CORE COURSE IN HEALTH POLICY 2021-2022
HEALTH POLICY 2000A/B

CLASS MEETINGS
Tuesday & Thursday, 4:15-6:00pm
Course sessions will take place at 14 Story Street in the 4th floor conference room
*Session location may change based on course needs

INSTRUCTORS
Meredith Rosenthal (HSPH)

TEACHING FELLOWS
Amanda Speller
Kacie Dragan
Office Hours: By appointment

COURSE OVERVIEW

This yearlong course (Core) is required for doctoral candidates in health policy and is open to other doctoral students at Harvard. The purpose of Core is to provide a foundational, interdisciplinary understanding of health policy for students who will undertake research that advances knowledge and leads to improvements in health.

Learning Objectives
After completing the course, students should be able to:
1. Describe and apply disciplinary frameworks and vocabulary used to formulate research questions in each discipline
2. Understand the methodological approaches that each discipline takes in answering research questions
3. Apply those frameworks in concert with one another to analyze policy tradeoffs and clearly communicate a case for or against specific policy options
4. Identify the interplay between social determinants of health, including racism and other forms of systemic oppression, and health policy
5. Anticipate the effects of policy on health equity, including consequences of health policies and practices that harm underserved groups
6. Practice critical reading of innovative scientific and policy papers from the disciplines that inform health policy

READINGS

Readings for the course will generally consist of journal articles assigned by the lecturer and should be read in advance of each lecture. These readings can be found on Canvas in the course Modules.

The majority of assigned readings are available electronically. Links are provided in the syllabus and on Canvas (under “Modules”), or students can search for the articles using the Harvard Library research website: https://hollis.harvard.edu. Some readings are available on the course website. Where readings are not available electronically or on the course website, it is suggested
that students use the Harvard Library’s Scan & Deliver service: [http://library.harvard.edu/scan-deliver](http://library.harvard.edu/scan-deliver).

**COURSE REQUIREMENTS**

**Attendance & Participation:** 33%
This course meets twice per week. Students are expected to attend and participate in the 105-minute lecture and discussion sessions. This participation includes reading 3-4 relevant articles assigned by the lecturers prior to each class. If you are unable to attend a lecture, please let the instructor and teaching fellows know by email in advance of the session.

**Written Assignments:** 67%
There will be short written assignments throughout the year, and a 15-page research proposal that students will develop throughout the Spring semester. Short assignments take the form of essay questions that resemble the health policy qualifying exam and critical appraisals of published research papers. Due dates are as follows:

**Fall**
- Assignment 1: 10/5
- Assignment 2: 10/26
- Assignment 3: 11/16
- Assignment 4: 12/9

**Spring**
- Assignment 1: Propose three possible questions for your research proposal and post on Canvas; give feedback to at least two other students.
  - February 8th by 4:15pm: Propose questions
  - February 14th by 4:15pm: Provide feedback to peers
- Interdisciplinary Essay #3
  - February 24th at 4:15pm
- Assignment 2: Pick and refine your final research question based on the first part of the assignment. Draft a literature review for that question (Section III).
  - March 8th by 4:15 p.m. (Shoot for 3-4 pages double spaced.)
- Assignment 3: A draft of Sections I and II.
  - March 29th by 4:15 p.m. (Shoot for 3-4 pages double spaced.)
- Assignment 4: A draft of Section IV.
  - April 7th by 4:15 p.m. (Shoot for 5-6 pages double spaced.)
- Assignment 5: Students will present their proposals (15 min each)
  - April 19th, 6-8pm: Half of students present
  - April 21st, 6-8pm: Half of students present
- Assignment 6: The final paper is due
  - April 28th by 4:15 p.m. (15 pages double-spaced maximum)

**Human Subjects Training:**
To pass the Spring semester, students will be expected to complete an online Human Subjects Training Course and present verification. The training can be accessed through the following link: [https://www.citiprogram.org/default.asp](https://www.citiprogram.org/default.asp). Students should do the Basic Course in the
Protection of Human Subjects for Social and Behavioral Research Investigators. For affiliation, please select Harvard University (Cambridge/Allston Campus). Completed training certificates should be e-mailed to both the teaching fellows and to Colleen Yout (colleen_yout@harvard.edu) no later than 4/28.

**Grades:**
Grades will be assigned separately for the first semester and the second semester.

**Academic Honesty:**
Students must observe Harvard University rules regarding the citation of sources. Any sentences or paragraphs taken verbatim from the writing of any other person or persons, or from your own writing that has been published elsewhere, must be placed in quotation marks and their source must be clearly identified. Changing the wording of a sentence or passage slightly does not evade the requirement for citation. Indeed, whenever you are drawing an important argument or insight from someone else, even if you reword it into your own words, a reference to the source is required. Including material from others in the assignments without appropriate quotation marks and citations is regarded, as a matter of School and University policy, as a serious violation of academic and professional standards and can lead to a failing grade in the course, failure to graduate, and even expulsion from the University.

**Classroom norms**
As scholars and policy influencers we need to engage with the full range of perspectives and ideas in health policy. Thus, diversity and inclusion are fundamental to our work and core values of our program. Course instructors share responsibility with students for creating a learning climate that is hospitable to all perspectives, identities and cultures.
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Section I: Overview

Session 1 (9/2): Introduction to Health Policy (D. Cutler)

Session Objectives:

This class addresses how to think about policy problems.

Session Activity:

At the start of class, you will be asked to provide an answer to the question:

“Suppose that COVID is largely contained in the next few months. The Biden Administration is wondering what its health policy goals should be after that. You are to provide advice to the Domestic Policy Advisor, Susan Rice, about an important area for the Administration.”

In preparation for class, you should come up with *one* area which the Biden Administration should focus on (example which might have been proposed for the Trump Administration: Action steps to dismantle the Affordable Care Act). In class, you will be put into groups to flesh out an area. You will put together 4-5 PowerPoint slides with the gist of your idea, pluses, and minuses. You will also indicate to the class what additional information you would need to know. These PowerPoints will be presented to your fellow classmates for comments and discussion.

Required Readings:

The background reading for the class is about how to construct a memo to a busy official. Here are some example memos to the president about health care.


