011;30(4):559-68. <http://content.healthaffairs.org/content/30/4/559.full.pdf>
4. Rajaram R, Chung JW, Kinnier CV, Barnard C, Mohanty S, Pavey ES, McHugh MC, Bilimoria KY. Hospital Characteristics Associated With Penalties in the Centers for Medicare & Medicaid Services Hospital-Acquired Condition Reduction Program. *JAMA*. 2015;314(4):375-83. <http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=2411284>
5. Rajaram R, Barnard C, Bilimoria KY. Concerns about using the patient safety indicator-90 composite in pay-for-performance programs. *JAMA*. 2015;313(9):897-8. <http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=2109967>

Be prepared to discuss:

1. What are the leading causes of preventable harm in healthcare?
2. What are some strategies to create a robust safety culture and quality infrastructure?
3. What do we mean by “safety culture,” and why is it important to create a strong culture of safety?

Learning Objectives:

By the end of this session, you will be able to:

1. Define patient-centered care and its key elements
2. Distinguish between patient-centered care and patient engagement
3. Describe how patient engagement leads to better clinical outcomes
4. Suggest ways that senior leaders can advance patient and family-centered care, and predict potential obstacles

Read:

1. Price RA, Elliott MN, Zaslavsky AM, Hays RD, Lehrman WG, Rybowski L, Edgman-Levitan S, Cleary PD. Examining the role of patient experience surveys in measuring health care quality. *Medical Care Research and Review*. 2014;71(5):522-54. <http://mcr.sagepub.com.ezp-prod1.hul.harvard.edu/content/71/5/522.long>
2. Barry MJ, Edgman-Levitan S. Shared decision making—the pinnacle of patient-centered care. *New England Journal of Medicine*. 2012;366(9):780-1. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1109283>
3. Edgman-Levitan S, Brady C, Howitt P. Partnering with patients, families, and communities for health: a global imperative. World Innovation Summit, Doha. 2013:10-1. <http://www.wish-qatar.org/app/media/387>
4. National Patient Safety Foundation's Lucian Leape Institute. Safety is Personal: Partnering with Patients and Families for the Safest Care. 2014. http://c.ymcdn.com/sites/www.npsf.org/resource/resmgr/LLI/Safety_Is_Personal.pdf

Be prepared to discuss:

1. How would you define patient-centered care? What are its key elements and how do we measure it?
2. How does patient-centered care differ from patient engagement?
3. Describe how patient engagement leads to safer care and better clinical outcomes.
4. How can senior leaders advance patient and family-centered care? What obstacles do you think they might face?

Learning Objectives:

By the end of this session, you will be able to:

1. Describe how quality and safety in hospitals is measured
2. Understand the hospital quality and safety measurement and incentive programs employed by Medicare
3. Examine the mechanism by which public reporting can work and its consequences

Read:

1. Jha AK, Epstein AM. The predictive accuracy of the New York State coronary artery bypass surgery report-card system. *Health Affairs*. 2006;25(3):844-55.
<http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/25/3/844.short>
2. Ryan AM, Nallamothu BK, Dimick JB. Medicare's public reporting initiative on hospital quality had modest or no impact on mortality from three key conditions. *Health Affairs*. 2012;31(3):585-92. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/31/3/585.short>
3. Rosenbaum, L.. One clinician's journey through a new world of unintended consequences. Penn LDI Blog. February 2014. <http://ldihealtheconomist.com/he000085.shtml>
4. Jha AK, Joynt KE, Orav EJ, Epstein AM. The long-term effect of premier pay for performance on patient outcomes. *New England Journal of Medicine*. 2012;366(17):1606-15.
<http://www.nejm.org/doi/full/10.1056/NEJMsa1112351>
5. Jha, A. Misunderstanding Propublica. The Health Care Blog. Oct 8, 2015.
<http://thehealthcareblog.com/blog/2015/10/08/misunderstanding-propublica/>

Be prepared to discuss:

1. What are the main hospital-focused quality measurement and incentive programs employed by Medicare?
2. Why has there been so much enthusiasm for public reporting of quality performance?
3. What's the mechanism by which public reporting works (if it works at all)?
4. What are some of its unintended consequences of public reporting, and how might we address them

Learning Objectives:

By the end of this session, you will be able to:

1. Identify the leading causes of ambulatory safety concern
2. Describe the core concepts of effective population health management
3. Explain the concept of patient-centered medical homes

Read:

1. Gandhi TK, Lee TH. Patient safety beyond the hospital. *New England Journal of Medicine*. 2010;363(11):1001-3. <http://www.nejm.org.ezpprod1.hul.harvard.edu/doi/full/10.1056/NEJMp1003294>
2. Singh H, Graber ML. Improving Diagnosis in Health Care—The Next Imperative for Patient Safety. *New England Journal of Medicine*. 2015;373(26):2493-5. <http://www.nejm.org.ezpprod1.hul.harvard.edu/doi/full/10.1056/NEJMp1512241>
1. McGlynn EA, Asch SM, Adams J, Keesey J, Hicks J, DeCristofaro A, Kerr EA. The quality of health care delivered to adults in the United States. *New England Journal of Medicine*. 2003;348(26):2635-45. <http://content.nejm.org.ezpprod1.hul.harvard.edu/cgi/content/full/348/26/2635>
2. Friedberg MW, Schneider EC, Rosenthal MB, Volpp KG, Werner RM. Association between participation in a multipayer medical home intervention and changes in quality, utilization, and costs of care. *JAMA*. 2014;311(8):815-25. <http://jama.jamanetwork.com.ezpprod1.hul.harvard.edu/article.aspx?articleid=1832540>
5. Song Z, Rose S, Safran DG, Landon BE, Day MP, Chernew ME. Changes in health care spending and quality 4 years into global payment. *New England Journal of Medicine*. 2014;371(18):1704-14. <http://www.nejm.org.ezpprod1.hul.harvard.edu/doi/full/10.1056/NEJMsa1404026>

Be prepared to discuss:

1. What are the leading causes of preventable harm in ambulatory care?
2. How is ambulatory safety different than hospital safety, and how does this affect improvement programs in each space?
3. What are the core concepts of effective population health management?
4. What is a patient-centered medical home and the evidence base for its effectiveness?

Learning Objectives:

By the end of this session, you will be able to:

1. Describe the major types of provider payment methods including “value-based” approaches
2. Explain the principles of incentive design
3. Analyze the likely effects and potential adverse consequences of alternative payment approaches

Read:

1. VanLare JM, Conway PH. Value-based purchasing—national programs to move from volume to value. *New England Journal of Medicine*. 2012;367(4):292-5. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/nejmp1204939>
2. Robinson JC. Theory and practice in the design of physician payment incentives. *Milbank Quarterly*. 2001 Jun 1;79(2):149-77. <http://www.ncbi.nlm.nih.gov.ezp-prod1.hul.harvard.edu/pmc/articles/PMC2751195/>
3. Rosenthal MB, Fernandopulle R, Song HR, Landon B. Paying for quality: providers’ incentives for quality improvement. *Health Affairs*. 2004 Mar 1;23(2):127-41. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/23/2/127.long>
4. Lindenauer PK, Remus D, Roman S, Rothberg MB, Benjamin EM, Ma A, Bratzler DW. Public reporting and pay for performance in hospital quality improvement. *New England Journal of Medicine*. 2007;356(5):486-96. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMsa064964>
5. Eijkenaar F, Emmert M, Scheppach M, Schöffski O. Effects of pay for performance in health care: a systematic review of systematic reviews. *Health Policy*. 2013;110(2):115-30. <http://www.sciencedirect.com.ezp-prod1.hul.harvard.edu/science/article/pii/S0168851013000183>

Be prepared to discuss:

1. How important are financial incentives as influences at the point of care (i.e., how much do they enter into a decision to do or not do something for a patient)?
2. What is the ideal way to pay doctors and hospitals?
3. What needs to happen for value-based purchasing to be successful in health care?

Learning Objectives:

By the end of this session, you will be able to:

1. List the major theories for why there are disparities in care in the U.S.
2. Identify current strategies for elimination of health disparities

Read:

1. [Institute of Medicine. Unequal Treatment. 2002. Executive Summary. pp. 1-23](#)
2. Trivedi AN, Nsa W, Hausmann LR, Lee JS, Ma A, Bratzler DW, Mor MK, Baus K, Larbi F, Fine MJ. Quality and equity of care in US hospitals. *New England Journal of Medicine*. 2014;371(24):2298-308. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMsa1405003>
3. Schulman KA, Berlin JA, Harless W, Kerner JF, Sistrunk S, Gersh BJ, Dube R, Taleghani CK, Burke JE, Williams S, Eisenberg JM. The effect of race and sex on physicians' recommendations for cardiac catheterization. *New England Journal of Medicine*. 1999;340(8):618-26. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM199902253400806>
4. Clarke AR, Goddu AP, Nocon RS, Stock NW, Chyr LC, Akuoko JA, Chin MH. Thirty years of disparities intervention research: what are we doing to close racial and ethnic gaps in health care? *Medical Care*. 2013;51(11). <http://www.ncbi-nlm-nih-gov.ezp-prod1.hul.harvard.edu/pmc/articles/PMC3826431/>
5. Bach PB, Pham HH, Schrag D, Tate RC, Hargraves JL. Primary care physicians who treat blacks and whites. *New England Journal of Medicine*. 2004;351(6):575-84. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMsa040609>

Be prepared to discuss:

1. What are the major theories for why there are disparities in care in the U.S.?
2. What are potential solutions for reducing disparities?
3. Do you support the new National Quality Forum policy to adjust performance measures for socioeconomic status?

Assignment: Quiz in class today

Learning Objectives:

By the end of this session, you will be able to:

1. Understand the role of process improvement in healthcare
2. Recognize the tools of performance improvement, and understand how and when to apply them
3. Distinguish between commonly used process improvement models used in healthcare
4. Understand the principles and the role of statistical process control in process improvement

Read:

1. Davidoff F, Dixon-Woods M, Leviton L, Michie S. Demystifying theory and its use in improvement. *BMJ Quality & Safety*. 2015. <http://qualitysafety.bmj.com.ezp-prod1.hul.harvard.edu/content/24/3/228.long>
2. Scoville R, Little K. Comparing lean and quality improvement. IHI White Paper. Cambridge, Massachusetts: Institute for Healthcare Improvement. 2014. <http://www.ihl.org/resources/pages/ihlwhitepapers/comparingleanandqualityimprovement.aspx>
3. James BC, Savitz LA. How Intermountain trimmed health care costs through robust quality improvement efforts. *Health Affairs*. 2011 Jun 1;30(6):1185-91. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/30/6/1185.long>
4. Benneyan JC, Lloyd RC, Pisek PE. Statistical process control as a tool for research and healthcare improvement. *Quality and Safety in Health Care*. 2003;12(6):458-64. <http://qualitysafety.bmj.com.ezp-prod1.hul.harvard.edu/content/12/6/458.long>

Be prepared to discuss:

1. What is process improvement and what is its role in healthcare?
2. What are the different approaches an organization can take to improve care?
3. What combination of strengths has allowed Intermountain Health Care to excel at process improvement and care delivery?
4. What is the role of statistical process control in measuring and improving healthcare?

Learning Objectives:

By the end of this session, you will be able to:

1. Describe the innovation adoption curve and what determines whether an innovation spreads
2. Recognize how diffusion research applies to quality improvement

Read:

1. Rogers, EM. Diffusion of preventive innovations. *Addictive Behaviors*, 2002;27(6):989-993.
<http://www.sciencedirect.com.ezp-prod1.hul.harvard.edu/science/article/pii/S0306460302003003>
2. Berwick, DM. Disseminating innovations in health care. *JAMA*, 2003;289(15):1969-75.
<http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=196400>
3. Soumerai, S., McLaughlin, T.J., Gurwitz, JH., et al. Effect of local medical opinion leaders on quality of care for acute myocardial infarction: a randomized controlled trial. *JAMA*, 1998;279(17):1358-63.
<http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=187490>

Be prepared to discuss:

1. What are the phases of the innovation adoption curve, and what are the characteristics of the adopters in each phase?
2. What are prerequisites for an individual to adopt a new behavior?
3. What are desirable characteristics of an innovation?
4. What are the key features of an opinion leader? How can opinion leaders be helpful in QI?

Assignment: Paper 1 is due today

Learning Objectives:

By the end of this session, you will be able to:

1. Describe adoption of health information technology in the health care system
2. Understand how EHRs can impact quality and safety

Read:

1. DesRouches CM, Charles D, Furukawa MF, Joshi MS, Kralovec P, Mostashari C, Jha AK, Worzala C. Adoption of Electronic Health Records Grows Rapidly, but Fewer than Half of US Hospitals Had at Least a Basic System in 2012. *Health Affairs*. 2013; 32(8):1486-1492 <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/32/8/1478>
2. Bates DW, Gawande AA. Improving safety with information technology. *New England Journal of Medicine*. 2003;348(25):2526-34. <http://www.nejm.org/doi/full/10.1056/NEJMsa020847>
3. Hsiao CJ, Jha AK, King J, Patel V, Furukawa MF, Mostashari F. Office-based physicians are responding to incentives and assistance by adopting and using electronic health records. *Health Affairs*. 2013;10-377. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/32/8/1470>
4. Buntin MB, Burke MF, Hoaglin MC, Blumenthal D. The benefits of health information technology: a review of the recent literature shows predominantly positive results. *Health Affairs*. 2011;30(3):464-71. <http://content.healthaffairs.org/content/30/3/464.short>

Be prepared to discuss:

1. What are the functions of electronic health records that contribute to improved quality and safety?
2. Why has there been so much consensus behind health IT as a tool for QI?
3. Do current health policies drive adoption and appropriate use of health IT to improve patient care and outcomes?

