Course Syllabus

Healthcare Reforms and Value-Based Biomedical Technology Innovation

Meeting time: Fridays 1:30 – 3:20 pm

Meeting time: Thornton Center, Room 110 (379 Santa Teresa Street, Stanford, CA 94305)

Units: 3 units (attendance and team project) - 1 unit (attendance only)

Course Summary: A fundamental transformation of the US medical care system is underway in which healthcare policymakers, payers, providers and innovators are intensely focused on redesigning healthcare to promote quality, outcomes and affordability. With the passage of the Patient Protection and Affordable Care Act in 2010, the US has entered a new era of health policy that many refer to as the “value era.” This class evaluates healthcare policy reforms in the U.S. and abroad with a specific focus on examining their impact on biomedical technology innovation. The course is designed to be highly interactive. Most classes will include an introductory lecture followed by a class break and a guest speaker to provide real-world perspective and case study examples on topics covered in the lecture. Guest speakers include experts from health plans, healthcare delivery systems, life sciences and digital health companies to share how they are responding to ongoing reforms and the implications for future innovation. Lectures will introduce a diverse range of biomedical innovations and provide a link to developments in the news and ongoing debates relevant to course topics. Students investigate real-world technology innovations in course projects.

Instructor: John Hernandez, Ph.D.
Vice President, Global Health Economics & Outcomes Research
Abbott Vascular and Abbott Electrophysiology
Lecturer, Department of Management Science & Engineering
E-mail: jhernan1@stanford.edu
Phone: (408) 402-1453
Office Hours: Fridays 3:30 – 4:30 pm, Huang 352

Co-Instructors: Jan Pietzsch, Ph.D., Cynthia Yock, M.S.

Prerequisites: No prerequisites are required. Open to students of all levels and majors that are interested in health policy, biomedical innovation and its commercialization. This includes students in MS&E, Stanford Biodesign, Biomedical Informatics, School of Medicine, Graduate School of Business, Health Policy and Research, Stanford Technology Ventures Program and the School of Law. It is recommended that course participants have general familiarity with the US healthcare system through prior coursework and/or personal experience. The class includes a broad range of experience levels, and the instructors will endeavor to strike an appropriate balance throughout the class to satisfy different levels of prior experience in the field.
It is also suggested that students enroll in MS&E 256 “Technology Assessment and Regulation of Medical Devices” (Spring quarters) either before or after taking MS&E 257.

Course Website:  http://www.stanford.edu/class/msande257

Class Materials:  No textbook required. Handouts, case studies, and references will be distributed during the quarter and available on the class Coursework site.

Paper/Project:  Students taking the class for 3 units will perform a team project. The project deliverable is a final team report and class presentation. Project topics will be shared during the first class. Students are welcome to suggest topics of their choice (approval of topic by instructor is required).

Students will form teams (3 students) and submit their project preferences after the first class (see below for details). Project teams will introduce their topics to the class in the first part of the course to provide context and stimulate class discussion. Final presentations will be on the last class.

The motivation behind the class project format is to encourage learning, sharing and interaction with your peers about the technologies they are working on and the insights they gain during the course.

Grading:  For 3 Units:  Letter or CR/NC

Midterm Outline & Meeting: 10%
Class Participation: 20%
Final Presentation: 20%
Final Paper: 50%

Participation and contributions to class discussions are a factor in grading, and will be taken into account in final grade determination. Attendance is required in all classes. Additional information on grading criteria for the paper and presentation are listed further below in this document.

For 1 Unit:  CR/NC Option Only (based on attendance and participation)

Course Schedule

INTRODUCTION

1 (Jan 8)  Introduction to US healthcare system and value-based policy reforms

Lecture Topics
- Course introduction
- What is “value” in healthcare?
- Introduction to the US healthcare system
- The Affordable Care Act and “value-based care”
- Roadmap for value-based biomedical innovation
• Presentation of course project topics

Guest Lecture

• Nancy McGee, DrPH, JD, MPH, Senior Vice President, Life Sciences Practice, Avalere Health

Suggested readings

• Porter ME. What is value in health care? NEJM 2010.
• Enthoven A. Reforming Medicare by reforming incentives. NEJM 2011.