[https://www.heritage.org/health-care-reform/report/ensuring-access-affordable-health-insurance-memo-president-elect-obama (Links to an external site.)]
Session 2 (9/7): Overview methods session on evidence for policy. Case Study: Workplace wellness. (L. Hatfield and Z. Song)

Session objectives:

- Explore the pros and cons of randomized controlled trials in health policy
- Understand how different methods can produce different answers to the same question
- Null findings and the problem of how to show that something *doesn't* work
- Studying politically popular ideas, especially ones with strong selection into treatment
- Evolution of beliefs-- are we Bayesian in how we update our priors?
- Navigating scholarly integrity, getting a reputation for one side of an issue

Required readings:

Session 3 (9/9): Efficiency as a goal of health policy: the marginal value of public funds (T. Layton)

Session objectives:

Economics focuses on the question of how to allocate scarce resources. Given a budget constraint, we want to allocate those resources in a way that maximizes social welfare. Most policies involve trade-offs, or "opportunity costs". The primary goal of economics is to provide an internally consistent framework that allows us to assess those trade-offs and determine optimal policy.

- We will start with a discussion about the (somewhat provocative) op-ed by Amy Finkelstein about cash versus expanded health insurance. First, we'll address the question of whether economics is even relevant today: Do we in fact live in a world with scarce resources? Do we have to choose one program or another? Assuming that there is scarcity, this piece provides an example of how economics can help us determine how to allocate a scarce resource (government spending) in a way that maximizes the welfare of the people we want to help. It also highlights the importance of the ability to estimate the value and the cost of public programs.

- We will then introduce the Marginal Value of Public Funds framework for comparing public programs, using the terrific work of Nathan Hendren to describe this framework and then use it to compare over 100 public programs. Importantly, the MVPF highlights the importance of accounting for "fiscal externalities" when assessing public programs.

- Then, we will use the Chetty and Finkelstein reading to take a look at how economics helps us clearly state the goals of public programs and how well different programs achieve those goals. Specifically, we will look at the example of social insurance (which could be health insurance, unemployment insurance, disability insurance, etc.), where the goal is equalizing marginal utility across "good" and "bad" states of the world and the key "fiscal externality" is the moral hazard problem, where more insurance leads to changes in individual behavior that increase fiscal costs of the program.

- Finally, we will discuss the market as the default mechanism for allocating scarce resources. The market may not be your desired mechanism for allocating healthcare goods and services, but it is the default mechanism: It is always acting in the background, even if there is a large government presence. It is thus important for us to understand how the market works, and economics provides us with a framework for understanding that. Unfortunately, the neo-classical economic framework does not work well in healthcare markets for a variety of reasons. Arrow originally outlined these reasons in 1963, and the field of health economics has spent the following 50-60 years enhancing the economic framework to account for these deficiencies. We will discuss the deficiencies and how modern economics deals with them.

Readings
  o [https://www.nytimes.com/2021/05/13/business/health-insurance-cash-Biden.html](https://www.nytimes.com/2021/05/13/business/health-insurance-cash-Biden.html)
  o [https://doi.org/10.1215/03616878-26-5-851](https://doi.org/10.1215/03616878-26-5-851)
  o [https://web.stanford.edu/~jay/health_class/Readings/Lecture01/arrow.pdf](https://web.stanford.edu/~jay/health_class/Readings/Lecture01/arrow.pdf)
    ▪ Skim Section 2. We will return to this reading in October.
  o For more, see slides from Hendren: [https://scholar.harvard.edu/files/hendren/files/addl_lecture_1_-_optimal_social_insurance.pdf](https://scholar.harvard.edu/files/hendren/files/addl_lecture_1_-_optimal_social_insurance.pdf)

**Other Required Materials**
● Take the guided tour here: [https://www.policyinsights.org/](https://www.policyinsights.org/)
● Econimate Video: “Which Public Policies are Most Effective?” [https://www.youtube.com/watch?v=qtl6RvuFlWs](https://www.youtube.com/watch?v=qtl6RvuFlWs)

**Optional Readings**
  o [https://doi-org.ezp-prod1.hul.harvard.edu/10.1093/qje/qjaa006](https://doi-org.ezp-prod1.hul.harvard.edu/10.1093/qje/qjaa006)
Session 4 (9/14): Equity and health policy (A. McGregor and B. Cook)

Session objectives:

- Provide definitions, conceptual foundations, and empirical strategies for understanding how health policy has impacted present day health inequities and evaluating how present day health policy can exacerbate or diminish health inequity

As you do the readings, please think about the implications for the design of health policies that improve equity and research designs to identify the causes of health inequities

Required readings:


- Barton Smith, D. Civil Rights and Medicare: Historical Convergence and Continuing Legacy. in *Medicare and Medicaid at 50: America’s Entitlement Programs in the Age of Affordable Care* 21–38 (Oxford University Press, 2015). [Scanned chapter will be available in "files"]

Optional readings:


Section II: Health systems

Session 5 (9/16): Comparative health systems (R. Atun)

This session introduces an analytical framework for examination of health systems and contexts within which health systems are situated. The session will use illustrative examples to discuss how the framework is used to examine and compare health system functions, namely, ‘Organization and Governance’, ‘Financing’ and ‘Resource Management’, how these functions are used to produce health system outputs (Public Health Services and Individual Health Services) and achieve a desired balance of Equity, Effectiveness, Efficiency and Responsiveness, in order to attain the right level and distribution of health systems outcomes of improved Health, Financial Protection and User Satisfaction. The session will use empirical cases and discuss various methods used in applying the framework to analyse and measure a health system’s performance in attaining a desired level of outputs and outcomes in relation to set output objectives (e.g. improving equity, efficiency, effectiveness and responsiveness) and outcome targets (e.g. improving financial protection), to compare performance over a period of time (longitudinal benchmarking) or in relation to performance of other health systems (comparative benchmarking).

Learning Objectives

The reading goals are to be familiarized with an analytical framework for examination of health systems and contexts within which health systems are situated, and how the framework can be used variously to analyze health system performance in producing health system outputs that are equitable, effective, efficient and responsive and attaining improved level and distribution of health system outcomes.

Required Readings:


Optional Reading:

- Hone T, Rasella D, Barreto M, Atun R, Majeed A, Millett C. Large Reductions in Amenable Mortality Associated with Brazil's Primary Care Expansion and Strong Health


  - [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6150612/Links to an external site.]

  - Chapter 1: [https://oxford-universitypressscholarship-com.ezp-prod1.hul.harvard.edu/view/10.1093/oso/9780197528549.001.0001/oso-9780197528549-chapter-1Links to an external site.]
  - Chapter 2: [https://oxford-universitypressscholarship-com.ezp-prod1.hul.harvard.edu/view/10.1093/oso/9780197528549.001.0001/oso-9780197528549-chapter-2Links to an external site.]
Session 6 (9/21): Introduction to ethical frameworks for allocating scarce resources (D. Jones)

Session Objectives:
For as long as we can tell, there has been more demand for health care services, and more providers eager to provide them, than there have been resources to pay for it all. Through the 19th century, this was managed through a mix of market mechanisms (fee for service) and charity (both formal and informal). With the increasing complexity of health care and health care financing in the 20th century, experts have taken a more deliberate approach to questions of resource allocation (also known as rationing). In this session we will explore the history and ethics of allocating scarce resources in health care.