Learning Objectives:

By the end of this session, you will be able to:

1. Distinguish conditions under which solving many small problems is more desirable than solving a few big impact problems
2. Distinguish between first order and second order problem solving and analyze their consequences for performance of healthcare organizations
3. Identify the potential conflicting incentives that cause people to choose to work around rather than resolve problems
4. Develop strategies for promoting sustainable second order change in organizations

Read:

1. **Case:** Edmonson AC, Tucker A. 2013. "Cincinnati Children's Hospital Medical Center." Harvard Business School. HBR # 609109.
<https://cb.hbsp.harvard.edu/cbmp/pl/48426185/48426187/86af0fdfeb63a6680ccd03c058107b35>
2. Tucker AL, Edmondson AC. Why hospitals don't learn from failures: Organizational and psychological dynamics that inhibit system change. *California Management Review*. 2003;45(2):55-72. <http://ezp-prod1.hul.harvard.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=heh&AN=9463647&site=ehost-live&scope=site>
3. Bohn R. "Stop Fighting Fires." *Harvard Business Review*, 2000; 78(4), 82–91. HBR # R00402.
<https://cb.hbsp.harvard.edu/cbmp/pl/48426185/48426192/e5f087f3a6aad3965f5e963e7770a665>
4. Repenning NP, Sterman JD. Nobody ever gets credit for fixing problems that never happened: creating and sustaining process improvement. *California management review*. 2001;43(4):64-88. <http://ezp-prod1.hul.harvard.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=5244741&site=ehost-live&scope=site>
5. Siracusa CM, Weiland JL, Acton JD, Chima AK, Chini BA, Hoberman AJ, Wetzel JD, Amin RS, McPhail GL. The impact of transforming healthcare delivery on cystic fibrosis outcomes: a decade of quality improvement at Cincinnati Children's Hospital. *BMJ Quality & Safety*. 2014;23:56-63. http://qualitysafety.bmj.com.ezp-prod1.hul.harvard.edu/content/23/Suppl_1/i56.full

Be prepared to discuss:

1. How has CCHMC designed its approach to improving quality to accommodate and leverage distinctive characteristics of healthcare organizations?

2. What do you think about CCHMC's improvement team's policy of transparency? Are they being too open with their performance data?
3. Consider Exhibit 3, Figure C. Which problem would you recommend they address first and why?
4. Moving forward, what would you recommend Kotagal do to sustain the hospital's improvement efforts?

Learning Objectives:

By the end of this session, you will be able to:

1. Describe current challenges in end-of-life care
2. Identify important elements in decision-making at the end of life

Read:

1. Gawande, A. Letting Go. *The New Yorker*. Aug 2, 2010.
<http://www.newyorker.com/magazine/2010/08/02/letting-go-2>
2. Bernacki, R.E & Block, S.D. Communication About Serious Illness Care Goals: A Review and Synthesis of Best Practices. *JAMA Intern Med*. 2014; 174(12):1994-2003. <http://archinte.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=1916912>

Additional reading:

1. Gawande, A, Being Mortal. Metropolitan Books, New York. 2014
2. "Being Mortal" FRONTLINE Documentary <http://www.pbs.org/wgbh/pages/frontline/being-mortal/>

Be prepared to discuss:

1. How do doctors approach end-of-life care in the U.S.? How should they?
2. How do people's values shape the end of their lives?
3. What are some ways to improve the quality of care at the end?

Learning Objectives:

By the end of this session, you will be able to:

1. Understand the changes in the healthcare marketplace which are driving the increased emphasis on accountable care
2. Describe key components of population health management and how they contribute to improved health and lower costs
3. Appreciate the structural elements of accountable care and how they foster all aspects of population health management

Read:

1. View Population Health video at: <http://www.partners.org/Innovation-And-Leadership/Population-Health-Management/Default.aspx>
2. Hong CS, Abrams MK, Ferris TG. Toward increased adoption of complex care management. *New England Journal of Medicine*. 2014 Aug 7;371(6):491-3. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1401755>
3. Kaiser Family Foundation Summary of the Affordable Care Act: <http://files.kff.org/attachment/fact-sheet-summary-of-the-affordable-care-act>
4. Fisher ES, Staiger DO, Bynum JP, Gottlieb DJ. Creating accountable care organizations: the extended hospital medical staff. *Health Affairs*. 2007;26(1):44-57. <http://content.healthaffairs.org/content/26/1/w44.full.pdf+html>

Be Prepared to Discuss:

1. What changes in the healthcare marketplace are driving the focus on accountable care?
2. Why is population health management a key strategy to improve care and lower costs?
3. What are the elements of population health management which are most likely to have an impact on value and costs?
4. How does the Affordable Care Act support accountable care (and detract from it)?
5. What disruptors are likely to play a role in the evolving healthcare marketplace?

Learning Objectives:

By the end of this session, you will be able to:

1. Assess how hospital and post-acute care payment models have historically influenced spending and care outcomes.
2. Understand the opportunities and challenges associated with new payment and delivery level reforms implemented under the ACA
3. Analyze how different payment and delivery level initiatives impact the coordination of acute and post-acute services.

Read:

1. Ackerly D.A. and D.C. Grabowski. "Post-Acute Care Reform – Beyond the ACA," *New England Journal of Medicine*. 2014; 370(8): 689-691. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1315350>
2. Grabowski, D.C., P.J. Huckfeldt, N. Sood, J.J. Escarce and J.P. Newhouse. "Medicare Postacute Care Payment Reforms Have Potential To Improve Efficiency Of Care, But May Need Changes To Cut Costs Over Time," *Health Affairs*. 2012; 31(9): 1941-1950. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/31/9/1941.long>
3. Mechanic R. "Post-Acute Care-The Next Frontier for Controlling Medicare Spending," *New England Journal of Medicine*. 2014; 370(8): 692-694. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1315607>

Be Prepared to Discuss:

1. How did the shift to prospective payment across the different post-acute settings influence spending and outcomes?
2. What are the opportunities and challenges for post-acute care in relation to ACA initiatives like bundled payment and accountable care organizations?
3. What are possible delivery-level approaches to improving the coordination of acute and post-acute services?

Assignment: Paper 2 due today

Learning Objectives:

By the end of this session, you will be able to:

1. Identify expected trends in **measurement** for quality and safety
2. Identify expected trends in **improvement** for quality and safety

Read:

1. Malphrus E, McGinnis JM, Blumenthal D, editors. Vital Signs: Core Metrics for Health and Health Care Progress. National Academies Press; 2015 Aug 26.
<http://www.nap.edu/catalog/19402/vital-signs-core-metrics-for-health-and-health-care-progress>
2. Porter ME, Lee TH. Why strategy matters now. *New England Journal of Medicine*. 2015;372(18):1681-4. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1502419>

Be Prepared to Discuss:

1. In what ways is our current measurement system failing us? How do we make it better?
2. What will be required to achieve large scale, sustainable success in improving quality and safety?

HPM520 Fall 2015

COMMUNITY ORGANIZING FOR HEALTH

Monday 3:30 – 5:20

Wednesday 3:30 – 5:20

FXB G-11

Instructor: Susan T. Sherry
ssherry@communitycatalyst.org

W: 617-275-2816
 H: 781-592-8671

This course focuses on organizing consumer and community interests in the American health system with particular emphasis on effective interventions by and for the traditionally disenfranchised. Using the framework of community organizing and advocacy, the course examines the elements of building and sustaining constituency involvement in health care. Analysis of American health policy and politics is used to identify strategic opportunities and challenges for consumer intervention. The course emphasizes the practical applications of organizing and policy analysis to influence health policy particularly at the institutional, local, and state levels. Extensive use of recent case examples ground the class in the current issues faced by community groups and other health interests in a rapidly changing health system.

Course Objectives:

At the completion of the course students will be able to:

- describe the principles and techniques of community organizing
- analyze the policy and political environment of a specific health issue and identify policy change opportunities and barriers to change
- design a community organizing strategy to achieve specific health care system or public health policy change
- develop and identify specific approaches to actively engaging community members and constituency groups in a range of health care and public health settings (institutional policy, health care delivery, health education, public policy advocacy, etc.)

Outcome Measures:

Class Participation

Classes will be seminar format with lectures, guest speakers, and active discussion. Students will be expected to complete readings prior to class and be prepared to participate in discussion based on the readings. Reading questions for each class are posted to the class website. Class discussion will also draw on students' experiences and specific interests. Small group discussion will provide opportunities to engage more deeply with the course content. Students are expected to attend and participate in all classes.

Group Exercise

There will be a small group exercise in which students will present positions on elements of current national reform proposals. The exercise is intended to develop an understanding of the positions of diverse political organizations and to apply political and policy analysis.

Written Assignment

The final assignment will be a 10 page strategy memo that defines an issue and outlines an organizing strategy to address the issue. Two shorter papers that will help formulate the final assignment will be required. The memo will be written from the perspective of a particular organization or agency involved with the issue

(although the strategy will address how to organize in the system and/or community beyond the specific organization). Specifications for the memo will be provided at the first class. The schedule for assignments will be:

11/9 first paper due

11/24 second paper due

12/18 final assignment due

Grading Criteria

Class Participation will comprise 40% of grade and the written assignment 60% of grade.

Course Materials

The course utilizes a text book that will be available at the bookstore. PDFs of other readings will be posted to the class website or linked by url in the course website syllabus.

The text is:

Community Organizing and Community Building for Health and Welfare, Meredith Minkler, editor (Rutgers University Press, 2012)

Course Evaluation

Completion of the evaluation is a course requirement. Your grade will not be available until you submit the evaluation. In addition, registration for future terms will be blocked until you have completed evaluations for courses in prior terms.

OCTOBER 26 Introduction

overview of course; student background and interests; exploration of how future professional roles may intersect with community organizing and consumer interests; student goals for class

OCTOBER 28 Politics & Participation in US

definition of politics; political change and participation; moving diffuse interests to be organized interests; unique features of U.S. health care politics

Deborah A. Stone, Policy Paradox: The Art of Political Decision Making, (W.W. Norton & Company, New York 2012) "Interests" pages 229 -247

NOVEMBER 2 Social Change and Social Movements

group exercise; U.S. social movements and social change; motivation for change; social movements and health

Andrea Boroff Eagan, "The Women's Health Movement and Its Lasting Impact, in An Unfinished Revolution: Women and Health Care in American, Emily Friedman, editor (United Hospital Fund of New York, 1994), pages 15-27

Richard Kluger, Ashes to Ashes, (Alfred A. Knopf, New York, 1996), pages 552-573

NOVEMBER 4 Social Change and Social Movements

James A. Morone, The Democratic Wish, (Yale University Press, 1998), pages 186-252

NOVEMBER 9 NO CLASS FIRST PAPER DUE

NOVEMBER 11 NO CLASS VETERANS DAY

NOVEMBER 16 Organizing Approaches

overview of community organizing approaches; role of self-interest and ideology and values; confrontation vs. collaboration

Saul D. Alinsky, Rules for Radicals (Vintage, 1989), pages 113–125

Mary Beth Rogers, Cold Anger, (University of North Texas Press, 1990), pages 93 – 101

Meredith Minkler and Nina Wallerstein, “Improving Health through Community Organization and Community Building: Perspectives from Health Education and Social Work” in Community Organizing and Community Building for Health, Meredith Minkler, editor (Rutgers University Press, 2012) pages 37 – 58

NOVEMBER 18 Engaging People

techniques for identifying and engaging people – surveys, door-to-door, existing organizations; precipitating event to develop community voice; listening to concerns and understanding self-interest; cultural considerations; identifying problems

Rogers, Cold Anger, pages 33 –39

Ronald LaBonte, “Community Development and the Forming of Authentic Partnerships: Some Critical Reflections” in Community Organizing and Community Building for Health and Welfare, pages 95 – 109

“Transforming Perception: Black Men and Boys”, Executive Summary, American Values Institute, 2013
<http://static.squarespace.com/static/538d8fd7e4b0aff4bbdaebba/t/539ab153e4b02bedb3a45697/1402646867341/Transforming%20Perception.pdf>

Community Catalyst, “Meaningful Consumer Engagement”, 2014,
<http://www.communitycatalyst.org/resources/tools/meaningful-consumer-engagement>

NOTE: click through and read the full consumer engagement toolkit

meeting facilitation guides

NOVEMBER 23 Identifying Issues

defining an issue; targets – primary and secondary; goals

Lee Staples, “Selecting and Cutting the Issue”, in Community Organizing and Community Building for Health, pages 173 - 192

Kim Bobo, Jackie Kendall, and Steve Max, Organizing for Social Change, (Seven Locks Press Santa Ana, CA 2001) pages 22-27

Trevor Hancock and Meredith Minkler, “Community Health Assessment or Healthy Community Assessment: Whose Community? Whose Health? Whose Assessment?” in Community Organizing and Community Building for Health and Welfare, pages 153 – 170

Community Catalyst, “Getting to No: How Kansas Advocates Derailed the Anthem Steamroller”, States of Health, Vol. 11, No. 4, summer 2002
http://www.communitycatalyst.org/doc_store/publications/getting_to_no_how_kansas_advocates_derailed_the_anthem_steamroller_jun02.pdf

NOVEMBER 24 SECOND PAPER DUE

NOVEMBER 30 Strategy and Campaigns

development of strategy; tactical choices; differences in policymaking arenas; sustaining effort and building capacity through issue campaigns

Andrew Mott, “Citizen Monitoring and Action” in The Nonprofit Quarterly, Vol 13, Issue 1, Spring 2006, (Third Sector New England, Boston) pages 18 -20 <http://www.nonprofitquarterly.org/philanthropy/644-citizen-monitoring-and-action.html>

Betsy Stoll and Rob Restuccia, “Community Monitoring and Free Care” in The Nonprofit Quarterly, Vol 13, Issue 1, Spring 2006, (Third Sector New England, Boston) pages 21 – 24
<http://www.nonprofitquarterly.org/governancevoice/40-community-monitoring-and-free-care.html>

Joel S. Weissman, “The Trouble with Uncompensated Hospital Care”, New England Journal of Medicine, 352;12, March 24, 2005 <http://content.nejm.org.ezp1.harvard.edu/cgi/content/full/352/12/1171>
<http://www.nejm.org/doi/full/10.1056/NEJMp048280>