Assignment Due: Monday, January 11th (by noon)

• Project teams and project preference submission
  Students to be notified of results on Tuesday, January 12th before noon.

Assignment Due: Thursday, January 14th

• First project team meeting with Dr. Hernandez (15 min per team)
  Meeting slots from 4:00 – 7:00 pm. Please sign up electronically on or before Wednesday, January 13th (noon).

MEDICAL DEVICES

2 (Jan 15)  Medical devices, market access fundamentals and strategy

Lecture Topics

• “In the news” and “Biomedical innovation of the day”
• Introduction to the medical device industry
• Reimbursement fundamentals including coverage, coding and payment
• Market access strategy
• New technology payment mechanisms
• Case studies including coronary stents and transcatheter valves
• Student course project introductions

Required reading

Suggested readings


**HEALTH PLANS**

**3 (Jan 22)**  Health plan strategies for managing biomedical innovation

**Lecture Topics**

- Health insurance exchanges and other insurance market reforms
- Preview of concepts for quantifying health economic value
- Adoption and procurement of biomedical technology innovations by payers
- Health plan initiatives to improve progress toward the “triple aim”
- Innovations to address health insurance market failures (e.g., Castlight Health)

**Guest Lecture**

- *Jo Carol Hiatt, MD, MBA, FACS, Surgeon and Chair, National Product Council and Inter-Regional New Technologies Committee, Kaiser Permanente*

**Suggested Readings**


- Steven Brill: What I Learned From My $190,000 Surgery; TIME Jan. 8, 2015

**MEASURING HEALTH ECONOMIC VALUE – PART 1**

**4 (Jan 29)**  Assessing affordability of biomedical innovations across the product lifecycle

**Lecture Topics**

- Introduction to health economic modeling for biomedical innovations
- Role in evaluating value of biomedical innovations
- Fundamentals of cost and budget impact modeling in medicine
- Real-world case studies
- Hands-on Excel example

**Guest Lectures**

- *Jan Pietzsch, PhD, Consulting Associate Professor, MS&E, President and CEO, Wing Tech Inc., Co-Instructor*
Required reading


Suggested readings


MEASURING ECONOMIC VALUE – PART 2

5 (Feb 5) Assessing the value and affordability of biomedical innovations

Lecture Topics

- Introduction to cost-effectiveness analysis methods in medicine
- Measuring patient reported outcomes and patient health preferences
- Quality adjusted life years (QALYs)
- Incremental cost-effectiveness ratios (ICER)
- Hands-on Excel example

Guest Lecture

- Doug Owens, MD, MS, Henry J. Kaiser, Jr. Professor of Medicine and Health Research and Policy, Professor of Management Science and Engineering, Stanford University

Required reading


Suggested readings


Assignment Due: Thursday, February 12th

- Second project team meeting with Dr. Hernandez (10 min per team)
  Meeting slots from 4:00 – 7:00 pm. Please sign up by Wed, February 11th (noon). Please submit a project outline and/or initial draft report at this meeting.
BIOPHARMACEUTICALS

6 (Feb 12)  Biopharmaceutical innovation, strategic pricing and value assessment

Lecture Topics
- Introduction to the biopharmaceutical industry
- Role of market access and health economic value analysis in the biopharmaceutical industry
- Case studies and controversies
- Pricing and market access strategy in biopharma
- Hepatitis C strategic pricing case study

Guest Lecture
- Scott Howell, MD, formerly SVP, Clinical Affairs, Cardinal Health Specialty Solutions and VP at Genentech and Highmark BCBS

Required reading

Suggested readings
- Peter Bach: Could High Drug Prices Be Bad For Innovation? Forbes 2014.