Required Readings:
  - Annas describes a classic case: rationing of renal dialysis in the 1960, before Congress acted to provide Medicare coverage for people with chronic kidney disease. What was the Seattle solution and where did it go awry? Scholars spent the subsequent decades arguing about the right (or better vs. worse) ways to ration.
  - Dan Brock provides a useful review of the key issues.
  - Persad et al. (2009) developed this thinking into a set of actionable principles. What are their values? Are they the right ones? Are you convinced by their arguments? All the while, an ugly truth persisted in the US: health care is often rationed by ability to pay for it (i.e., the rich get more care than the poor), even though rationing by wealth has never been on ethicists’ lists of the right way to ration. COVID pulled these scholarly debates into the public spotlight.
  - Persad et al. (2020) revisited their 2009 framework to offer recommendations for rationing COVID vaccines.
  o Fink describes the dilemmas of ECMO rationing. Despite the renewed effort by ethicists to demonstrate just ways to allocate resources, financial considerations remain prominent (i.e., which countries have high vaccine rates at the moment?).

  o Sayeed and Taylor offer a critique of the bioethical discourse that has led to this state of affairs. What do you think should be done?
Session 7 (9/23): Introduction to Health Decision Science and Cost-Effectiveness Analysis (N. Menzies)

Session Objectives:

This session introduces conceptual frameworks that have been used to facilitate optimal policy choice for health and healthcare. These frameworks assess the optimality of a given policy based on its likely consequences, as compared to the consequences of other policies that might be adopted. One challenge of comparing policies is the task of achieving fair comparisons between different kinds of health improvements. Another challenge is the need to trade-off spending on health against consumption or other use of resources. This session discusses cost-effectiveness analysis as one widely used way to resolve these challenges.

Required Reading:


Supplementary Articles:

Session 8 (9/28): Technology assessment and resource allocation (A. Pandya)

Session objectives:

[TF note: It happens to be Ankur's birthday! Happy birthday to Ankur!]

Cost-effectiveness analysis is used widely in most high-income countries to guide decisions about payment and reimbursement of medical services. In the US, use of cost-effectiveness analysis using quality-adjusted life years as the measure of health improvement is forbidden from policy decision making by the Affordable Care Act. It is used mainly behind the scenes in the private insurance sector, by medical professional organizations in guideline formulation, and to evaluate prevention programs such as vaccination.

Key questions for this session (including the readings):

- Can and should cost-effectiveness information be explicitly used in US health care decision-making, and if so, how?
- How should decision-makers weigh outcomes that are not fully captured by conventional cost-effectiveness analysis (such as distributional equity or budgetary impact)?

Required readings:


Optional readings:


Session 9 (9/30): Ethics of Universal Health Coverage in Low- and Middle-Income Countries (O. Norheim)

Session Objectives:

- Learn about the ethical basis for efforts to achieve universal health coverage (UHC) under the Sustainable development Goals
- Apply this knowledge in a discussion of a real-life policy decision.

Required Reading:


Case study:


Optional Reading:

Section III: Health insurance in the U.S.: coverage and market structure

Session 12 (10/5): Private insurance markets and adverse selection (T. Layton)

Session Objectives:

We will discuss the economics of insurance, starting with the motivation for insurance as a means for providing risk protection and improving welfare by equalizing marginal utility in good and bad states of the world. We will then discuss the key market failures affecting insurance markets and causing markets to fail to deliver first-best outcomes. Specifically, we will focus on the economic concepts of moral hazard and adverse selection. The Cutler-Zeckhauser reading lays out the key conceptual issues around the value of insurance and the problem of moral hazard. The Einav and Finkelstein reading lays out the economics of adverse selection in the simple case where insurance contracts are assumed to be fixed, including its primary consequences for prices and welfare. The Cutler-Reber and Washington Post readings provide a case study and an accessible explainer of the problems caused by adverse selection in this context. Finally, the Geruso and Layton reading discusses the economics of adverse selection in the more complicated case where contracts are endogenous (i.e., can respond to adverse selection) and lays out the economics of the various policies used to combat selection-related inefficiencies.

The optional readings provide an overview of more recent advances in the economic literature on adverse selection. Chetty and Finkelstein provide a deeper overview of the economics of social insurance. Marone and Sabety study the question of whether any of this literature is relevant at all by asking whether we should even have any choice in health insurance. Geruso et al. study interactions between selection on the intensive (more vs. less generous insurance) and extensive (insurance vs. uninsurance) margins.

Required reading:

  Focus on Sections 2 and 3

Optional reading:

  ○ Through the end of section 2
Session 11 (10/7): Introduction to the U.S. Health Insurance System (H. Huskamp)

Session Objectives:

- Identify key dimensions of health care financing and delivery in the U.S.
- Describe current policy challenges including aggregate spending trends and health disparities

Required Readings:


Optional readings:

Session 12 (10/12): Health system quality (M. Kruk)

Session objectives:

- Define health system quality in global contexts and identify a handful of useful metrics
- Discuss theory and evidence on more and less effective means for improving quality at scale

Required readings:

  - Please read the Executive summary + Panel 9 + Section 5


Optional readings:

Session 13 (10/14): Politics, public opinion and health policy in the U.S.
(A. McIntyre)

Session Objectives:
- Characterize structural political factors and attitudes toward government in the United States that inhibit efforts at large-scale health reform.
- Describe smaller-scale and less politically volatile opportunities to improve coverage by targeting administrative processes.
- Develop an understanding of the policy feedback process: how policy design can mediate public opinion and political behavior, with implications for future policy.

Key takeaways:
Results from public opinion surveys should be used with care; policy views often are not strongly held and can be highly malleable.
Public opinion is only one part of the politics of coverage policy; structural features of the policymaking process (including the privileged position of some stakeholders relative to others) are also important on a first-order basis.

Required readings.

Optional readings:
Session 14 (10/19): Congress and health insurance coverage policy-making (S. Burke)

Required Readings:

- From Bill to Law. Stages of the Legislative Process. [File]
- Catastrophic Coverage Act Time Line. [File]
- **Case study**: Catastrophic Health Insurance for the Elderly. The Harvard Kennedy School Case Program. C18-95-1278.0
Session 15 (10/21): Consumer choice and behavioral economics in health care (A. Sinaiko)

Learning Goals:

● To examine the health insurance choice implications of the rational (e.g. neoclassical) model of consumer health insurance choice, and when and why the model fails.
● To spark your thinking about, in a choice-based market like the US health insurance market, potential policies that can harness the value of competition while minimizing inefficiencies and inequities.