Community Catalyst, “Summary of Proposed Rules for Non-profit Hospitals’ Financial Assistance, Billing and Collection Practices”, October 9, 2012 http://www.communitycatalyst.org/initiatives-and-issues/initiatives/hospital-accountability-project/resources/document/Summary_Notice_of_Proposed_Rules_Financial_Assistance_Debt_Collection.pdf

DECEMBER 2 Media & Communication

media impact on public and elites; the mechanics of media work -- what they need, when they need it, how they need it; constituency skill development

Lori Dorfman and Priscilla Gonzalez, “Media Advocacy: A Strategy for Helping Communities Change Policy” in Community Organizing and Community Building for Health and Welfare, pages 407 – 420

Closing the Medicaid Coverage Gap materials:

Engaging Hospitals in Campaigns to Close the Gap: Best Practices from the Field
http://www.communitycatalyst.org/resources/publications/document/Hospital_Advocate_Engagement_Strategies_04.01.15_formatted.pdf

Closing the Coverage Gap Helps Combat Drug and Alcohol Problems,
<http://www.communitycatalyst.org/resources/publications/document/SUD-2-Pager-National-Formatted-1-6-15-final.pdf>

Movement to Close the Coverage Gap,
<http://www.communitycatalyst.org/resources/publications/document/Coverage-Gap-Movement.pdf>

Closing the Gap in Kentucky Brings Better Coverage, New Jobs, State Savings, and a Boost to Providers, <http://www.communitycatalyst.org/blog/closing-the-gap-in-kentucky-brings-better-coverage-new-jobs-state-savings-and-a-boost-to-providers#.VgcJDJfQOJ8>

States Report that Closing the Coverage Gap is Good for Budgets,
<http://www.communitycatalyst.org/blog/states-report-that-closing-the-coverage-gap-is-good-for-budgets#.VgcJTzfQOJ8>

Building a Case for Medicaid, <http://www.communitycatalyst.org/resources/tools/defending-medicaid>
 NOTE: explore the different types of tools in the toolkit

Center for Social Inclusion, “Let’s Talk About Race: How Racially Explicit Messaging Can Advance Equity” 2015, <http://www.centerforsocialinclusion.org/wp-content/uploads/2015/08/Lets-Talk-About-Race.pdf>

Supplemental:

Spitfire Strategies, Planning to Win, 2014
http://planningtowin.org/?utm_source=Spitfire+Newsletter+Subscribers&utm_campaign=7dc4554ff9-PTW_announcement_8_5_148_4

Nickie Bazell Satariano and Amanda Wong, “Creating an Online Strategy to Enhance Effective Community Building and Organizing” in Community Organizing and Community Building for Health and Welfare, pages 269 – 287

DECEMBER 7 Role of Policy and Political Analysis

effective use of policy and legal analysis in organizing and policy-making context; leadership development; use with media and policymakers

Stone, Policy Paradox: The Art of Political Decision Making , “Numbers” pages 183-- 205

Jim Shultz, The Democracy Owners’ Manual, (Rutgers University Press, 2003), “Research and Analysis: Advocacy by Fact, Not Fiction”, pages 83-95

Community Catalyst, “Grasstops Engagement and Grassroots Activation: How Advocates Improved Pennsylvania’s Medicaid Waiver”, August 2015

<http://www.communitycatalyst.org/resources/publications/document/Pennsylvania-Waiver-Case-Study-final-edits.pdf>

DECEMBER 9 Campaigns and Coalitions

coalition – advantages and disadvantages of coalitions; principles for success; issue-specific coalitions; coalitions with “untraditional” allies; broad-based coalitions – limits and potential

Alinksy, Rules for Radicals, pages 126 – 136

Shultz, The Democracy Owner’s Manual, “Developing a Strategy, Advocacy’s Road Map”, pages 71 -82

Shultz, The Democracy Owner’s Manual, “Building and Maintaining Advocacy Coalitions”, pages 120 - 131

one of the following (to be designated):

Randy Shaw, The Activist’s Handbook (University of California Press, 1996), pages 212 – 235

Anne Standley, Nicholas Herold, Marcia Hams, Case Study: The Boston Health Access Project of Health Care For All (The Access Project, Boston, 2000)

DECEMBER 14 Applications

organizational structures to institutionalize constituency involvement; role of philanthropy in supporting consumer efforts; CBPR

Pam Tau Lee, Niklas Krause, Charles Goetchius, Jo Marie Argriesti & Robin Baker, “Participatory Action Research with Hotel Room Cleaners in San Francisco and Las Vegas” in Community-Based Participatory Research for Health, Meredith Minkler & Nina Wallerstein, editors, (Jossey-Bass, 2008), pages 335 – 353

“Consumer Health Advocacy: A View from 16 States”, (Community Catalyst, Boston, 2006), pages 1 - 13
http://www.communitycatalyst.org/doc_store/publications/consumer_health_advocacy_a_view_from_16_states_oct06.pdf

Community Catalyst System of Advocacy, <http://www.communitycatalyst.org/work> NOTE: expand boxes

Community Catalyst, “The Path to a People-Centered Health System: Next Generation Consumer Health Advocacy”, 2015, pages 1-5 and 35 – 45.

<http://www.communitycatalyst.org/resources/publications/document/Next-Generation-HST-Report.pdf>

Supplemental:

Grantmakers in Health, “Health Reform 5 Years Later”, May 2015,
[http://www.gih.org/files/FileDownloads/Health Reform 5 Years Later May 2015.pdf](http://www.gih.org/files/FileDownloads/Health%20Reform%205%20Years%20Later%20May%202015.pdf)

DECEMBER 16 Applications

applications of organizing in different settings – local community, institutional settings, inside/outside bureaucracy, think tanks, etc.; skill sets required; values around constituency engagement; sharing power; challenges to meaningful constituency engagement

Meredith Minkler and Cheri Pies, “Ethical Issues and Practical Dilemmas in Community Organization and Community Participation” in Community Organizing and Community Building for Health , pages 116 - 134

John Kania and Mark Kramer, “Collective Impact”, Stanford Social Innovation Review, Winter 2011, pages 36 – 41 <http://ezp-prod1.hul.harvard.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=bth&AN=55818295&site=ehost-live&scope=site>.

National Preparedness Leadership Initiative, “The Dimensions of Meta-Leadership”, HSPH and HKS
<https://npli.sph.harvard.edu/meta-leadership/>

DECEMBER 18 FINAL PAPER DUE

Measuring and Analyzing the Outcomes of Health Care



HPM 530

SUMMER 1, 2015

Course Instructors

**Marcia A. Testa, MPH, MPhil, PhD
Donald C. Simonson, MD, MBA, MPH, ScD**

Guest Lecturers

John E. Ware, Jr., PhD

Teaching Fellow

Linda G. Marc, MPH, ScD

Harvard T.H. Chan School of Public Health

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Measuring and Analyzing the Outcomes of Health Care

Registrar Description

Measuring and Analyzing the Outcomes of Health Care

School of Public Health: HPM 530, Summer1

Summer 2015

Dr. M. Testa, Dr. D. Simonson

2.5 credits

Lectures, case studies. Five 1.75-hour sessions each week.

This course emphasizes introductory concepts, methods, and practical procedures for measuring and analyzing patients' health status, quality of life, satisfaction and cost-effectiveness for health outcomes research. The course reviews the fundamentals of health outcomes research methods necessary for 1) demonstrating improvement in patient outcomes, 2) controlling costs and allocating resources, 3) implementing disease management programs and 4) making effective public health, health technology and clinical decisions.

Statistical methods needed to evaluate and use scales and indices are also presented and discussed. The course would be useful to public health and clinical researchers who must critically review and utilize outcomes data for public health, health care and clinical decision-making.

The course should enable students to 1) conceptually define the meaning and purpose of outcomes research, 2) understand the role of epidemiology, health economics and database and information technology in conducting outcomes research, 3) evaluate the usefulness and utility of outcomes measures, 4) recognize the different types of measures used in outcomes research, including clinical, health status, quality-of-life, work/role performance, health care utilization, and patient satisfaction, 5) adopt new methods for modeling patient responses, interpret the meaning of measurement concepts and obtain a basic appreciation of the statistical analyses appropriate for outcomes research, 6) locate available research-quality instruments for measuring health care outcomes in order to make informed choices among existing instruments and 7) interpret the results of health outcomes research.

HPM 530 - Summer 1

Detailed Course Description and Objectives

This course emphasizes introductory concepts, methods, and practical procedures for measuring and analyzing the outcomes of health care as part of comparative effectiveness research with a special emphasis on “patient-centered outcomes” including patients' health status, quality of life and satisfaction. It also introduces methods for cost-effectiveness and cost-utility research studies. The course reviews the fundamentals of health outcomes research methods necessary for 1) demonstrating improvement in patient outcomes, 2) controlling costs and allocating resources, 3) implementing disease management programs and 4) making effective public health, health technology and clinical decisions. It is expected that at the end of this course that the student will achieve the follow competencies:

- Conceptually define the meaning and purpose of outcomes research
- Understand the role of measurement, epidemiology, health economics and database and information technology in conducting outcomes research
- Evaluate the usefulness and utility of outcomes measures
- Recognize the different types of measures used in outcomes research, including clinical, health status, quality-of-life, work/role performance, health care utilization, and patient satisfaction
- Critically review and interpret the scientific literature on health outcomes research
- Adopt methods for modeling patient responses, interpret the meaning of measurement concepts and obtain a basic appreciation of the statistical analyses appropriate for outcomes research.

Course Overview

The course begins with a brief introduction to the areas of quality of care, outcomes research and outcomes management which attempts to clarify and explain why it is important to measure health outcomes in a uniform, systematic and reliable manner.

With this introduction, class lectures then focus primarily on the types of studies, designs, measures and analyses required for evaluating the consequences of health care and for undertaking comparative effectiveness research. The overall goal of the course is to present outcomes research to the practitioner in such a way as to provide the necessary groundwork to enable effective clinical decisions related to improving health outcomes. Class examples will demonstrate that by effectively utilizing health outcomes data in the practice of outcomes management new interventions can be identified which will improve the health, functional status and well being of patients.

The course stresses that since evaluation most often involves assessment of individuals, the techniques covered will demonstrate how individual patients can be evaluated using patient health status, quality of life, satisfaction and other patient-centered measures. However, the course also considers instruments for evaluating the outcomes of health systems and technologies including health programs, medical therapies, health care delivery services and the health care workforce. The health outcomes research techniques presented will illustrate steps of outcomes research so that improvements in processes (treatment and health promotion strategies) can be made.

In order to complete these steps, the course material stresses methods for measuring and quantifying the needs, processes, patient reactions, and the immediate, intermediate and long-term outcomes of health care. It also focuses on methods for patient-centered outcomes and comparative effectiveness research.

The course will work through teaching the student how to build the outcomes conceptual model and how to evaluate the impact of a new treatment or intervention while adjusting for clinical and patient factors. First, the outcomes hierarchy involving the physiologic status, clinical status, functional health status and quality of life of the patient will be set in the context of a measurement model. An introduction to the measurement model, involving the use of clinical assessments and questionnaires will be given including a review of generic, condition-specific and satisfaction questionnaires. Basic psychometrics, techniques and type of analyses for comparing treatment effects and methods for measuring the effects of treatment and interpreting the treatment effects will be briefly introduced.

Course Competencies and Learning Objectives

Since it is important to individually evaluate students according to a structured set of learning objectives, two graded assignments will be given (a course project assignment and a final examination). These assignments will be used to help evaluate whether the course learning objectives have been achieved. The learning objectives are directed to allow the student to:

- Gain an understanding of the terms and definitions relating to quality of care, outcomes research and outcomes management in the context of evaluating and measuring the performance of health programs, medical and pharmacologic therapies, health care delivery and the health care workforce.
- Acquire the knowledge necessary to conceptualize the outcomes model in terms of the appropriate health constructs and domains.
- Gain an understanding of the concepts, methods, and practical procedures for using and analyzing instruments, surveys and questionnaires necessary for evaluating the outcomes of health care.
- Explain the role of health economic assessment and measurement for evaluating the cost-effectiveness, cost-benefit and cost utility of treatments and interventions.

- Define and apply the various measures and terms used to determine evaluate the performance properties of outcomes assessment instruments (e.g., validity, reliability, responsiveness, sensitivity, minimally clinically important difference (MCID)] in a health outcomes intervention study
- Acquire a basic appreciation of the analytical and statistical analyses appropriate for evaluating and using outcomes measures.

Prerequisites

Although there are no formal course prerequisites because it is necessary to use descriptive and basic inferential statistical methods to effectively design studies and understand measurement and analysis, *prior exposure to introductory epidemiology and biostatistics is recommended*. For example, students should be familiar with basic descriptive (mean, median, variance, standard deviation) and inferential statistics (correlations, t-test, analysis of variance). Many students will be taking introductory epidemiology and biostatistics at the same time they are taking this course

Course Faculty

HSPH and HMS Faculty

Marcia Testa, M.P.H., M.Phil., Ph.D. <http://www.hsph.harvard.edu/faculty/marcia-testa/>
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 Harvard School of Public Health
 Building 1, 417
 617-432-2818
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Donald C. Simonson, M.D., M.B.A., M.P.H., Sc.D.
 Brigham and Women's Hospital
 221 Longwood Avenue
dsimonso@hsph.harvard.edu

Guest Lecturers

John E. Ware, Jr., PhD <http://profiles.umassmed.edu/Profiles/display/130104>
 Professor
 Department of Quantitative Health Sciences
 University of Massachusetts School of Medicine

Teaching Fellow

Linda Marc, MPH, ScM ScD lmarc@hsph.harvard.edu
 Research Associate
 Department of Biostatistics

Lectures

Lectures are held from 1:30 PM. to 3:20 PM Monday through Friday in Kresge 502. Please check for any last minute changes in room assignments.

