

LHS 671: Ethics and Policy of Learning Health Systems

COURSE OUTLINE

Winter 2024

LHS 671: 2817 Med Sci 2 or on ZOOM, TUESDAY 1pm-4pm

<u>Date</u>	<u>Week</u>	<u>Session and Title</u>
1/16	Week 1	<u>Introduction and Course Objectives</u>

MODULE 1: Introduction to Policy and Ethics

1/23	Week 2	<u>Policy fundamentals: how do we know what to do? (TC)</u>
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Required pre-reading

1. O'Hare M, A Typology of Governmental Action, Journal of Policy Analysis and Management 1989; 8:670-672.
2. Bodenheimer T, Grumbach K, "Chapter 17: Conclusion: Tensions and Challenges" in Understanding health policy: A clinical approach. 6th Ed. McGraw-Hill.
3. Pahlka J. Delivery-Driven Policy. Medium. Published November 6, 2019. Accessed January 8, 2024. <https://pahlkadot.medium.com/delivery-driven-policy-cac3a822a2e2>
4. Blumenthal D, Tavenner M. The "meaningful use" regulation for electronic health records. New England Journal of Medicine. 2010 Aug 5;363(6):501-4.
5. Feeley TW, Landman Z, Porter ME. The Agenda for the Next Generation of Health Care Information Technology. *NEJM Catalyst*. 2020;1(3). doi:[10.1056/CAT.20.0132](https://doi.org/10.1056/CAT.20.0132)
6. Eddy DM. Designing a practice policy: Standards, guidelines, and options. *JAMA*. 1990;263(22):3077-3084. doi:[10.1001/jama.1990.03440220105041](https://doi.org/10.1001/jama.1990.03440220105041)
7. Jacobson PD, Transforming Clinical Practice Guidelines into Legislative Mandates: Proceed with Abundant Caution, *JAMA* 2008; 299(2):208-210.

Optional:

Understanding core principles from economics is a powerful way to think about policy (and any decision you make as an individual). If you don't mind listening to podcasts while exercising, cooking dinner, or walking your dog, this podcast series might be a great way to bring these core principles when thinking about policy (and in everyday life).

[“Think Like an Economist” Podcast](#) (Listen at 1.5x)

You can find the podcasts on these channels: [iTunes](#); [Spotify](#); [Himalaya](#)

Episodes:

0. Why should you Think Like an Economist? (15min)
1. Core Principle 1 – The Cost-Benefit Principle (17min)
2. Core Principle 2 – The Opportunity Cost Principle (17min)
3. Core Principle 3 – The Marginal Principle (15min)
4. Core Principle 4 – The Interdependence Principle (11min)
5. Listen to more in the first season if desired!

1/30

Week 3 **Ethics: How do we decide what is right? (DT)**

GROUP 1: Philosophical - Utilitarianism

Get Oriented: Utilitarianism Crash Course https://youtu.be/-a739VjqdSI?si=XUQ-4_m1a-izuNeD

Background Reading: Rachels, J *The Elements of Moral Philosophy*, Ch. 8 “The Debate Over Utilitarianism”

Watch: Michael Sandel: [What’s the right thing to do?](#) - The whole hour is helpful, especially to get oriented in moral philosophy, the discussion of Utilitarianism proper starts around 27 minutes in.

Questions to Consider: Can the end justify the means? How might a Utilitarian moral justification for the implementation of a Learning Health System look? How would you weigh the effort and costs of building the infrastructure necessary for such systems against the existence of other needed investments in our health care system? Does Utilitarianism persuade you or do you find its flaws too problematic?

GROUP 2: Philosophical - Deontology and The Categorical Imperative

Get Oriented: Deontology and the Categorical Imperative: Crash Course <https://youtu.be/8blys6JoEDw?si=VpvP8y8lhZQOPvHq>

Background Reading: Fisher and Dimmock, Kantian Ethics

<https://open.library.okstate.edu/introphilosophy/chapter/kantian-ethics/>

Watch: Michael Sandel: Mind Your Motive <https://youtu.be/8rv-4aUbZxQ?si=EFELjeWInX71rwBJ>

Questions to consider: How might an LHS succeed or fail to respect the inherent dignity of all individuals? Kant’s view was that the Categorical Imperative sets up a series of duties that everyone is required to follow. What are some important sets of duties, and reciprocal obligations, that are provoked when we consider the development of a Learning Health System?