Reading guide:

● What does the rational (e.g. neoclassical model) predict about health insurance plan selection when consumers have a choice among plans?
● What do consumers say they want to know when they are choosing plans (e.g., what do they say they value?)
● What are some of the drivers of consumers’ health insurance choice challenges?
● What is behavioral economics? Why is the behavioral economics literature important to health insurance choices?
● How do the biases and heuristics that commonly impact health insurance choices contribute to inefficiencies and inequities in health insurance coverage?

Required Readings:


Optional Readings:
  ○ There are many empirical analyses of consumer health insurance choice in real-world settings, presenting evidence of different biases and heuristics that affect health insurance choices. This Madrian and Shea article is the classic article from the savings literature illustrating the power of defaults in a similar context – choice of retirement savings plans.

  ○ There are many articles that apply findings from behavioral economics to policies that aim to improve health behaviors (e.g. smoking cessation, weight loss, adherence to chronic condition maintenance medications). This paper provides an overview of these ideas.
Session 16 (10/26): Mental health parity and related insurance issues (adverse selection, carveouts) (R. Frank)

Session Goals:

- Review history of financing arrangements for mental health and substance use disorder (MHSUD) services.
- Discuss role of moral hazard and adverse selection in insurance markets for MHSUD services, and legislative and regulatory efforts to ensure parity in coverage for MHSUD vs. other types of health care services.

Required Readings:

- Huskamp, HA. Mental Health Insurance Parity – How full is the glass? [Courseweb]
Session 17 (10/28): The Oregon health insurance experiment: methods insights (video module on moral hazard in advance) (M. Landrum)

Session Objectives:
- To discuss the role of experimental evidence in health policy
- To identify methodological strengths and weakness of the OHE

Required Videos:
- RAND and the Moral Hazard: Healthcare Triage #10 [https://www.youtube.com/watch?v=q0OtUbDYdxw]

Required Readings:
- A Note on Moral Hazard [File in Canvas Module]

Optional Video:
- The RAND Health Insurance Experiment: A Retrospective at 40 Years [https://www.youtube.com/watch?v=HtoUs_4OYV]
Session 18 (11/2): Preferences and tradeoffs in health insurance decisions (D. Wright)

Learning Goals:
- To introduce the concepts of preferences, utility, and heuristics in the context of health plan choice
- To explore outcomes other than financial efficiency that need to be maximized in a consumer's utility function

Reading Guide:
- This literature in the context of Anna's lecture. Specifically, what are the common heuristics people use to make decisions and biases people have in decision making and which (other than cheapest plan) may apply to health insurance decision making?
- What is the difference between values and preferences highlighted in the Witteman paper?
- How do the authors integrate values and preferences into decision making tools?
- The role of uncertainty-- how decision making about treatment may differ from decision making about insurance.
- Weaknesses of values clarification methods.
- Do outcomes like decisional conflict and decision regret matter with respect to health insurance choice and how?

Required Readings
- Wright DR, Sinaiko AD, Galbraith AA. "You Can't Always Get What You Want: Preferences and Trade-offs for Health Insurance Plan Decisions?" JAMA Health Forum. Published online July 17, 2020. [https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jama-health-forum/fullarticle/2768694?resultClick=1Links to an external site. ]

Optional Readings:

Instructions:
Please read the following articles to prepare for this session. You will be assigned to a small group to focus on one article that you will present to the seminar. Please plan on making a brief presentation (say, 3-5 minutes) on the main points of the reading, and give some initial reactions to the discussion question for your reading. You do not need to prepare slides for the presentation.

Group Assignments for 3-5 minute presentation.
- Group 1: Katie, Derrick
- Group 2: Connie, Ibou, Celia
- Group 3: Carolyn, Marema
- Group 4: Andrea, Lindsay, Andrew
- Group 5: Hailey, Tai

Group 1
  - What’s special about “interventions” (implying human agency) in demonstrating causality?
  - In the obesity example, what might be advantages and disadvantages of the following types of study:
    - Intervention on soda drinking with high school students participating in a broad health promotion program
    - Intervention on soda drinking with a general population
    - Collection of survey data on soda consumption from patients of a clinic (assuming that it can be linked to an electronic medical record).

Group 2
  - What’s special about “interventions” (implying human agency)?
  - Does the approach taken here solve the “immutable characteristics” problem?
  - If not, what problem (if any) does it solve?
  - What kinds of research question would be best addressed by each of the competing study designs?
  - What kinds of research question would be best addressed by the study design described in this article versus a retrospective study of sentencing in relation to race?

Group 3
  o Describe some examples and/or general types of questions for which a multilevel approach as described here would be advantageous

**Group 4**

  o What value, if any, would the analysis described here have for answering causal or noncausal questions relevant to reporting of quality?

**Group 5**

  o (Skim for overview of the study.) What are the relevant levels/units for this study design? Any implications for causality?

**Optional reading for those interested**


**Section IV: Social stratification and health**

**Session 20 (11/9): Structural racism and health (N. Linos)**

[TF Note: Natalia is planning for a discussion-oriented session, so please come prepared with questions, reflections, or ideas for how you might design research in this area for some of the unanswered questions/apply these concepts to your own research area. In addition to the readings, you can also take a look at the FXB Center's website (which Natalia now leads) to get an idea of the research & advocacy work they do, if it helps inform your reflections: The [FXB Center's general website](#), and their [racial justice projects](#).]

**Learning objectives:**

1) Understand the ways in which racism acts as a cause of health inequities in the United States, as well as the difference between structural racism and other forms of racism (like interpersonal racism).

2) Discuss standards for approaching and conducting research on race and racism in health policy and public health settings.

3) Discuss policy recommendations and current proposals for addressing racial health inequities.

**Required Readings:**


Session 21 (11/11): Income and life expectancy/health (E. Meara)

Over the last several decades, differences in mortality and life expectancy in the United States have widened along multiple dimensions. Using the assigned readings, we will first characterize major trends over recent decades to summarize what is known about changes by income, by education, and across U.S. states and regions. We will consider the nature of evidence presented in each paper – What methods have been used and what are the strengths and weaknesses of such an approach? What inference can we make from these approaches about the source of inequality in mortality? We will also touch upon whether explanations for inequality grounded in economic frameworks (i.e. utility maximization) yield different hypotheses from those grounded in public health. We will spend the rest of our time considering support for (and against) key hypotheses to explain trends in mortality and life expectancy. Please come to class prepared to share one hypothesis you think has support or one not covered in the articles that should be explored further to understand growing inequality in mortality and life expectancy. As a bonus, think about a policy, current, historical, or hypothetical, that you think might mitigate inequalities.