Grading and Incompletes

Students are allowed to choose either an ordinal grading option or PASS/FAIL. Please be aware that after the final exam is completed, the course grade is considered final. According to Harvard Chan Policy, students may not ask for an Incomplete once the course project and final exams are submitted. A request for an Incomplete must be made by the student no later than 3 days prior to the final exam in the form of an Incomplete Contract between the Instructor and the Student. A request for an Incomplete is not always granted. Incompletes are only given for exceptional circumstances, such as missing a significant proportion of classes due to an acute illness or death of a family member. Please refer to your Harvard Chan student handbook for more details regarding grading and other academic matters.

Reading Assignments

Homework involves readings from the text book, several assigned articles, as well as work on the course project.

Evaluation and Grading

The **Course Project** (described below) counts for 40%, the **Final Exam** 40% and class attendance and participation for 20%.

The **Final Exam** is a closed book, multiple choice, short answer, brief essay exam given on the last day of class.

Class attendance and active participation

If an emergency arises or if the student cannot attend a lecture or a lab, an email should be sent to testa@hsph.harvard.edu prior to the missed class if possible, or shortly thereafter.

Textbook

Required text reading can be found in *Kane, R.L. and Radosevich D.M. Conducting Health Outcomes Research (First Edition)*, 2010 Jones & ISBN = 9780763786779. -- can be ordered at a number of places, including:

Amazon.com *Kane, R.L. and Radosevich D.M. Conducting Health Outcomes Research (First Edition)*, 2010 Jones & ISBN = 9780763786779. You can order online in either the **paperback** or **e-book** (Kindle Edition) via www.amazon.com by searching on the

authors and title (Conducting Health Outcomes Research by Robert L. Kane and David M. Radosevich). You can also order the paperback version from Barnes and Noble (www.bn.com), or other online bookstores. Just look for the lowest price.

Course Web Page

<https://canvas.harvard.edu/courses/3066>

HPM 530 - Measuring and Analyzing the Outcomes of Health Care



Course Info

Getting Started

Teaching Staff

Week 1

Week 2

Week 3

Week 4

The HPM 530 course Web Page will be used as a primary point of communication and will contain all handouts (posted only after the class session is complete), URL surveys and publications links, and other required materials. The Web Page may be accessed through your Harvard Chan Course Gateway. Since announcements, assignments, data sets and linked Web pages will be posted on this Web site, it is *extremely important that you have access through your Harvard ID and PIN.*

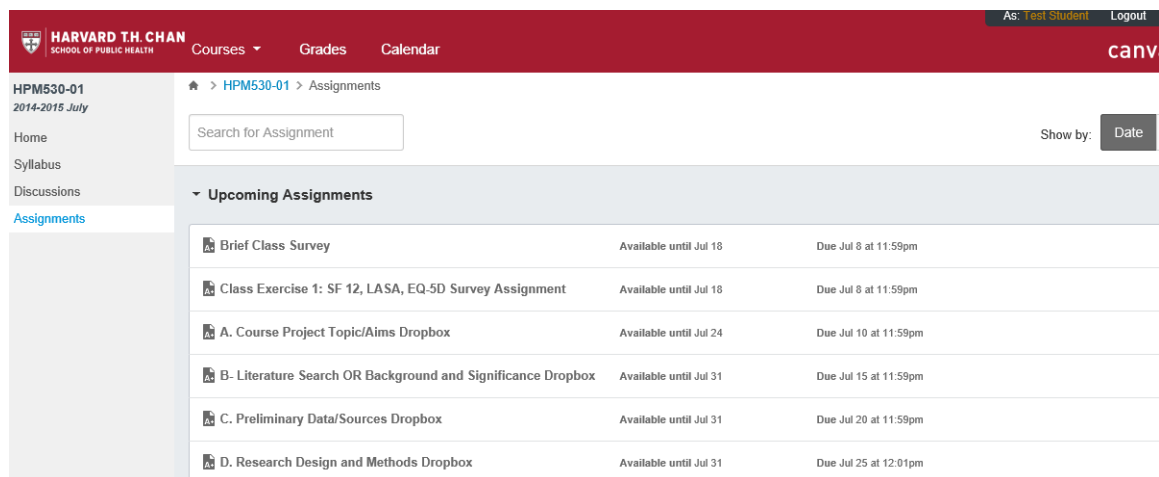
The Course Webpage recently switched to a new system, so the course pages may not be available until the end of the week of July 6th.

Course Project Description: Literature Review or Outcomes Research Grant Proposal

Assignment: You will develop either a

- *Comprehensive review of the literature on a health outcomes related topic of interest in your field of practice or research, OR*
- *Research grant proposal outlining how you would design a health outcomes study, collect data, and analyze data to address a relevant research hypothesis of interest to you*

You must submit your title, literature search topic area (if you are doing a literature review) OR specific aims (if you are submitting a grant proposal) **by Friday, July 10, 2015**. Please see details on topic “A. Title and Topic Area OR Specific Aims – Friday, July 10, 2015” below. You will need to complete your course project by the last day of class, but you will have until noon on Saturday, July 25, 2015 to upload it. There are a series of brief interim course project assignments to keep you on pace with the course. You will submit all assignments through the course web page by going to the Assignments Page which will look like the screenshot below.



The screenshot shows the Canvas LMS interface for the course HPM530-01. The navigation menu on the left includes Home, Syllabus, Discussions, and Assignments. The main content area displays a search bar and a table of upcoming assignments. The table has three columns: Assignment Name, Available until, and Due date. The assignments listed are:

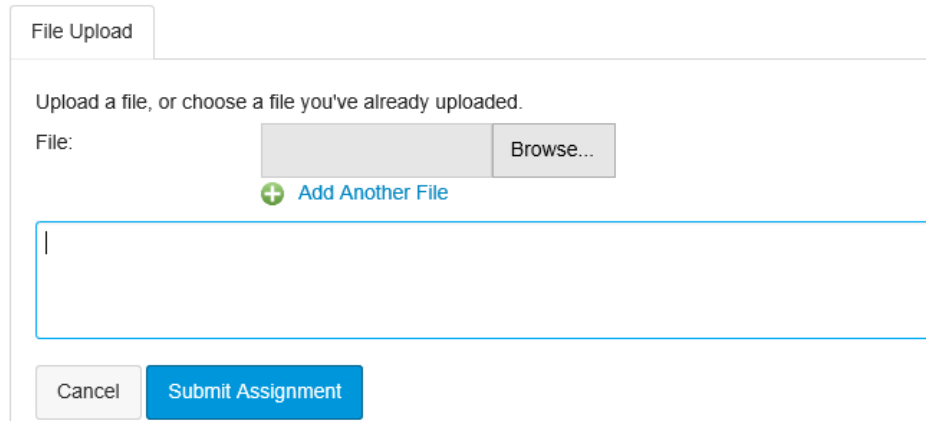
Assignment Name	Available until	Due date
Brief Class Survey	Available until Jul 18	Due Jul 8 at 11:59pm
Class Exercise 1: SF 12, LASA, EQ-5D Survey Assignment	Available until Jul 18	Due Jul 8 at 11:59pm
A. Course Project Topic/Aims Dropbox	Available until Jul 24	Due Jul 10 at 11:59pm
B. Literature Search OR Background and Significance Dropbox	Available until Jul 31	Due Jul 15 at 11:59pm
C. Preliminary Data/Sources Dropbox	Available until Jul 31	Due Jul 20 at 11:59pm
D. Research Design and Methods Dropbox	Available until Jul 31	Due Jul 25 at 12:01pm

Submitting Course Project Files

When you open the Assignment, you will see that you each have your own submission area. You will be given instructions on naming your files within the Dropbox description. For example, it might say for Assignment A. Course Project Topic/Aims Dropbox. **“Please create your submission file as a WORD DOCUMENT with the following file naming convention: Last = Your Last Name, F = Your First Initial, so filename will be “Last_F_HPM530_Topic.doc”**

Course Project Questions

If you have questions about your progress on the course project, please submit a draft of your work (add the word “Draft” to the end of the filename) and add your question(s) to the “Comments” text box which will appear under the File Upload menu as shown below.



The screenshot shows a 'File Upload' dialog box. At the top, it says 'File Upload'. Below that, it instructs the user to 'Upload a file, or choose a file you've already uploaded.' There is a 'File:' label followed by a text input field and a 'Browse...' button. Below the input field is a green plus icon and the text '+ Add Another File'. A large, empty text box is provided for comments. At the bottom, there are two buttons: 'Cancel' and 'Submit Assignment'.

You will need to pace yourself to ensure that you can meet the course project deadline. To keep pace with the course, there are three interim assignments A, B and C (see descriptions below) . You are not graded on these assignments but we will review your progress. Only Assignment D (also described below) is graded.

A. Title and Topic Area OR Specific Aims – Friday, July 10, 2015

List the broad objectives and the goal of the specific literature review or outcomes research project proposed. Some examples are: 1) reviewing the literature involving health outcomes measures for assessing the impact of asthma on health functioning, 2) developing a research proposal to test a hypothesis involving a comparison of a new treatment or program versus usual care, 3) analysis of a database to assess the impact of patient characteristics, behaviors or other risk factors on health outcomes, 4) evaluate the effectiveness and/or cost effectiveness of a new versus existing medical/health care practice. *One page is recommended.*

B. Literature Search OR Background and Significance – Wednesday, July, 15, 2015

Briefly sketch the literature search criteria OR research proposal background justifying your project proposal, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health relevance of the outcomes literature search or research described in your proposal by relating the specific aims to the broad, long-term objectives and potential health care practice or system improvements. If the aims of the review/application are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the effect of these studies on the concepts, methods, technologies, treatments, services or preventative

interventions relating to your specific research hypothesis. ***Two to three pages are recommended.***

C. Preliminary Data/Sources – Monday, July 20, 2015

Preliminary Studies. Provide any ***preliminary data*** or ***sources of data*** to support your review or proposal. You may use your own data, data that you have abstracted and compiled from the published literature, or data that you have obtained from publicly available databases. If you are conducting a literature review, you should focus on organizing your critical comments. Critical comments examine the data and evidence available in the literature reviewed. You do not have to analyze the data you cite in your proposal if you are not yet at that stage, but you should provide evidence of how you will obtain the data (if using secondary data), or the data collection survey or instrument (if your proposal calls for primary data collection). You may also show evidence that you have already done descriptive analyses, downloaded and read the variables listings, or mapped a survey instrument to a database if you are using publicly available data or your own data source. Examples of publicly available data bases can be found at <http://www.cdc.gov/DataStatistics/>
<http://surveillance.cancer.gov/>
<http://www.ahrq.gov/data/>
<http://www.hosonline.org/>

D. Research Design and Methods - Due by Final Report Submission – Must be posted to the Dropbox by July 25, 2015 12 noon.

Complete the critical review of the literature (not merely a catalogue or summary) OR describe the research design conceptual model, clinical framework, procedures, and analyses to be used to accomplish the specific aims of your project. For research proposals, include specifically the type of study design and why it is appropriate, how the data will be collected, analyzed, and interpreted. If appropriate, describe any new methodology and its advantage over existing methodologies. Describe any novel concepts, approaches, tools, or technologies for the proposed studies.

Make sure to discuss the potential difficulties and limitations of the literature based-studies reviewed or proposed research methods and procedures.

The total number of pages (A-D) should be ***no longer than 12 double-spaced pages*** of text (approximately 3000 words) plus up to 2 pages of references (approximately 25-30 references). You may also include up to 2 figures or tables. Please note that figures or tables should be your own creation, and not simply copied from the literature.

NOTE: For all research involving human subjects, you should provide a careful consideration of protections from research risks, as well as the appropriate inclusion of women, minorities, and children.

HPM 539

Health Care Organizations and Organizational Behavior: Leadership and Management for Learning, Innovation, and Performance Improvement

Spring-2 2016

Monday and Wednesday, 10:30-12:20, Room G-2

Instructor:

Laurie S. Pascal, MBA, MPH

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Course Description

The Institute of Medicine's goal of health care that is safe, effective, patient-centered, efficient, timely and equitable won't be accomplished primarily through policy reform. Health care organizations individually and collectively must learn to innovate, change, and improve continuously.

Health care organizations are made up of individuals, groups and teams – their customers, suppliers, and employees – who make each organization unique. Successfully leading in this context, at any level (executive, manager, frontline worker, or consultant) requires understanding and applying knowledge about how people and groups act in organizations. People and groups interrelate with each other, with the organization, and within the system in which they work; and the health care system presents distinctive challenges and constraints.

This course aims to help participants understand health care organizations and organizational behavior through discussion of case studies of organizational challenges, through contemporary and seminal literature addressing major theoretical perspectives on organizations, and through exercises and simulations designed to experience and practice what is learned. We will examine both macro issues (that impact organizations as a whole) and micro issues (that impact individuals and teams). To develop your abilities to apply the theoretical and practical concepts, students will work together in teams to address organizational problems. Written assignments are designed to allow students to reflect on and apply lessons drawn from personal experience in organizations as well as the theories drawn from the literature.

This course supports students in being able to:

- Understand and use contemporary theories in organizational behavior
- Apply major themes in organizational theory to evaluate decisions facing health care organizations
- Use an organizational behavior perspective to develop evidence-based strategies for leading and managing health care organizations
- Identify unique challenges and opportunities for operating health care organizations, presented by the nature of health care and features of the health care system, and formulate strategies to address them
- Understand the role of individual differences in group dynamics
- Work effectively in teams

Assignments and Expectations

Please bring and display your name placard at each class so that we all get to know each other.

Classes have assigned readings, cases, exercises and simulations designed to inform and structure class discussion. The complete list of required assignments is included with the course syllabus. Additional recommended readings may be announced throughout the term and will be noted on Canvas.

Questions designed to guide your analysis of each case, including your critical evaluation of the situation and ideas for problem resolution, will be provided. Thoughtful consideration of these questions will greatly enhance your ability to contribute to class discussion.