ADVANCED DIAGNOSTICS

7 (Feb 19)  Big data in genomics and real-world case studies in advanced diagnostics

Lecture Topics
- Diagnostic industry overview
- Introduction to personalized genomics and genomic bioinformatics
- Case studies involving Genomic Health and InVitae

Guest Lecture
- Randy Scott, Co-Founder, Genomic Health and CEO, Invitae

Suggested Readings

HEALTHCARE REFORMS AND PATIENT CENTERED INNOVATION

8 (Feb 26)  Healthcare reforms and innovations focused on patient engagement
Lecture Topics

- Healthcare reforms focused on patient engagement and patient-centered care (including PCORI and patient-based performance measures)
- Emerging technology solutions that target patient engagement including mobile health, telehealth, patient portals, and others
- Case studies of innovative technology for wellness, chronic disease, and health care services

Guest Lecture

- Carolyn Bradner Jasik, MD, Vice President of Medical Outcomes, Mango Health, Associate Professor of Pediatrics, UCSF

Suggested Reading


HEALTHCARE REFORMS AND BIG DATA

9 (Mar 4) Healthcare reforms accelerate electronic health records and clinical informatics

Lecture Topics

- Affordable Care Act incentivizes EHRs through Meaningful Use Standards
- FDA, CMS and PCORI drive HER efforts for post-approval surveillance, coverage with evidence development and patient-centered outcomes research involving biomedical innovations
- Overview of EHRs, claims databases and other innovative real-world data efforts to transform healthcare practice
- Case studies of real-world data aggregation and analytics (e.g., registries, electronic medical records, claims data) to evaluate treatment effectiveness in support of the shift to value-based payment and accountable care

Suggested Readings

- Stanford launches smartphone app to study heart health. March 9, 2015.

Guest Lecture

- Euan Ashley, MB ChB, MRCP, DPhil, Associate Professor of Cardiovascular Medicine & Genetics, Co-Director Clinical Genomics & Precision Medicine, Chair, Biomedical Data Science Initiative, Stanford University

Assignment Due: Thursday, March 10th Midnight PST

- Electronic submission of class project presentations
  Please upload your final presentations to Coursework
10 (Mar 11)  Course summary, global perspective and class project presentations

Lecture Topics
- Summary of US healthcare reforms and evidence of outcomes to date
- Healthcare policies and reforms in the rest of the world
- Impact of value-based payment reforms on biomedical technology innovation
- Student project team final presentations

Class project presentations: March 11th

Additional Information about Project and Evaluations

Grading Criteria for Final Papers

The key criteria we are looking for in the papers are substance and form: These involve content, clarity and conciseness, analysis and insight, quality of references, structure of the paper, appropriate use of citations, and overall appearance (layout and editing). You will be able to get additional bonus points for compelling use of tables and figures. Below is some guidance for the 3-unit papers. Please keep in mind that high quality content is most important, and is always preferred over quantity with limited insight.

3 unit papers
3-person teams: max 30 pages plus appendices.

[if only two persons working on 3-unit topic: max. 23 pages plus appendices; if only one person: max. 15 pages plus appendices]

Among the important evaluation criteria, please put sufficient emphasis on the “appropriate use of citations” criterion. By definition, many of your papers need to rely heavily on a review of existing data and material, which requires significant inclusion of original contributions by others. Please make sure that you cite these sources appropriately, and that you follow the appropriate academic protocols for doing so (the following websites contain some useful information on how to avoid insufficient referencing of the work of others: http://www.stanford.edu/dept/vpsa/judicialaffairs/students/plagiarism.htm, http://www.northwestern.edu/uacc/plagiar.html). If you have questions about citations that are not answered to your satisfaction by these websites, please raise the question with one of us in the teaching team.

To give you some guidance of what we expect in the papers, we will post a couple of high-quality projects from previous years of MS&E 256 and 257 in Coursework. You may find review of these documents helpful as you are getting started with your papers.
Structure of the Final Papers

Be sure that your paper includes the following:

- Brief abstract or executive summary at the beginning of the paper, summarizing the objective of your paper, how you approached the topic from a methodological point of view, and what are the main findings and conclusions of your work (this can be brief and should certainly not be more than one page overall; if necessary, the abstract can be counted as an additional page outside the page requirements outlined earlier)

- Introduction section to your paper in which you, again, briefly outline the objective/motivation of your work, and introduce the field of your study (what is the disease that's treated with your device, etc.)

- Summary/conclusion section in the end, in which you clearly identify the main findings of your work, and share/reiterate the major insights you have gained. Remember that analysis and insight gained should be one of the pivotal elements of your paper, and this is where you can reflect on it.

Information about Final Presentation

Students are expected to distill their research into a 10 minute slide presentation (15 minutes total including Q&A). Additional information on the final presentations and a slide template will be distributed in the first part of the course.