Learning objectives:

- Characterize inequality in mortality and life expectancy by income, education, and place
- Consider hypotheses consistent with the uneven changes in mortality/life expectancy observed
- Weigh evidence supporting institutions (i.e. policies) versus culture to explain

Questions to guide your reading:

1. What does it mean that adults in the 99th percentile of income have higher life expectancy than adults in the 90th percentile?
2. How does the area (commuting zone) where people live affect differences in life expectancy at the bottom of the income distribution and at the top?
3. What are the leading explanations to explain why deaths of despair increase more for non-Hispanic non-Latinx White middle aged adults compared with other groups?
4. How does the income in a state compare to mortality rates in that state (circa 2016?)
6. Do you agree with the authors of these papers regarding conclusions about what drives inequality in mortality or life expectancy

Required Readings


Optional Readings

Session 22 (11/16): Quasi-experimental methods to measure the impact of racial injustice on health (L. Hatfield)

Learning objectives:

By the end of this session, students will be able to

- Identify mechanisms and health impacts of racism in the carceral system
- Explain and critically evaluate the causal and statistical assumptions of this study
- Propose policy solutions to address police violence and its direct and indirect health consequences

Required Readings

Session 23 (11/18): Commodification: selling eggs, organs, and other things. (G. Cohen)

[TF note: Glenn has cold called students during this session in the past -- he is a law professor & that is more common in law schools! -- so be prepared!]

Learning Goals:

- Students will learn how to reason ethically through a difficult question, when compensation commodifies, and use it to shape policy-setting for the law.

Required Readings:

- In Re Baby M, 537 A.2d 1227 (N.J. 1988) [File linked in Canvas]
  - pp. 131-140 (Beginning of chapter on Prostitution and Baby Selling only until “A Special Case of Commissioned Adoptions”)
  - Chapter 6 (Organ Sales)
Session 23 (11/23): Characterizing variation. Disparities in health care

(L. Hatfield)

Required Readings:

Thanksgiving holiday
Session 25 (11/30): Access to and quality of care for people with disabilities (L. Iezzoni)

Session objectives:

1. Discuss the roles of structural and interpersonal discrimination against people with disabilities (i.e., ableism) as determinants of health care access and outcomes
2. Identify opportunities and challenges for health policy to promote health equity for people with disabilities

As you prepare for the class and read the materials: (1) consider the mechanisms through which people with disabilities are denied the same opportunities for health and well-being as others – it may help to think back to the Camara Jones paperLinks to an external site. that Alecia and Ben discussed on September 14th; (2) map out in your mind the ways in which health policies (provider regulations, payment, coverage, etc.) negatively affect health equity for people with disabilities and what reforms might have the biggest impact on access and outcomes, including patient experience.

Required readings:


**Session 24 (12/02): Disability policy** (N. Maestas)

**Session objectives:**

- Understand the major federal and state policies that provide income support and access to health insurance and other services for people with disabilities
- Understand the insurance-incentive tradeoffs and potential for moral hazard in this unique context
- Describe current policy challenges and pathways for improving program design
- Tour the research frontier in this area

**Required Reading:**

  - [Focus on the quasi-experimental design, be prepared to discuss strengths and limitations]
  - [Skim this one, provides background for Longmore article]
  - [Read pp. 230-246, skim the rest].
  - File linked in Canvas

**Optional reading:**


Section V: Health care delivery: management and quality

Session 1 (01/25): Organizing Health Care for Learning, Improvement, and Innovation (R. Huckman)

[TF Note: Welcome back! Rob will be using an HBS Case to guide the discussion. Please note his discussion questions for the case below and think about them before class.]

Learning Objectives:

- Develop an understanding of a key theme in the health care management literature—designing and operating organizations to foster improvement and innovation
- Appreciate the tension between standardization and local autonomy as approaches for stimulating improvement and innovation
- Consider the extent to which improvement tools developed in manufacturing (e.g., lean production, learning curves and focused factories) can be applied to health care delivery

Required Readings:

  - TO ACCESS THE CASE: You can access a copy of the case in "Files: File Linked in Canvas.
  - Please do not distribute the PDF to others. HBS cases are purchased by the program and distributed on a per-user basis. We purchased 12 copies, but we are uploading a single PDF to Canvas for your convenience.
  - You can also use this link to access the case directly on the HBS site, but you'll need to make a (free) Harvard Business Publishing account.

Note: To focus your preparation, please read the three items above. Please read the Rittenhouse Medical Center case closely and come prepared to discuss the following questions related to it:

1. What is your assessment of the 3B Orthopedics model relative to that used for typical procedures performed by the faculty practice surgeons? Which is better? What are the key criteria for your assessment?
2. What are the possible sources of conflict between Booth’s model of care and the faculty
practice’s model? How might this potential conflict be reduced?
3. Should Neela Wilson accede to Dr. Booth's request? If not, how should she respond?

Optional readings:

Session 2 (01/27): Introduction to the spring (M. Rosenthal)

**Learning objectives/preparation:**
There are no required readings for the session, but please spend time on the 2 tasks below prior to class:

1. Meredith will be introducing the arc of the spring semester and invite a discussion about your research projects. **Please review the latest spring assignment instructions come prepared with questions.**
   - More details, including links to examples of proposals from last year, are available on the Assignments page. Please also feel free to review one or two (or three!) of these as you prepare for Thursday.

2. As we set up for the spring, please also come prepared to tell us about one thing you learned in Core last semester that surprised you and one thing about health policy or any of the "institutional" details that we discussed that still puzzles you.
Session 3 (02/01): Organizational behavior (M. Kerrissey)

[TF note: Michaela would like you to read an HBS case, like you did for Rob's class. She included some discussion questions to consider – see below. However, she said you can skim the case (you do not have to read it as in-depth as Rob's case). But spend a few minutes thinking about the questions, especially as they pertain to the other readings.]

Learning Objectives:
- Develop familiarity with organizational behavior scholarship and its application in healthcare research
- Explore the value, benefits and limits of social factors in care delivery
- Identify key issues in the measurement of social and team factors

Required Readings:
- Kerrissey, M. & Edmondson A. Enabling Teamwork at the Cleveland Clinic. Harvard Business School Case No. 621040. (you can skim this – it is intended to give a concrete example of team issues in health systems but we will not delve into the details in class)
  - TO ACCESS THE CASE: You can access a copy of the case in File linked in Canvas.
  - Please do not distribute the PDF to others. HBS cases are purchased by the program and distributed on a per-user basis. We purchased 12 copies, but we are uploading a single PDF to Canvas for your convenience.
  - You can also use this link to access the case directly on the HBS site, but you'll need to make a (free) Harvard Business Publishing account.