This class is designed to have all participants learn from each other as well as from faculty. It is highly interactive to support real-time learning by doing. Therefore, on-time and each-time attendance of all participants is critical. Active involvement in every session contributes substantially to your participation grade. If you must miss a class, please notify the instructor and TA in advance via email. Because of the participatory nature of this course, more than one absence will negatively affect your final grade. If you wish to receive credit for one missed class (you may exercise this option only once during the term), you may:

1. *If readings and a case are assigned for that class:* Submit a two-page discussion of how the readings for that date helped you think about and respond to the questions as well as responding to the case questions themselves. This paper is due to the instructor via email no later than midnight of the day following the class you missed.
2. *If readings, but no case, are assigned for that class:* Submit a two-page discussion about how each of each of the readings for that class session apply to a situation you currently have, or previously had, at work or at school. This synopsis paper is due to the instructor via email no later than midnight of the day following the class you missed.

3. *If no case or readings are assigned (i.e., in-class simulation, classmates' presentations):*
There is no "make-up"

Grading

Since the case-study teaching method, role plays and simulations involve interactive discussion among students and faculty, a large portion of your grade will be based on classroom preparation and participation. It is important that you do the reading assignments and think about how this material applies, not only to the case example, but also to you in your previous and current life as well as in your future career. Learning the material requires engaging with it.

Participation: The class participation grade is determined by:

- (a) Your ability to thoughtfully answer questions, informed by case facts and analysis and the assigned readings
- (b) Your contribution of ideas and analysis relevant to the discussion, based on the readings and your personal experiences
- (c) Your ability to build on classmate's comments with reinforcement, debate, disagreement and new perspectives that move the discussion in productive directions
- (d) Your timely attendance

Quality of involvement is more important than quantity. You will assess your own class participation towards the beginning of the term and then again at the end of the term, not to grade yourself or be graded, but rather to see what progress you have made against your own goals for improvement. This class provides an opportunity to learn and enhance leadership skills in listening, speaking, and engaging others in discussion.

Written and oral assignments:

Papers and presentations will be graded on the overall power of the analysis and creation of realistic recommendations, i.e. the ability to critically examine and apply organizational theory to specific issues and arrive at solutions to organizational problems. Grading will also be based on the professionalism of the presentation itself, which includes the persuasiveness of the argument together with correct use of grammar, spelling and careful editing. When researching topics, appropriate academic sources are preferred (e.g. do not cite sources like Wikipedia).

Format: All written assignments are to be in **Word** (not PDF), typed in 12-point font, double spaced, with one inch margins. Presentations are to be in **PowerPoint** (not PDF), with effective use of margins, white space, and templates that are professional and easy to read. Insert page numbers on all assignments.

Due dates/times: Assignments are due by the **beginning** of class on the dates noted in the syllabus. Written case analysis papers will not be accepted late, as we will be discussing the case in that day's class. If you miss your date, you will receive a grade of zero (0) on that paper. The final group paper/presentation similarly will not be accepted late. Grades for any other assignments will be reduced by one full letter grade for each day that the assignment is late.

This policy is a matter of equity for all students in the class. Students are expected to adhere to the School's standards on academic integrity.

Each student will be responsible for the following six assignments. Specific instructions for the written assignments are in Canvas.

Assignments which will be read but not graded. Their thoughtful completion will factor into the participation grade.

- Initial class participation self-assessment (**Due April 13th**) and final class participation self-assessment (**Due May 11th**). These are required, but not graded.
- A written press release based on the Judgment in Crisis simulation. This is required and will be used in class. It will be read but not graded. **Due April 11th**

Assignments which will be graded.

- 1) Individual case analysis paper (maximum 4 pages double spaced) on a case which you will select at the beginning of the term. Cases appropriate for this assignment are noted with an asterisk on the syllabus. **Due before class the date the case is assigned for class.**
- 2) Reflection and application paper (maximum 3 pages double-spaced) which applies key theoretical and practical concepts from this class to your personal previous experience in an organization. **Due April 18th**
- 3) A team (5-6 people) project based on an organizational behavior issue in a health care organization. Topic will be the team's choice. Team's will analyze and make recommendations about an issue or problem in their chosen organization and submit the following on **May 9th**:
 - A written Executive Summary memo to the client summarizing the team's findings and recommendations (maximum 4 pages, excluding appendices)
 - An in-class presentation (maximum 10 minutes) followed by Q&A session
 - Written feedback on each of your fellow team members

Your final grade in the course will be determined by:

- 1) 15% - Case Analysis Paper
- 2) 15% - Reflection and Application Paper
- 3) 35% - Team Project Executive Summary Paper, Presentation and Completion of Teammate Feedback
- 4) 35% Class Participation/Preparation (includes Simulation press release and submission of both self-assessments)

Laptop and Phone Policy:

Technology in support of learning is wonderful. You will be notified in advance when your laptop will be required for in-class exercises. Laptops and/or tablets may be used to refer to

case material when we are doing a case discussion or a simulation. Otherwise, they tend to be a distraction to being actively involved in classroom discussion. Please turn phones off (not on vibrate, unless you are a clinician on call) and stow them in your backpack/briefcase/coat pocket or other location during the class.

Readings:

Please read assigned articles and cases before coming to class unless otherwise noted. Required course readings, cases and simulations will be available online via Canvas, the Internet, and a course pack from Harvard Business Publishing. To purchase the simulation from Harvard Business Publishing, please use this link:

<https://cb.hbsp.harvard.edu/cbmp/access/48087577>

Optional Journal: You may find keeping a journal helpful as you progress through the course. Capturing thoughts about yourself, teams and groups, and organizations at the end of each class – what did you discover, what does this mean for you in other situations and organizations – makes for interesting reading as you move along this exploratory journey.

Course Outline (May change for scheduling of invited guests)

Class	Date	Topic	Case/Exercise
Organizational Behavior in the Health Care Industry			
1	Mon, Mar 21	<p>Leading Organizations in Times of Change</p> <ul style="list-style-type: none"> Gain an appreciation for the difficulties and dilemmas in leading and managing healthcare organizations <p><u>Reading:</u></p> <ul style="list-style-type: none"> <i>Jeanette Clough at Mt. Auburn Hospital</i> case 	Case: <i>Jeanette Clough at Mt. Auburn Hospital</i>
2	Wed, Mar 23	<p>Organizational Behavior in a Dynamic Environment</p> <ul style="list-style-type: none"> Develop a framework for thinking about organizational behavior in healthcare organizations Understand the forces acting upon healthcare organizations Discuss final project <p><u>Watch:</u></p> <p>Lee, S. YouTube. "Reframing Organizations"</p> <p><u>Readings:</u></p> <p>Borkowski: "Overview and history of organizational behavior" Ramanujam: "The challenges are organizational not just clinical"</p> <p><u>Recommended Reading</u></p> <p>Deloitte: "2016 Global Healthcare Outlook"</p>	<p>Reflection: <i>What are the best and worst experiences you've had in organizations? What factors contributed to each of those situations?</i></p> <p>DUE: sign up for case analysis by 6:00 pm</p>

Seeing Organizations Through Different Lenses			
3	Mon, Mar 28	<p>Human Resources and Motivation</p> <ul style="list-style-type: none"> Gain an understanding of the drivers of individual behavior and how to effect behavior <p><u>Watch:</u></p> <ul style="list-style-type: none"> Daniel Pink. Ted Talk: “The Puzzle of Motivation” <p><u>Readings:</u></p> <ul style="list-style-type: none"> Barbara Norris case Nohria et.al.: “Employee motivation: A Powerful New Model” <p><u>Recommended Reading:</u></p> <ul style="list-style-type: none"> Herzberg: “One More Time: How Do You Motivate Employees?” 	<p>*Case: <i>Barbara Norris</i></p> <p>DUE: <i>project ideas by 8:00 am via Canvas</i></p>
4	Wed, Mar 30	<p>Organizational Structure</p> <ul style="list-style-type: none"> Gain an understanding of various organizational structures and their implications for organizational effectiveness <p><u>Readings:</u></p> <ul style="list-style-type: none"> <i>Intermountain Health Care</i> case Bohmer: “Fixing Health Care on the Front Lines” Nohria: “Note on Organizational Structure” <p><u>Recommended Reading</u></p> <ul style="list-style-type: none"> Charles Fishman: “Miracle of Birth” 	<p>*Case: <i>Intermountain Health Care</i></p> <p>DUE: <i>Sign up for Final Project by 8:00 am</i></p>
5	Mon, Apr 4	<p>Politics and Power</p> <ul style="list-style-type: none"> Gain an understanding of sources of power and the role of power in organizational behavior and change <i>Announce Project Assignments</i> <p><u>Watch:</u></p> <ul style="list-style-type: none"> Adichie: “The Danger of a Single Story” <p><u>Readings:</u></p> <ul style="list-style-type: none"> <i>Helen Drinan: Giving Voice to Her Values</i> case Pfeffer: “Power Play” Slaughter: “Why Women Still Can’t Have It All” <p><u>Recommended Reading:</u></p> <ul style="list-style-type: none"> Halverson: “Lessons from a Veteran Diversity Advocate” Hunt et. al.: “Why Diversity Matters” 	<p>*Case: <i>Helen Drinan: Giving Voice to Her Values</i></p> <p>DUE: <i>Team Project Proposal before class</i></p>

6	Wed, Apr 6	<p>Organizational Culture</p> <ul style="list-style-type: none"> Gain an understanding of organizational culture and the implications of culture for organizational effectiveness <p><u>Readings:</u></p> <ul style="list-style-type: none"> <i>Johnson & Johnson (A) case</i> Schein: "What You Need to Know About Organizational Culture" Christensen & Shu: "What is an Organization's Culture" 	*Case: <i>Johnson & Johnson (A)</i>
Individuals and Groups in Organizations			
7	Mon, Apr 11	<p>Individual Decision Making</p> <ul style="list-style-type: none"> Gain an understanding of how individuals approach decision making and how to improve personal decision making <p><u>Preparation:</u> Complete the on-line simulation "Judgment in Crisis" before class</p>	<p>Simulation: <i>Judgment in a Crisis</i> debrief</p> <p>DUE: <i>Simulation press release. Submit via Canvas and also bring a copy of your press release to class</i></p>
8	Wed, Apr 13	<p>Group Decision Making</p> <ul style="list-style-type: none"> Gain an understanding of how groups approach decision making and how to improve group decision making <p><u>Readings:</u></p> <ul style="list-style-type: none"> Kahneman et. al: "Before You Make That Big Decision" Harvey, "The Abilene Paradox" 	<p>Role Play: <i>TBA</i></p> <p>DUE: <i>Class Participation initial self-assessment via Canvas before class</i></p>
9	Mon, Apr 18	<p>Creating Teams That Work</p> <ul style="list-style-type: none"> Gain an understanding of behaviors and approaches that increase the likelihood of effective team efforts <p><u>Readings:</u></p> <ul style="list-style-type: none"> Edmondson: "Teamwork on the Fly: How to Master the New Art of Teaming" Hackman & Coutu: "Why Teams Don't Work" <p><u>Recommended Reading</u></p> <ul style="list-style-type: none"> Duhigg, Charles: "What Google Learned from the Quest to Build the Perfect Team" 	<p>In Class Experiential Exercise: <i>TBA</i></p> <p>DUE: <i>Reflection and Application Paper before class</i></p>

10	Wed, Apr 20	<p>Conflict Management and Negotiation</p> <ul style="list-style-type: none"> Gain an understanding of your own preferred conflict style and options for other approaches <p><u>Preparation:</u> Self-assessment of individual conflict mode</p> <p><u>Readings:</u> Garvin and Roberto: "What you don't know about making decisions"</p>	<p>In Class Experiential Exercise: <i>TBA</i></p> <p><i>DUE:</i> <i>Self-assessment of conflict mode</i></p>
11	Mon, Apr 25	<p>Managing People in Organizations: Difficult Conversations</p> <ul style="list-style-type: none"> Develop skills in undertaking challenging professional conversations <p><u>Readings:</u> Weeks: "Acting Unilaterally: Bringing Balance to Difficult Conversations" Gabarro & Kotter: "Managing Your Boss"</p> <p><u>Recommended Reading:</u> Morgan: "Truth Behind the Smile and Other Myths"</p>	<p>Role Play: <i>Engaging in challenging professional conversations</i></p>
Bringing about Change			
12	Wed, Apr 27	<p>Change and Transition Management</p> <ul style="list-style-type: none"> Develop skills in bringing about change in an organization <p><u>Readings:</u></p> <ul style="list-style-type: none"> <i>Just Clean Your Hands</i> case Kotter: "Leading Change: Why Transformation Efforts Fail" Kanter: "The Change Wheel" Bridges: "Getting Them Through the Wilderness" 	<p>*Case: <i>Just Clean Your Hands</i></p>
13	Mon, May 2	<p>Change and Learning Organizations</p> <ul style="list-style-type: none"> Gain an understanding of how organizations bring about change <p><u>Readings:</u></p> <ul style="list-style-type: none"> <i>Dana Farber Cancer Institute</i> case Leape et. al.: "A Culture of Respect, Part 1: The Nature and Causes of Disrespectful Behavior by Physicians" Leape et. al.: "A Culture of Respect, Part 2: Creating a Culture of Respect" Jick: "The Vision Thing" 	<p>Case: <i>Dana Farber Cancer Institute</i></p>

Summary and Conclusions			
14	Wed, May 4	<p>Where is Health Care Going? What Does That Mean for Today's Organizations?</p> <p><u>Readings:</u></p> <ul style="list-style-type: none"> • Christenson et. al.: "Disruptive Innovation for Social Change" • Porter & Teisberg: "Redefining Competition in Health Care" 	Guest Speaker TBA
15	Mon, May 9	<p>Group Presentations I</p> <p><i>DUE: All Team Project Papers & Presentations via Canvas by 10:00 am</i></p> <p><i>DUE: Team Evaluations via Canvas before class</i></p>	Presentations
16	Mon, May 11	<p>Group Presentations II</p> <p><i>DUE: Final self-assessment of class participation</i></p>	Presentations

HPM 543: QUANTITATIVE METHODS IN PROGRAM EVALUATION
MW 1:30 – 3:20 Kresge 502

INSTRUCTOR INFORMATION

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COURSE OBJECTIVES

The goal of this course is to give students the tools that they need to evaluate policy interventions, social programs, and health initiatives. Did the program achieve its goals? Did it reach its target audience? Who benefited most? Could it have been more effective? While we will touch on other areas of program evaluation, the focus will be on impact analysis – what did the program actually do?

In order to be able to answer these questions, students will develop a flexible set of analytical tools, including both the ability to design an evaluation study using new or (more often) existing data and the ability to assess existing studies critically.

The focus will be on health policies and programs such as public insurance expansions, smoking cessation programs, vaccination initiatives, public health campaigns, quality improvement efforts, etc., but the techniques will be broadly applicable to other programs, such as in the realm of education, welfare, job training, or philanthropic initiatives.

Guest speakers will highlight real-world program evaluations and describe their experiences using these tools in different settings, including both domestic and international projects.

The goal of the course is to prepare students both to conduct program evaluations and to make sophisticated assessments of others' evaluations. By the end of the course students will be able to:

- Construct a well-designed study to answer well-posed questions
- Gauge the adequacy of available data to answer the study's questions
- Implement an experimental or econometric analysis to answer the study's questions
- Interpret the results of such studies, including major findings and potential weaknesses
- Draw policy implications from that analysis, including effectiveness of the program, distribution of costs and benefits, and areas for improvement

OUTCOME MEASURES AND GRADING CRITERIA

Students will be evaluated on five short assignments during the term designed to apply the concepts covered in class to real programs. These exercises will be worth 50% of the final grade and will involve analysis for which students will be given the data. For these exercises, students will be permitted to work in small groups, but each student must turn in an individual write-up.

The in-class final exam for the course will cover all of the material presented in the term, and will be worth 40% of the final grade. The exam will be open-book and open-note, much like life.

Class participation will be worth 10% of the final grade. Active class participation is expected – learning the material from the readings alone is extremely difficult.

PREREQUISITES

The material covered in this course is inherently quantitative, and builds on a base of probability and statistics fundamentals. The prerequisite is a course in basic probability and statistics, such as BIO 200, BIO 201, BIO 202/203, ID538, ID 201, or an equivalent. You should have an understanding of and comfort with constructing confidence intervals and performing hypothesis tests. You should also have experience working with at least one statistical software package – ideally STATA, but R, SAS or SPSS are also fine. During the course you will be given data sets to analyze, but there will be very little instruction on the mechanics of opening and manipulating the data. A helpful Stata tutorial can be found at: <http://www.ats.ucla.edu/stat/stata/>. Please see me if you are uncertain about whether you have adequate preparation for the class.

TEXTS AND READING MATERIALS

The main text books for this course are *Multiple Regression: A Primer* (Allison; Pine Forge Press) and *Handbook on Impact Evaluation: Quantitative Methods and Practices* (Khandker, Koolwal, and Samad; World Bank Training Series; available for download). There are additional readings from academic journals on specific social programs and policies that accompany each unit of the course. They are all available through the library, and links are provided on the course web page.

Some students may want to refer to supplemental texts. *Mostly Harmless Econometrics* (Angrist and Pischke; Princeton University Press) is an excellent overview. *Applied Regression Analysis and Other Multivariable Methods* (Kleinbaum, Kupper, Nizam, Muller; Duxbury Press) and *Counterfactuals and Causal Inference* (Morgan, Winship; Cambridge Press) cover the course's technical material in greater depth. *Thinking About Program Evaluation* (Berk and Rossi; Sage Press) gives more background on the broad concepts of evaluation. Those looking to brush up on statistics may find <http://www.openintro.org/stat/> (open-source intro statistics text) and *Statistical Methods for the Social Sciences* (Agresti and Finlay; Pearson) helpful.

ADDITIONAL INFORMATION*Class materials and attendance*

Class attendance is required. Notes and handouts will be posted on the course web page, but there is no substitute for attending class. The concepts covered are inherently cumulative, so failure to keep up with the course content would be very hard to overcome later in the term. Please let me know in advance if you will need to miss class.

Computers

Use of computers and tablets in class is in general not permitted, as it can be distracting to both you and your neighbors.

Teaching assistant

The teaching assistant for the course will offer weekly office hours, provide statistical help with the data exercises, and give a review section before the final. She will also offer sessions in the computer lab the first week of the course to help students use the course data sets and perform analysis in Stata. Her contact information and office hours appear on the course web page.

Course evaluations

As with other courses at HSPH, completion of course evaluations is mandatory. Your grade will not be available and you will not be able to register for future terms until you have completed an evaluation.

COURSE SCHEDULE

This is a roadmap of the topics that the course will cover, but may be adjusted as the course proceeds. Updates will be posted on the course web page, as will supplemental readings.

	Day	Topic	Notes
1	M 3/21	Course overview; Designing an evaluation	
2	W 3/23	Causal inference	<i>Stata Boot Camp</i>
3	M 3/28	Social experiments	<i>Assignment 1 due 3/29</i>
4	W 4/30	Designing and fielding RCTs	
5	M 4/4	Designing and fielding RCTs	<i>Assignment 2 due 4/5</i>
6	W 4/6	Regression framework	
7	M 4/11	Regression and omitted variable bias	
8	W 4/13	Observational study design	<i>Assignment 3 due 4/14</i>
9	M 4/18	Interaction terms	
10	W 4/21	Quasi-experimental methods	
11	M 4/25	Fixed effects and diff-in-diff	<i>Assignment 4 due 4/26</i>
12	W 4/27	Regression discontinuity	
13	M 5/2	Implementing evaluations	Guest Lecturer: David Hemenway
14	W 5/4	Instrumental variables	<i>Assignment 5 due 5/5</i>
15	M 5/9	Wrap-up and review	
16	W 5/11	Final Exam	<i>In-class exam</i>

Assignments are due at **4 pm** on Tuesday (1, 2, and 4) or Thursday (3 and 5), and are to be turned in via the course website.

READINGS

Readings noted as “recommended” are often more technical and are optional.

Class 1

- Intro
- Review your pre-requisite text on hypothesis testing, confidence intervals, p-values

Class 2

- Khandker, Koolwal, and Samad (KKS) Ch 1-2
- Baicker, Katherine. *Cooper’s Analysis Is Incorrect*. Health Affairs, Vol. 28, 2008, pp w116-w118
- Precipitating articles: Baicker and Chandra. *Medicare Spending, the Physician Workforce, and Beneficiaries’ Quality of Care*, Health Affairs, Vol. 23, no. 3, pp 184-197, 2004; Cooper. *States with More Physicians Have Better-Quality Health Care*, Health Affairs, Vol. 28, no.1, 2009, pp w91–w102 (Recommended)

Class 3

- KKS Ch 3
- Burtless, Gary. *The Case for Randomized Field Trials in Economic and Policy Research*, Journal of Economic Perspectives, Vol. 9, 1995, pp 63-84
- Brian MacMahon, M.D., Stella Yen, M.D., Dimitrios Trichopoulos, M.D., Kenneth Warren, M.D., and George Nardi, M.D. *Coffee and Cancer of the Pancreas*, New England Journal of Medicine, Vol. 304, pp 630-633, March 12, 1981
- Silverman, Debra, et al., *The Prevalence of Coffee Drinking Among Hospitalized and Population-Based Control Groups*, JAMA, 1983, Vol. 249, pp 1877-1880

Class 4

- Newhouse, Joseph, *Consumer-Directed Health Plans and the RAND Health Insurance Experiment*, Health Affairs, 2004, Vol. 23, no. 6
- Baicker, Katherine and Amy Finkelstein, *The Effects of Medicaid Coverage – Learning from the Oregon Experiment*, New England Journal of Medicine, Vol. 365, pp 683-685, August 25, 2011
- Manning, Willard G. *Health Insurance and the Demand For Medical Care: Evidence From a Randomized Experiment*. American Economic Review, Vol. 77, 1987, pp 251-277 (Recommended)
- Finkelstein et al., *The Oregon Health Insurance Experiment: Evidence from the First Year*, *Quarterly Journal of Economics*, Vol. 127, no. 3, August 2012, pp 1057-1106 (Recommended)
- Aviva Aron-Dine, Liran Einav, & Amy Finkelstein. *The RAND Health Insurance Experiment, Three Decades Later*. Journal of Economic Perspectives, 2013 Vol 27, pp 197-222. (Recommended) http://www.jstor.org.ezp-prod1.hul.harvard.edu/stable/41825468?seq=1#page_scan_tab_contents

Class 5

- Taubman, S., H. Allen, B. Wright, K. Baicker, and A. Finkelstein, *Medicaid Increases Emergency Department Use: Evidence from Oregon's Health Insurance Experiment*, Science, Vol. 343, pp 263-286, January 17, 2014
- Baicker et al., *The Oregon Experiment – Effects of Medicaid on Clinical Outcomes*, New England Journal of Medicine, Vol. 368, no. 18, pp 1713-1722, May 2, 2013
- Trenholm, Christopher. *Impacts of Abstinence Education on Teen Sexual Activity, Risk of Pregnancy, and Risk of Sexually Transmitted Diseases*. Journal of Policy Analysis and Management, Vol. 27, 2008, pp 255-276

Class 6

- Allison Ch 1-2
- Deaton, Angus, *Instruments of Development: Randomization in the Tropics, and the Search for the Elusive Keys to Economic Development*, NBER Working Paper 14690, 2009 (Recommended)
- Imbens, Guido, *Better Late Than Nothing: Some Comments On Deaton (2009) And Heckman And Urzua (2009)*, NBER Working Paper 14896, 2009 (Recommended)

Class 7

- Allison Ch 3-5

Class 8

- Stampfer, M. J., Willett, W. C., Colditz, G. A., Rosner, B., Speizer, F. E., & Hennekens, C. H. (1985). *A prospective study of postmenopausal estrogen therapy and coronary heart disease*. New England Journal of Medicine, 313(17), 1046
- Writing Group for the Women's Health Initiative Investigators (2002). Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results from the Women's Health Initiative randomized controlled trial. *JAMA*, 288(3), 326
- Taubes, G. (2007). Do we really know what makes us healthy? *New York Times*, September 16, 2007
- Mendelsohn, Michael E. and Richard H. Karas, *HRT and the Young at Heart*, New England Journal of Medicine, 356(25), p. 2639-41, June 21, 2007
- Soumerai SB, Starr D, Majumdar SR. *How Do You Know Which Health Care Effectiveness Research You Can Trust? A Guide to Study Design for the Perplexed*, *Prev Chronic Dis* 2015;12:150187.
- Hernan, MA et al, *Observational Studies Analyzed Like Randomized Experiments: an Application to Postmenopausal Hormone Therapy and Coronary Heart Disease*, *Epidemiology*, 19(6): 766-69, Nov 2008 (Recommended)
- Petitti, D. B., Perlman, J. A., & Sidney, S. (1987). *Noncontraceptive estrogens and mortality: Long-term follow-up of women in the Walnut Creek Study*, *Obstetrics and Gynecology*, 70(3-1), 291 (Recommended)

Class 9

- Allison Ch 6-9
- KKS Ch. 8

Class 10

- KKS Ch. 5
- Waldfogel, Jane. *The Impact of the Family and Medical Leave Act*. Journal of Policy Analysis and Management, Vol. 18, 1999, pp 281-302

Class 11

- Sommers, Benjamin, Sharon Long, and Katherine Baicker, *Changes in Mortality After Massachusetts Health Care Reform*, Annals of Internal Medicine, Vol. 160, no. 9, pp 585-594, May 6, 2014 (joint with B. Sommers and S. Long)
- McWilliams, Zaslavsky, Meara, and Ayanian, *Impact of Medicare Coverage on Basic Clinical Services for Previously Uninsured Adults*, JAMA, Aug 13 2003, Vol. 290 no. 6, pp 757-64
- Finkelstein, Amy. *The Aggregate Effects of Health Insurance: Evidence from the Introduction of Medicare*, Quarterly Journal of Economics, Vol. 122, no. 3, 2007, pp 1-37 (Recommended)

Class 12

- KKS Ch. 7
- Almond, Douglas. *Is the 1918 Influenza Pandemic Over? Long-term Effects of In Utero Influenza Exposure in the Post-1940 U.S. Population*. Journal of Political Economy. Vol. 114 no. 4, 2006, pp 672-712
- Douglas Almond, Joseph J. Doyle, Jr., Amanda E. Kowalski, Heidi Williams, *Estimating Marginal Returns to Medical Care: Evidence from At-Risk Newborns*, Quarterly Journal of Economics, May 2010, Vol. 125, no. 2, pp 591-634
- David Card, Carlos Dobkin, and Nicole Maestas, *Does Medicare Save Lives?*, Quarterly Journal of Economics, 2009, Vol. 124, no. 2, pp 597-636, May (Recommended)
- Card, David, Carlos Dobkin and Nicole Maestas. *The Impact of Nearly Universal Insurance Coverage on Health Care: Evidence from Medicare*, American Economic Review, Vol. 98, no. 5, December 2008, pp 2242-58 (Recommended)

Class 13

- Hemenway D. *How to Find Nothing*. Journal of Public Health Policy. 2009; 30:260-68
- Greenberg-Seth J, Hemenway D, Gallagher SS, Ross JB, Lissy KS. *Evaluation of a Community-Based Intervention to Promote Rear Seating in Children*, American Journal of Public Health, 2004, Vol. 94, pp 1009-1013.
- Hemenway D., Reviews of Lott J., *More Guns, Less Crime: Understanding Crime and Gun-Control Laws*; and Diaz T., *Making a Killing: The Business of Guns in America*, New England Journal of Medicine, 1998, Vol. 339, pp 2029-30

Class 14

- KKS Ch. 6
- Gennetian, Bos, and Morris, *Using Instrumental Variables Analysis to Learn More from Social Policy Experiments*, MDRC Working Paper, Oct 2002
- McClellan, Mark. *Does More Intensive Treatment of Acute Myocardial Infarction in the Elderly Reduce Mortality? Analysis Using Instrumental Variables*, JAMA. 272, 1994, pp 859-866

Class 15

- KKS Ch. 9
- Bitler, Marianne and Janet Currie. *Does WIC Work? The Effects of WIC on Pregnancy and Birth Outcomes*. Journal of Policy Analysis and Management, Vol. 24, no 1, 2005, pp 73-91
- Joyce, Ted. *The Changing Association Between Prenatal Participation in WIC and Birth Outcomes in New York City*. Journal of Policy Analysis and Management, Vol. 24, no 4, 2005, pp 661-685
- Bitler, Marianne, and Janet Currie. *The Changing Association Between Prenatal Participation in WIC and Birth Outcomes in New York City: What Does It Mean?* Journal of Policy Analysis and Management, Vol. 24, no 4, 2005, pp 687-690
- Ludwig, Jens. *Interpreting the WIC Debate*. Journal of Policy Analysis and Management, Vol. 24, no 4, 2005, pp 691-701
- Currie, Janet and Ishita Rajani, *Within-Mother Estimates of the Effects of WIC on Birth Outcomes in New York City*, NBER Working Paper 20400, Aug 2014 (Recommended)
- Cook, Thomas. *Three Conditions Under Which Experiments and Observational Studies Produce Comparable Causal Estimates: New Findings from Within-Study Comparisons*. Journal of Policy Analysis and Management, Vol. 27, 2008, pp 724-750 (Recommended)

HPM 544: THE LAW AND CLINICAL MEDICINE

**Harvard School of Public Health
2016 Spring 2 Term
Room: FXB G12
Tuesdays/Thursdays 3:30-5:20**

Allen Kachalia, MD, JD
akachalia@partners.org

Important Note on Course Schedule

This class will NOT ALWAYS meet twice a week, but instead meet on average one time a week (on Tuesdays and Thursdays) for a total of 8 sessions (including one for the final exam) over the 8 weeks of the Spring 2 Semester. Please see below for the currently planned dates.