Questions to Guide your Preparation:
- Why did the Cleveland Clinic move to an institute model?
- How would you assess the benefits and drawbacks or risks of this transition?
- How is the current environment for the Clinic changing and what are the implications for teamwork?
- What kind of study would you set up to evaluate the newer teamwork issues surfaced in the Cleveland Clinic case? How would you approach it? What would you worry about?
- What are the benefits and limits of considering social features of care delivery (such as teamwork, norms, culture) in research?
• What do you think is required to make managerial research both rigorous and relevant to contemporary healthcare?

Optional Readings:

- **Perspectives on the field and methodological approaches:**

- **Examples of multi-method papers on teams:**

- **Papers on integration from social/organizational perspectives:**
Session 4 (02/03): Quality improvement/patient safety and health equity

(T. Sequist)

Learning Objectives:
1. To introduce the concept of quality improvement in health care
2. To explore what we know and need to know about improving quality of care for racial/ethnic/linguistic minority populations and other groups that experience worse health outcomes

Required Readings:
Session 5 (02/08): Quality measurement (N. Keating)

Learning Objectives
- Review definition of “quality”
- Understand goals of quality measurement & what makes a good quality measure
- Understand challenges of quality measurement
- Consider the role of equity in quality measurement

Required Readings
  - note that this manuscript is under revision at a journal so do not circulate or cite to anyone outside the class

Optional Readings
Session 6 (02/10): Methods: qualitative research in health management

(E. Aveling)

[TF note: Emmilie would like you to watch a 45-min video lecture as preparation for class. Be sure to budget enough time to do so! Links to the 4 parts of the video (and 2 readings) are below.]

Learning objectives:
- Describe key features and foundational assumptions of the qualitative research paradigm
- Identify types of healthcare research questions that qualitative approaches can address
- Describe key considerations for assessing the quality and utility of qualitative research

Required reading/viewing:

Video lecture: Introduction to the Qualitative Research Paradigm (Emmilie Aveling) (From Chan School Course: MPH 101 – Qualitative Methods for Public Health)
Slides to accompany the videos are attached. Kaltura links below (it’s divided into shorter segments totaling 45 minutes)
1.1 What is Qualitative Research? [http://www.kaltura.com/tiny/02o0w](http://www.kaltura.com/tiny/02o0w)
1.2 Philosophical Assumptions and Methodological Choices [http://www.kaltura.com/tiny/0vblb](http://www.kaltura.com/tiny/0vblb)
1.4 Fundamental Assumptions of the Qualitative Paradigm [http://www.kaltura.com/tiny/03a0v](http://www.kaltura.com/tiny/03a0v)
Section VI: Health care delivery: models and incentives

Session 7 (02/15): Methods for adjustment (J. Zubizarreta)

Learning goals:
• To understand how different methods for adjustment, such as regression, matching, and weighting, act on the individual-level data to approximate a hypothetical randomized experiment under different identification strategies.
• To understand the strengths and weaknesses of these methods in terms of study design, statistical efficiency, and computational tractability.

Readings:
  o [https://arxiv.org/abs/2104.06581]
  o [https://www-sciencedirect-com.ezp-prod1.hul.harvard.edu/science/article/pii/0167629696000021]

Optional/Recommended readings:
  o [https://muse-jhu-edu.ezp-prod1.hul.harvard.edu/article/581179]
Session 8 (02/17): Outsourcing Responsibility for Social Health Insurance: Design of Health Plan Payments (T. McGuire)

The U.S. and many countries subcontract paying for/providing health care to private health plans. The contract between payers and health plans is arguably the most important contract in health policy. The purpose of this session is to introduce issues and methods of analysis for health plan payment.

To set the stage, the class will be asked to:

- Explain the choice of health insurance coverage from the standpoint of a Medicare beneficiary, focusing on the choice to remain in Traditional Medicare or choose a Medicare Advantage plan. Students unfamiliar with this aspect of Medicare should consult MedPAC material that contains the relevant background.
- In this context of beneficiary choice, enumerate the major policy problems you see for Medicare related to incentives and methods of health plan payment.

Required Readings

  - [McGuireVanKleef_RegulatedCompetitionHealthInsuranceMarkets_BookChapter1.pdf](https://example.com)
  - [Ellis_Martins_Rose_RiskAdjustmentHealthPlanPayment_BookChapter3.pdf](https://example.com)

Optional Readings

Risk adjustment heresy: take stuff out rather than put stuff in:

  - [McGuire_Zink_Rose_ImprovingPerformanceRiskAdj_AJHE2021.pdf](https://example.com)

Risk adjustment can be combined with risk sharing:

Dissertation essays on risk adjustment by students in our program:

Session 9 (02/22): Alternative payment models (M. Rosenthal)

Learning Objectives:
By the end of this session, you will be able to:
• Describe the major types of provider payment methods including “value-based” approaches
• Explain the principles of incentive design
• Analyze the likely effects and potential adverse consequences of alternative payment approaches

Be prepared to discuss:
• How important do you think financial incentives are at the point of care (i.e., how much to they enter into a decision to do or not do something for a patient)?
• What is the ideal way to pay doctors and hospitals?
• What unintended consequences might ensue as we incorporate quality and cost measures into payment formulas?
• What needs to happen for value-based purchasing to be successful in health care?

Required Readings

Required Video
• Watch the short video here for an introduction to ACOs: [https://innovation.cms.gov/innovation-models/aco](https://innovation.cms.gov/innovation-models/aco)
Session 10 (02/24): Performance-Based Financing in Low- and Middle-Income Countries (S. Bauhoff)

[TF note: The required readings are bolded and highlighted. The readings are organized by theme (with some of the optional readings mixed in) because Sebastian would like you to think about the variation in perspectives on this topic -- see Learning Objectives. But only the highlighted ones are required.]

Learning Objectives:
1) Become familiar with performance-based financing (PBF) initiatives and policies in low- and middle-income countries
2) Consider the range of perspectives on PBF (e.g., economic/impact-evaluation versus health systems/policy perspectives). What differences are there and how do they create tensions?