Introduction

This course will examine what impact health policy and law has on the quality of health care. The course will examine the legal system's evaluation and treatment of quality and safety of health care and how it has--or has not--inspired change and innovation within the medical profession. Topics will include: medical malpractice law, new programs created by the Accountable Care Act, and new innovations from within the clinical profession. In addition, students will analyze and interpret some legal dilemmas created by new developments in medical care that can outpace the laws. Students will have the opportunity to describe challenges in the delivery of high quality care, examine why they occur, and formulate policy approaches that might solve them.

Learning Objectives

Students completing this course will be able to:

1. Explain and apply medical malpractice principles to historical and current court cases, and evaluate the performance of the malpractice system, including appraising the system's ability to foster quality improvement.

2. Describe many fundamental legal issues that arise in clinical practice, examine why they occur, and formulate policy approaches to address them.
3. Analyze and interpret the legal dilemmas created by new developments in medical care that can outpace existing laws, and propose possible solutions for these challenges.
4. Critique and design potential options for legal reform that can spur the improvement of health care quality and delivery.

Grading

The course grade will be based on class participation (40% of total grade) and an in-class final examination (60% of total grade). The class participation grade will be based on (1) attendance, (2) preparation (demonstrating knowledge of the reading assignments), and (3) contribution to class discussion. All students will be strongly encouraged to engage in class discussion and debate. The final exam will be an in-class written essay exam based on the learning objectives.

A Note on the Course Readings: This course does **NOT** require a medical or legal background. Class discussion will be focused on issues raised in the readings. For the legal cases, reading and discussion will primarily be focused on the facts and the issues, and not the technical or procedural legal matters. For the medical literature, reading and discussion will primarily be focused on the background and the discussions sections of the papers, and not the methods. The reading lists for some of the classes may look long, but many of the pieces are either brief or optional.

Session 1: Course Introduction and Medical Malpractice Tue March 22, 2016

Readings

- Studdert DM, Mello MM, Brennan TA. Medical Malpractice. *New England Journal of Medicine* 2004;350(3);283-92. <http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/reprint/350/3/283.pdf>
- Localio AR, Lawthers AG, Brennan TA, et. al., Relation Between Malpractice Claims And Adverse Events Due To Negligence. Results Of The Harvard Medical Practice Study III. *New England Journal of Medicine* 1991;325(1991): 245-251. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM199107253250405>
- Studdert DM, Mello MM, Gawande AA, Gandhi TK, Kachalia A, Yoon C, Puopolo AL, Brennan TA. Claims, errors, and compensation payments in medical malpractice litigation. *New England Journal of Medicine*. 2006;354(19);2024-2033. <http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/content/abstract/354/19/2024>
- Gawande A, The Malpractice Mess. *The New Yorker*. Nov 14, 2005. http://www.newyorker.com/archive/2005/11/14/051114fa_fact_gawande
- Jena AB, Seabury S, Lakdawalla, Chandra A. Malpractice risk according to physician specialty. *New England Journal of Medicine*. 2011;365(7);629-636. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMsa1012370>
- Mello MM, Chandra A, Gawande AA, Studdert DM. National Costs Of The Medical Liability System. *Health Affairs* 2010; 29(9):1569-1577. <http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/29/9/1569.long>

Optional Readings

- *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 113 S.Ct. 2786 (1993). [http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=6443&sr=cite\(113+S.Ct.+2786\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=6443&sr=cite(113+S.Ct.+2786))
- Bertin JE and Henifin MS, Science, Law and the Search for Truth in the Courtroom: Lessons from *Daubert v. Merrell Dow*. *Journal of Law, Medicine & Ethics* 1994;22: 6–20. <http://www.heinonline.org.ezp-prod1.hul.harvard.edu/HOL/Page?page=6&handle=hein.journals%2Fmedeth22&collection=journals&id=6>

Session 2: Institutional Liability

Tue Mar 29, 2016

Readings

- *Schloendorff v. N.Y. Hospital*, 105 N.E. 2d 92 (N.Y. 1914)
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9096&sr=cite\(105+N.E.+92\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9096&sr=cite(105+N.E.+92))
- *Darling v. Charlestown Community Memorial Hospital*, 211 N.E. 2d 253 (1956), cert. denied, 383 U.S. 946 (1956).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=6662&sr=cite\(211+N.E.2d+253\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=6662&sr=cite(211+N.E.2d+253))
- *Williams v. St. Claire Med. Ctr.*, 657 S.W. 2d 590 (Ct.Aps.Ky. 1983).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=7238&sr=cite\(657+S.W.+2d+590\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=7238&sr=cite(657+S.W.+2d+590))
- *Tunkl v. Univ. Calif.*, 383 P.2d 441 (Cal. 1963).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite\(383+P.2d+441\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite(383+P.2d+441))
- *Jackson v. Powers*, 743 P.2d 1376 (Alaska 1987).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=3825&sr=cite\(743+P.2d+1376\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=3825&sr=cite(743+P.2d+1376))
- Annas GJ. The Patient's Right to Safety--Improving the Quality of Care through Litigation against Hospitals. *New England Journal of Medicine* 2006;354(19):2063-2066.
<http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/reprint/354/19/2063.pdf>
- Asch DA and Parker RM. The Libby Zion Case. One Step Forward or Two Steps Backward? *New England Journal of Medicine* 1998;318(12):771-75.
<http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJM198803243181209>

Optional Readings

- *Karibjanian v. Thos. Jefferson Univ. Hosp.*, 717 F. Supp. 1081 (E.D. Pa. 1989).

[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=149274&sr=cite\(717+F+Supp.+1081\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=149274&sr=cite(717+F+Supp.+1081))

- *Pedroza v. Bryant*, 677 P.2d 166 (Wash. 1984).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=10840&sr=cite\(677+P.2d+166\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=10840&sr=cite(677+P.2d+166))

Session 3: Informed Consent

Tue Apr 5, 2016

Readings

- *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=6320&sr=cite\(464+F.2d+772\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=6320&sr=cite(464+F.2d+772))
- *Truman v. Thomas*, 611 P.2d 902 (Cal. 1980).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite\(611+P.2d+902\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite(611+P.2d+902))
- *Tisdale v. Pruitt*, 394 S.E. 2d 857 (S.C. 1990).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9570&sr=cite\(394+S.E.+2d+857\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9570&sr=cite(394+S.E.+2d+857))
- *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990) (Focus on the facts of the case)
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite\(793+P.2d+479\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=4861&sr=cite(793+P.2d+479))
- Merenstein D, Winners and Losers. *JAMA* 2004, 291:15-16.
<http://jama.ama-assn.org.ezp-prod1.hul.harvard.edu/content/291/1/15.long>
- Miller TE and Horowitz CR. Disclosing Doctors' Incentives: Will Consumers Understand and Value the Information? *Health Affairs* 2000;19(4):149-155.
<http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/cgi/reprint/19/4/149>

- Iezzoni LI, Rao SR, DesRoches CM, Vogeli C, and Campbell EG. Survey Shows That At Least Some Physicians Are Not Always Open Or Honest With Patients. *Health Affairs* 2012;31(2):383-391.
<http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/31/2/383.long>
- Halpern SD, Shaked A, et al. Informing Candidates for Solid-Organ Transplantation About Donor Risk Factors. *New England Journal of Medicine* 2008;358(26):2832-37.
<http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/reprint/358/26/2832.pdf>
- Cassel CK and Guest JA. Choosing Wisely: Helping Physicians And Patients Make Smart Decisions About Their Care. *JAMA* 2012;307(17):1801-1802.
<http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=1150103>

Optional Readings

- *Natanson v. Kline*, 354 P.2d 670 (Kan. 1960).
http://www.leagle.com/decision/1960579186Kan393_1510/NATANSON%20v.%20KLINE
- *Johnson v. Kokemoor*, 545 N.W.2d 495 (Wis. 1996).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=10983&sr=cite\(545+N.W.2d+495\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=10983&sr=cite(545+N.W.2d+495))
- *Gracia v. Meiselman*, 531 A.2d 1373 (N.J. 1987).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9074&sr=cite\(531+A.2d+1373\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lacademic/api/version1/sr?shr=t&csi=9074&sr=cite(531+A.2d+1373))
- King JS and Moulton BW, Rethinking Informed Consent: The Case for Shared Decision-Making. *American Journal of Law & Medicine* 2006;32(9):429-501.
<http://ezp-prod1.hul.harvard.edu/login?url=http://search.ebscohost.com/login.aspx?direct=true&db=aph&AN=23581016&site=ehost-live&scope=site>
- Brody H, From An Ethics Of Rationing To An Ethics Of Waste Avoidance. *New England Journal of Medicine* 2012;366(21):1949-1951.
<http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1203365>

Session 4: How Far Does The Patient-Provider Relationship Go? Limits on Duty of Care and Duty to Warn

Tue Apr 12, 2016

Readings

- *Tarasoff v. Univ. of Calif.*, 17 Cal. 3d 425, 131 Cal. Rptr. 14 (1976).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=4861&sr=cite\(17+Cal.+3d+425\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=4861&sr=cite(17+Cal.+3d+425))
- Mass. Gen. Laws Chapter 123: Section 36B. Duty to warn patient's potential victims; cause of action.
<https://malegislature.gov/Laws/GeneralLaws/PartI/TitleXVII/Chapter123/Section36B>
- *Calwell v. Hassan*, 925 P.2d 422 (Kan. 1996).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=6805&sr=cite\(925+P.2d+422\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=6805&sr=cite(925+P.2d+422))
- *Coombes v. Florio*, 450 Mass. 182, 877 N.E.2d 567 (Mass. 2007).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=7683&sr=cite\(450+Mass.+20182%20877%20N.E.2d+567\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=7683&sr=cite(450+Mass.+20182%20877%20N.E.2d+567))
- Annas GJ. Doctors, Drugs, and Driving -- Tort Liability for Patient-Caused Accidents. *New England Journal of Medicine* 2008;359(5):521-5.
<http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/content/full/359/5/521>
- *Safer v. Pack*, 677 A.2d 1188 (Sup.Ct. A.D.N.J. 1996).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=9074&sr=cite\(677+A.2d+1188\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=9074&sr=cite(677+A.2d+1188))

Optional Readings

- *MacDonald v. Ortho Pharmaceutical Corp.*, 475 N.E.2d 65 (Mass. 1985).
[http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=7683&sr=cite\(475+N.E.2d+65\)](http://www.lexisnexis.com.ezp-prod1.hul.harvard.edu/us/lnacademic/api/version1/sr?shr=t&csi=7683&sr=cite(475+N.E.2d+65))
- Gostin L., The AIDS Litigation Project, *JAMA* 1990;263: 1961-1970.
<http://jama.ama-assn.org.ezp-prod1.hul.harvard.edu/content/263/14/1961.full.pdf+html>

Session 5: Fixing the System—What Have We Tried? How Has it Worked?

Thu Apr 21, 2016

Readings

- Executive Summary, from Institute of Medicine Report, *To Err is Human: Building a Safer Health System* (2000). pages 1–16.
http://www.nap.edu/openbook.php?record_id=9728&page=1
- Gallagher TH, Studdert DM, et al. Disclosing Harmful Medical Errors to Patients. *New England Journal of Medicine* 356(26)(2007): 2713-2719.
<http://content.nejm.org.ezp-prod1.hul.harvard.edu/cgi/reprint/356/26/2713.pdf>
- Studdert DM, Mello MM, et al. Disclosure of Medical Injury to Patients: An Improbable Risk Management Strategy. *Health Affairs* 2007;26(1):215-226.
<http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/cgi/content/full/26/1/215>
- Kachalia A, Kaufman SR, Boothman R, Anderson S, Welch K, Saint S, Rogers, MAM. Liability Claims and Costs Before and After Implementation of a Medical Error Disclosure Program. *Annals of Internal Medicine* 2010;153:213-221.
<http://annals.org.ezp-prod1.hul.harvard.edu/article.aspx?articleid=745972>
- Massachusetts General Laws Chapter 233 Section 79L: Statements or conduct expressing regret, apology, condolence by health care provider; admissibility available at: <https://malegislature.gov/Laws/GeneralLaws/PartIII/TitleII/Chapter233/Section79L>
- Massachusetts General Laws Chapter 231 Section 60L: Written notice requirement for actions against health care providers available at:
<https://malegislature.gov/Laws/GeneralLaws/PartIII/TitleII/Chapter231/Section60L>
- Kachalia A and Mello MM. New Directions In Medical Liability Reform, *New England Journal of Medicine* 2011;364:1564-1572.
<http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMhpr1012821>

Optional Readings

- Blumstein J. The Legal Liability Regime: How Well Is It Doing in Assuring Quality, Accounting for Costs, and Coping with an Evolving Reality in the Health Care Marketplace? *Annals of Health Law* 2002;11:125-45.
<http://www.heinonline.org.ezp-prod1.hul.harvard.edu/HOL/Page?collection=journals&handle=hein.journals/ano111&id=139#139>

- Mello MM and Brennan TA, Deterrence of Medical Errors: Theory and Evidence for Malpractice Reform, *Texas Law Review* 2002;80:1623-1637.
<http://www.heinonline.org.ezp-prod1.hul.harvard.edu/HOL/Page?collection=journals&handle=hein.journals/tlr80&id=1609>
-

Session 6: Medical Malpractice Law: Future Options for Reform Tue Apr 26, 2016

Readings

- Weiler PC, et al. Proposal for Medical Liability Reform. *JAMA* 1992;267:2355.
<http://jama.ama-assn.org.ezp-prod1.hul.harvard.edu/content/267/17/2355.full.pdf+html>
- Mello MM, Studdert DM, et al. Health Courts And Accountability for Patient Safety. *The Milbank Quarterly* 2006;84:459-492.
<http://www3.interscience.wiley.com.ezp-prod1.hul.harvard.edu/journal/118629347/abstract?CRETRY=1&SRETRY=0>
- Mello MM, Of Swords And Shields: The Use Of Clinical Practice Guidelines In Medical Malpractice Litigation, *University of Pennsylvania Law Review* 2001;149:668-678.
<http://www.heinonline.org.ezp-prod1.hul.harvard.edu/HOL/Page?collection=journals&handle=hein.journals/pnlr149&id=655>
- Kachalia A, Little A, Isavoran M, Crider L, Smith J. Greatest Impact Of Safe Harbor Rule May Be To Improve Patient Safety, Not Reduce Liability Claims Paid By Physicians. *Health Affairs (Millwood)*;2014;33(1)59-66.
<http://content.healthaffairs.org.ezp-prod1.hul.harvard.edu/content/33/1/59.long>
- Mello MM, Studdert DS, Kachalia A. The Medical Liability Climate And Prospects For Reform. *JAMA* 2014;312(20):2146-2155.
<http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=1921690>

Optional Readings

- Kachalia A, Mello MM, et al. Beyond Negligence: Avoidability and Medical Injury Compensation. *Social Science & Medicine* 2008;66(2):387-402.
<http://ezp-prod1.hul.harvard.edu/login?url=http://dx.doi.org/10.1016/j.socscimed.2007.08.020?nosfx=y>
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Session 7: Where Are We Today? The Accountable Care Act's Programs to Improve Clinical Care / Review Session
Tue May 3, 2016

Readings

Burwell SM. Setting value-based payment goals—HHS efforts to improve U.S. health care. *New England Journal of Medicine* 2015;372:897–899.

<http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1500445>

Kachalia A, Mello MM, Nallamothu BK, Studdert DS. Legal and policy interventions to improve patient safety. *Circulation* 2016;133:661-71

<http://circ.ahajournals.org.ezp-prod1.hul.harvard.edu/content/133/7/661.long>

McWilliams JM, Chernew ME, Landon BE, Schwartz AL. Performance differences in year 1 of pioneer accountable care organizations. *New England Journal of Medicine* 2015;372:1927–1936. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMs1414929>

Rajaram R, Chung JW, Kinnier CV, Barnard C, Mohanty S, Pavey ES, McHugh MC, Bilimoria KY. Hospital characteristics associated with penalties in the Centers for Medicare & Medicaid Services Hospital-Acquired Condition Reduction Program. *JAMA* 2015;314:375–383.

<http://jama.jamanetwork.com.ezp-prod1.hul.harvard.edu/article.aspx?articleid=2411284>

Joynt KE, Jha AK. Thirty-day readmissions—truth and consequences. *New England Journal of Medicine* 2012;366:1366–1369. <http://www.nejm.org.ezp-prod1.hul.harvard.edu/doi/full/10.1056/NEJMp1201598>

Session 8: FINAL EXAMINATION
Thu May 12, 2016

Responsible Conduct of Research
Fall 1, September 4- October 23, 2015
Day/Time of Class: Friday/8:30 a.m. – 10:20 a.m.
Location of Class: Kresge G1

Instructor Information

Instructor: Delia Wolf, MD, JD, MSCI
Instructors' Title: Lecturer, Health Policy and Management, HSPH
Associate Dean, Regulatory Affairs and Research Compliance
Depart. Association: Health Policy and Management, HSPH
Email Address: dywolf@hsph.harvard.edu
Phone Number: (617) 432-2148
Office Hours: By appointment
Office Address: 90 Smith Street, 3rd Floor

Course Manager: Alyssa Speier
Email Address: aspeier@hsph.harvard.edu
Phone Number: 617-432-2140
Office Address: 90 Smith St, 3rd Floor

Texts and Reading Materials

- a) Required text book:
- 1) "On Being a Scientist, A Guide to Responsible Conduct in Research," 3rd Edition, by National Academy of Sciences, National Academy of Engineering, and Institute of Medicine
http://www.nap.edu/openbook.php?record_id=12192&page=8
 - 2) ORI Introduction to the Responsible Conduct of Research
<http://ori.dhhs.gov/documents/rcrintro.pdf>
- b) Additional reading materials will be posted on the course website.

Course Objectives:

At the end of the course the student will be able to:

- 1) Describe the concepts of research misconduct and research integrity.
- 2) Describe basic ethical and regulatory requirements for conducting bench, animal, clinical, and public health research and apply them to research practice.

- 3) Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements.
- 4) Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of research.

Outcome Measures

- a) Class participation – Class participation consists of attending a minimum of six lectures, preparation, and constructive contributions to class discussion. Attendance will not be met if over 15 minutes late to class.
- b) Case studies – students are expected to submit their written answers to all 12 cases during the 8 week period.

Grading Criteria

Pass/Fail – for students, who take the course for credit

Certificate of Completion – for all participants, who attend a minimum of 6 lectures, participate in class discussions, and complete 12 case-study assignments

Additional Information

This course meets the NIH training requirement for all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant, or dissertation research grant. HSPH’s, as well as other Harvard catalyst institutions’ graduate students, post-doctoral fellows, and junior faculty members will be allowed to take the course without paying tuition (if not taking this course for credit) but are expected to attend a minimum of six lectures, participate in class discussions, and complete all case study assignments. RCR participants not taking this course for course credit, please register at:

https://harvard.az1.qualtrics.com/SE/?SID=SV_cVfnrbn4xPr9QtD

*Course platform: <https://canvas.harvard.edu/>

**You will need and HUID or XID to log into this system. You can obtain and XID here: <https://xid.harvard.edu/xid-apps/>

Session by Session Detail

Date	Topic	Instructor
Week 1 9/4	<ul style="list-style-type: none"> • Introduction to the responsible conduct of research • Regulations and guidelines governing research involving human subjects • Cases 1 & 2 will be distributed 	D. Wolf
Week 2 9/11	<ul style="list-style-type: none"> • Cases 1 & 2 assignment due • Peer review, responsible authorship and publication • Data acquisition, sharing research results, and ownership • Case 3 & 4 will be distributed 	E. Langdon-Gray D. Wolf

Week 3 9/18	<ul style="list-style-type: none"> • Case 3 & 4 assignment due • Research Misconduct • Cases 5 & 6 will be distributed 	D. Wolf
Week 4 9/25	<ul style="list-style-type: none"> • Case 5 & 6 assignment due • Intellectual Property • Mentor/Mentee Relationships • Case 7 & 8 will be distributed 	J. Rice D. Wolf / A. Speier
Week 5 10/2	<ul style="list-style-type: none"> • Case 7 & 8 assignment due • Safe Laboratory Practice • Regulations and guidelines governing research involving live vertebrate animal subjects • Case 9 will be distributed 	M. Corrigan B. Corning
Week 6 10/9	<ul style="list-style-type: none"> • Case 9 assignment due • Export Controls • Grant writing, budgeting, and adequate allocation of resources • Case 10 will be distributed 	E. Nielsen A. Spickard
Week 7 10/16	<ul style="list-style-type: none"> • Case 10 assignment due • Collaborative Research • Financial and Non-Financial Conflicts of Interest • Cases 11 & 12 will be distributed 	D. Wolf
Week 8 10/23	<ul style="list-style-type: none"> • Cases 11 & 12 due • Scientist as a Responsible Member of Society- ethical issues in biomedical and public health research • RCR Review/Case Discussions 	D. Wolf

Course Evaluations

Completion of the evaluation is a requirement for the course. Student grades will not be available until an evaluation is completed.

Responsible Conduct of Research
Spring 1, January 29- March 11, 2016
Day/Time of Class: Friday/8:30 a.m. – 10:20 a.m.
Location of Class: Kresge G1

Instructor Information

Instructor: Delia Wolf, MD, JD, MSCI
Instructors' Title: Lecturer, Health Policy and Management, HSPH
Associate Dean, Regulatory Affairs and Research Compliance
Depart. Association: Health Policy and Management, HSPH
Email Address: dywolf@hsph.harvard.edu
Phone Number: (617) 432-2148
Office Hours: By appointment
Office Address: 90 Smith Street, 3rd Floor

Course TA: Alyssa Speier
Email Address: aspeier@hsph.harvard.edu
Phone Number: (617) 432-2140
Office Address: 90 Smith St, 3rd Floor

Course Coordinator: Alexis Fagan
Email Address: afagan@hsph.harvard.edu
Phone Number: (617) 432-2157
Office Address: 90 Smith St, 3rd Floor

Texts and Reading Materials

- a) Required text book:
- 1) "*On Being a Scientist, A Guide to Responsible Conduct in Research*," 3rd Edition, by National Academy of Sciences, National Academy of Engineering, and Institute of Medicine
http://www.nap.edu/openbook.php?record_id=12192&page=8

- 2) ORI Introduction to the Responsible Conduct of Research
<http://ori.dhhs.gov/documents/rcrintro.pdf>
- b) Additional reading materials will be posted on the course website.

Course Objectives:

At the end of the course the student will be able to:

- 1) Describe the concepts of research misconduct and research integrity.
- 2) Describe basic ethical and regulatory requirements for conducting bench, animal, clinical, and public health research and apply them to research practice.
- 3) Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements.
- 4) Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of research.

Outcome Measures

- a) Class participation – Class participation consists of attending a minimum of six lectures, preparation, and constructive contributions to class discussion. Attendance will not be met if over 15 minutes late to class.
- b) Case studies – students are expected to submit their written answers to all 12 cases during the 7 week period.

Grading Criteria

Pass/Fail – for students, who take the course for credit

Certificate of Completion – for all participants, who attend a minimum of 6 lectures, participate in class discussions, and complete 12 case-study assignments

Additional Information

This course meets the NIH training requirement for all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant, or dissertation research grant. HSPH's, as well as other Harvard catalyst institutions' graduate students, post-doctoral fellows, and junior faculty members will be allowed to take the course without paying tuition (if not taking this course for credit) but are expected to attend a minimum of six lectures, participate in class discussions, and complete all case study assignments. RCR participants not taking this course for course credit, please register at:

https://harvard.az1.qualtrics.com/SE/?SID=SV_ddmNPXeaBm71mWp

*Course platform: <https://canvas.harvard.edu/>

**You will need and HUID or XID to log into this system. You can obtain and XID here:
<https://xid.harvard.edu/xid-apps/>

Session by Session Detail

Date	Topic	Instructor
Week 1 1/29	<ul style="list-style-type: none"> • Introduction to the responsible conduct of research • Regulations and guidelines governing research involving human subjects • Cases 1, 2 & 3 will be distributed • Case 3 to be completed for Week 2 (Export Controls) 	D. Wolf
Week 2 2/5	<ul style="list-style-type: none"> • Cases 1, 2 & 3 assignment due • Intellectual Property • Export Controls (Flipped) • Case 4 will be distributed 	J. Rice E. Nielsen
Week 3 2/12	<ul style="list-style-type: none"> • Cases 4 assignment due • Financial and non-financial conflict of interest • Mentor/ Mentee Relationships • Cases 5 & 6 will be distributed 	D. Wolf A. Speier
Week 4 2/19	<ul style="list-style-type: none"> • Case 5 & 6 assignment due • Peer review, responsible authorship and publication, responding to suspected violations of professional standards • Safe Laboratory Practice (Flipped) • Case 7 will be distributed 	E. Langdon Gray M. Corrigan
Week 5 2/26	<ul style="list-style-type: none"> • Case 7 assignment due • Collaborative Research • Data acquisition, sharing research results, and ownership • Case 8 & 9 will be distributed 	D. Wolf
Week 6 3/4	<ul style="list-style-type: none"> • Case 8 & 9 assignment due • Regulations and guidelines governing research involving live vertebrate animal subjects • Grant writing, budgeting, and adequate allocation of resources • Case 10, 11 & 12 distributed 	B. Corning A. Spickard
Week 7 3/11	<ul style="list-style-type: none"> • Case 10, 11 & 12 assignment due • Research Misconduct (Flipped) • Scientist as a responsible member of society- ethical issues in biomedical and public health research 	D. Wolf

Course Evaluations

Completion of the evaluation is a requirement for the course. Student grades will not be available until an evaluation is completed.