Readings:

Conceptual issues
  - Describes the economic perspective on PBF in these settings
  - Conceptual framework for thinking about possible negative effects of PBF

Evidence
  - Very influential early trial that set off the policy interest in PBF and also served as template for subsequent impact evaluations of PBF pilots
- **Diaconu K, Falconer J, Verbel Facuseh AV, Fretheim A, Witter S.** Paying for Performance to Improve the Delivery of Health Interventions in Low- and Middle-Income Countries. Cochrane Database of Systematic Reviews. 2021
  - Most recent systematic review

Policy debate
  - Motivation for PBF to drive health systems reform
  o Summarizes many of the concerns with PBF / policy focus on PBF

Additional optional readings
  o How do conscientiousness and neurotic respond to performance incentives?
  o Directly compares output vs input-based contracts
  o Conceptual explanation why it’s not so obvious what happens when a PBF program rewards some activities but not others
  o Using secondary data to learn more from pilot studies
Session 11 (03/01): Long-term care (D. Grabowski)

Objectives:

- Understand the basic economics of the long-term care market.
- Review the reasons for long-standing quality of care problems in long-term care.
- Learn about potential policy factors to address these performance issues.
- Identify how COVID exacerbated these issues and further suggests reform is needed.

Required Readings:

  - [https://journals-sagepub-com.ezp-prod1.hul.harvard.edu/doi/pdf/10.5034/inquiryjrnl_45.01.58]


Session 12 (03/03): Behavioral design and global health (M. McConnell)

Session goals:
The overall objective of the session is to familiarize students with how an interdisciplinary approach to behavioral design can support the design of interventions in global health to improve health outcomes. The session has the following specific goals:

- To introduce students to the process of behavioral design including the identification of a problem, diagnosis of behavioral challenges, design of intervention and evaluation of the intervention’s effectiveness using specific examples from applied health settings
- To compare disciplinary approaches to both the design and evaluation of behavioral interventions
- To prepare students to critically evaluate evidence from field experiments to evaluate behavioral interventions in global health

Required readings:

  - Online Here: https://economics.mit.edu/files/16499
  - File in Canvas Kremer_Rao_Schilbach_Chapter 5 -- Behavioral development economics.pdf
- Chapters 8 and 11 of the 2015 World Development Report
  - [https://gh-bmj-com.ezp-prod1.hul.harvard.edu/content/3/5/e000888 ]
  - [https://www-aeaweb-org.ezp-prod1.hul.harvard.edu/articles?id=10.1257/aer.p20171104 ]
Session 13 (03/08): Competition (L. Dafny)

Learning Objectives:
- Understand the general motivations for consolidation
- Learn about the recent trends in health care consolidation in the US (particularly among providers)
- Describe the evidence regarding costs and benefits of consolidation
- Familiarize yourself with the regulations and regulators that promote competition and enforce competition law

Readings:
  - [https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jama/fullarticle/1884584]
- KFF: What we know about providers
  - [https://www.kff.org/health-costs/issue-brief/what-we-know-about-provider-consolidation/]
Section VII: Public Health Policy
Session 14 (03/10): Harm reduction (A. Brandt)

Objectives

This session will assess the history and philosophy of health interventions that focus on reducing risks of morbidity and mortality. Over recent decades these strategies and technologies have proven controversial. These debates have centered on problems of reducing versus eliminating serious risks to health, and the relationship of alternative approaches. The class will center attention on several cases: methadone and other medically-assisted treatments for substance use disorders; safe-infection equipment and sites for opiate use; e-cigarettes and vaping technology to reduce tobacco related harms. We will discuss strategies for the evaluation of harm reduction interventions, as well as cultural and political obstacles to their implementation.

Readings:

Methadone and medically assisted treatment:

- Kuehn, Bridget M. “Methadone Treatment Marks 40 Years.” JAMA 294, no. 8 (August 24, 2005): 887–89.
  - [https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jama/fullarticle/1719708]

Safe injection of opiates:

  - [https://www-sciencedirect-com.ezp-prod1.hul.harvard.edu/science/article/pii/S0376871614018754]
  - [https://ajph-aphapublications-org.ezp-prod1.hul.harvard.edu/doi/10.2105/AJPH.2018.304588]
- Harm Reduction Grant Program


Optional

Spring Recess: No class 03/15 and 03/17

Session 15 (03/22): Cancer modeling for policy development (J. Kim)

This session brings together core concepts of decision analysis and cost-effectiveness analysis as a methodological approach to informing health policy, using cancer prevention as an applied example. Principles of decision analysis, including framing of policy questions and consideration of tradeoffs in decision making, will be reinforced; the advantages and limitations of mathematical modeling for decision making will be discussed; and the emerging use of modeling to evaluate the impacts of structural racism on cancer disparities will be introduced. The session will conclude with a conversation and Q&A of how and why decision analysis has shaped policy decisions in certain areas of health, and what barriers remain.

Required Readings:


Optional Reading:

Session 16 (03/24): Mental health policy: Global Perspectives (S. Saxena)

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

- Describe the place of mental health policy within the global health and development agenda
- Explain the core characteristics of evidence and value based mental health policy
- Provide some examples of opportunities and challenges for implementation of mental health policy during COVID-19 pandemic

Required Readings:

- WHO Comprehensive Mental Health Action Plan 2013-2030
  - [https://www.who.int/publications/i/item/9789240031029]
  - [https://www.thelancet.com/action/showPdf?pii=S2215-0366%2821%2900025-0]

Optional Reading:

  - [https://www.thelandt.com/pdfs/journals/lancet/PIIS0140-6736(18)31612-X.pdf]
Session 17 (03/29): Obesity/Nutrition policy (A. Grummon)

Learning Objectives:

1. Describe and apply a framework for evaluating food policies
2. Describe how warning labels and taxes are likely to influence:
   - Consumer behavior
   - The food supply
   - Population health and health equity
3. Describe key methods for evaluating the impact of food policies and compare their strengths and weaknesses

Required Readings:

  - Students can skim intro, figures, discussion – a detailed read is not needed


Additional Optional Readings:


Session 18 (03/31): Methods workshop (L. Garabedian)

Learning objectives:
- Become familiar with threats to internal validity that are common in health policy research.
- Consider how different study designs protect against these threats to internal validity.
- Review rigorous quasi-experimental research designs and understand the conditions under which each design is feasible and appropriate.
- Consider the generalizability (i.e., external validity) of different study designs.
- Apply these concepts to the development of your Core Research Proposal.
- Understand the components of a strong research proposal and the criteria on which research proposals are evaluated by external funders.

Required Readings:
   - Plus skim Appendices A and B.
3. Find an organization (i.e., NIH, AHRQ, foundation) that funds grants in your area of research. Read through a request for proposal (aka program announcement or program opportunity), paying particular attention to the criteria on which the proposals are evaluated.

Optional:
- Primers on the quasi-experimental research designs we will discuss:
  - Garabedian LF. Key Points: Quasi-experimental study designs.
Venkataramani AS, Bor J, Jena AB. Regression discontinuity in health care research. BMJ. 2016; 352:i1216. [https://www-bmj-com.ezp-prod1.hul.harvard.edu/content/352/bmj.i1216].


• Overview of threats to validity and weak vs. robust study designs.

  • Review Internal Validity, pages 53 – 63.
  • Chapter 5 (Designs that Use Both Control Groups and Pretests)
  • Chapter 6 (Interrupted Time Series)
  • Chapter 7 (Regression Discontinuity)

Session 19 (04/05): AI and Health (D. DiSanzo)

Learning Objectives
At the end of the class -- including the mini lectures and readings -- students will:

- Understand the history, terminology, and types of artificial intelligence.
- Learn practical uses of AI in health today as well as possible uses of AI in the next 3-5 years.
- Discuss Ethics in data and AI algorithms.

Mini Lectures

- Definitions of Artificial Intelligence. History of Artificial Intelligence
  - https://www.youtube.com/watch?v=dS2jMKq6hqE (9.40 minutes)
- Artificial Intelligence/Machine Learning/Deep Learning/ Artificial Neural Networks
  - https://www.youtube.com/watch?v=2t73foQXOj0 (6.27 minutes)
- Types of Deep Learning
  - https://www.youtube.com/watch?v=uy_v-owMWaU (7.19 minutes)

Required Readings

   - **TO ACCESS THE CASE**: You can access a copy of the case in "Files:'
     download here
   - **Please do not distribute the PDF to others.** HBS cases are purchased by the program and distributed on a per-user basis. We purchased 12 copies, but we are uploading a single PDF to Canvas for your convenience.
   - You can also use this link to access the case directly on the HBS site, but you'll need to make a (free) Harvard Business Publishing account.


Session 20 (04/07): COVID, disparities and health (M. Alsan)

Required readings:

  - [https://www-aeaweb-org.ezp-prod1.hul.harvard.edu/articles?id=10.1257/jep.35.3.25]
  - [https://www-acpjournals-org.ezp-prod1.hul.harvard.edu/doi/10.7326/M20-6141]

Optional Readings

Session 21 (04/12): Impact evaluation (J. Cohen)

[TF note: Please read these papers closely, as you will be working through the key assumptions, identification strategies, statistics/models, and results interpretation with Jessica in class.]

Learning Objectives:
- Discuss design decisions for sampling and intervention in randomized controlled trials (RCTs).
- Discuss how null results inform us about what works and what doesn’t and how this relates to our theory of change.

Required Readings
Section VIII: Innovation and health

Session 22 (04/14): Missing Innovations: Prevention, Diagnostics, Treatments, Delivery (A. Chandra)

Learning Objectives

- Discuss how patent policy drives investment in certain types of innovation.
- Describe the key challenges in designing the optimal patent policy.
- Discuss the social welfare consequences of our current patent policy in relation to pharmaceuticals.
- Discuss the optimal allocation of resources for innovation in Alzheimer’s disease that addresses the interests of both society and private firms.
- Give examples of factors that are important to consider in when thinking through an economic framework for a disease in which a person is (or will be) cognitively constrained.

Required Readings

  
  o  https://www-aeweb-org.ezp-prod1.hul.harvard.edu/articles?id=10.1257/aer.20131176
  
  o  PDF file linked in Canvas.

  
  o  PDF file linked in Canvas.
Session 23 (04/19): Digital health (A. Stern)

Learning objectives:

- Describe different applications of digital products and the opportunities and risks are associated with each product type
- Consider and evaluate strategies and incentives for implementing digital health tools in practice (generally) and within complex health systems (in particular)
- Discuss promising research areas in the various areas of digital health and how they may overlap with other topical interests you may have (e.g., value-based care, precision medicine, quality improvement initiatives, bundled payments, technology adoption, health disparities and under-served populations)

Required Readings:

Please read the first item on the list (a non-peer-reviewed blog post from the Digital Medicine Society) as background and for a few clear definitions. The other six readings are all short articles that touch on different aspects of digital health/digital medicine. Our discussion during this session of the course will focus on exploring promising research topics for health policy in various areas of digital health.

   - Blog Post (Medium.com)
   - [https://www-nature-com.ezp-prod1.hul.harvard.edu/articles/s41746-020-0260-4](https://www-nature-com.ezp-prod1.hul.harvard.edu/articles/s41746-020-0260-4)
   - [https://www-nature-com.ezp-prod1.hul.harvard.edu/articles/s41746-020-0259-x](https://www-nature-com.ezp-prod1.hul.harvard.edu/articles/s41746-020-0259-x)
5. Marwaha, Jayson S., Adam B. Landman, Gabriel A. Brat, Todd Dunn, and William J. Gordon. "Deploying digital health tools within large, complex health systems: key


Session 24 (04/21): Gun Policy and Injury Prevention (M. Miller)

Learning Objectives

- Describe the epidemiology of firearm exposure and injury in the U.S.
- Describe the epidemiology of gun deaths.
- Understand the contributions, strengths, and weaknesses of ecologic, case-control, and cohort studies of the gun-suicide relationship and distinguish these studies from those that evaluate the effect of gun legislation.
- Understand the evidence and rationale for means restriction.

Required Readings

  - https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jamanetworkopen/fullarticle/2777216

Optional Readings


  o https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jama/fullarticle/200330

  o https://academic-oup-com.ezp-prod1.hul.harvard.edu/epirev/article/38/1/62/2754867

  o https://www-clinicalkey-com.ezp-prod1.hul.harvard.edu/#!/content/playContent/1-s2.0-S0196064420301049


  o https://www-clinicalkey-com.ezp-prod1.hul.harvard.edu/#!/content/playContent/1-s2.0-S0749379721005547
Session 25 (04/26): Regulation of drugs and devices (A. Kesselheim)

Learning Objectives

- Understand the basic FDA rules for drug approval and how the accelerated approval program adjusts those rules
- Consider the appropriateness of the approval of aducanumab under the accelerated approval program and policy options for changes to the accelerated approval program
- Understand the strategies manufacturers use to delay generic entry and extend market exclusivity for brand-name drugs
- Evaluate the costs of those strategies and consider proposals for reform.

Required Readings

  - https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jamainternalmedicine/fullarticle/2770468
  - https://www-healthaffairs-org.ezp-prod1.hul.harvard.edu/journals/jamainternalmedicine/fullarticle/2653452
  - https://jamanetwork-com.ezp-prod1.hul.harvard.edu/journals/jamainternalmedicine/fullarticle/2653452