GROUP 3: Theories of Justice

Get Oriented: What is Justice? Crash Course

<https://youtu.be/H0CTHVckm90?si=cQl3Dx-wSA5D0vHR>

Case Study: Fritz et al. Conflicting Demands on the Modern Health Care System

Helpful Background Reading: “Rights and Justice”, Chapter 4 of Philosophy of Law: A Very Short Introduction

Optional (helpful) video: Introduction to Rawls’ Theory of Justice

https://youtu.be/n6k08C699zI?si=C-lakn98Fceul_Xr

Questions to consider: What are some issues relating to the LHS that challenge our ideas about fairness and justice? Does the idea of the LHS provoke any particular challenges regarding fair treatment in the health care system? Or perhaps you see it another way...maybe the absence of a robust LHS represents a problem of unfairness or injustice? Consider how differently situated groups in society may be impacted by the implementation of the LHS...what justice considerations come up?

GROUP 4: Bioethical Principlism: Focus on Respect for Persons/Autonomy

Get Oriented:

Introduction to the Four Principles (~5 minutes)

<https://youtu.be/u6WXDTfmxAw?si=1yYXYejT5ovZCPGU>

Maggie Little, Introduction to Bioethics (~10 minutes)

<https://youtu.be/c3l0Sxl2grM?si=XjcyPV5vcgsyeVnK>

Background Reading: The Nuremberg Code, Declaration of Helsinki and The Belmont Report (reprinted in Vaughn L. *Bioethics, Principles, Issues and Cases*, Ch. 6 “Human Research” pp. 213-220)

Reading for inspiration: Kayhan Parsi (2016) The Unbearable Whiteness of Bioethics: Exhorting Bioethicists to Address Racism, *The American Journal of Bioethics*, 16:4, 1-2, DOI: 10.1080/15265161.2016.1159076

Questions to consider: In what ways might the bioethical principle of respect for persons be implicated in the development of Learning Health Systems (e.g. consider such issues as informed consent, patient autonomy, secondary use of individual data etc.)? How can designers and users of LHSs uphold this duty and maximize the benefits of an LHS?

GROUP 5: Bioethical Principlism: Focus on Beneficence and Non-Maleficence

Get Oriented:

Introduction to the Four Principles (~5 minutes)

<https://youtu.be/u6WXDTfmxAw?si=1yYXYejT5ovZCPGU>

Maggie Little, Introduction to Bioethics (~10 minutes)

<https://youtu.be/c3l0Sxl2grM?si=XjcyPV5vcgsyeVnK>

Background Reading: The Nuremberg Code, Declaration of Helsinki, The Belmont Report (reprinted in Vaughn L. *Bioethics, Principles, Issues and Cases*, Ch. 6 “Human Research” pp. 213-220)

Questions to consider: The Belmont Report suggests that “In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.” Do you

agree? Does this imply that patients have an obligation to participate in the creation of the LHS? If so, how does this obligation square with the principles of beneficence and non-maleficence?

NOTE Date & Time Shift!

Monday Feb 5 12-1pm

Week 4

ELSI of LHS - Faden et al's Challenge (DT)

Guest Speaker: Nancy Kass, PhD

ZOOM Session: <https://umich.zoom.us/j/6770747986> Pass: 520782

1. R. Faden et al, "An Ethics Framework for a Learning Health Care System: A Departure from Traditional Research Ethics and Clinical Ethics" + associated articles in the special issue of the *Hastings Center Report*
2. Lecture by Nancy Kass
<https://www.youtube.com/watch?v=pLUDuLE8V14> (available in the media gallery)

MODULE 2: Health Data and Learning Health Systems in Context

2/13

Week 5

Data "Ownership" and Knowledge Sharing (Part 1)

Guest Speaker: [Kenneth Goodman, Ph.D., FACMI, FACE \(University of Miami\)](#) ZOOM Session

1. Goodman, K. New challenges for the clinician-patient relationship, *Journal of Law, Medicine and Ethics* 2010;38(1):58-63. doi: 10.1111/j.1748-720X.2010.00466.x
2. Mikk KA, Sleeper HA, Topol EJ. The Pathway to Patient Data Ownership and Better Health. *JAMA*. 2017;318(15):1433–1434. doi:10.1001/jama.2017.12145
3. McGuire AL, Roberts J, Aas S, Evans BJ. Who Owns the Data in a Medical Information Commons?. *The Journal of Law, Medicine & Ethics*. 2019 Mar;47(1):62-9.
4. Majumder MA, Guerrini CJ, Bollinger JM, Cook-Deegan R, McGuire AL. Sharing data under the 21st century cures act. *Genetics in Medicine*. 2017 Dec;19(12):1289-94.
5. Mello MM, Adler-Milstein J, Ding KL, Savage L. Legal barriers to the growth of health information exchange—boulders or pebbles?. *The Milbank Quarterly*. 2018 Mar;96(1):110-43.

6. Wilkinson MD, Dumontier M, Aalbersberg IJ, Appleton G, Axton M, Baak A, Blomberg N, Boiten JW, da Silva Santos LB, Bourne PE, Bouwman J. The FAIR Guiding Principles for scientific data management and stewardship. *Scientific data*. 2016 Mar 15;3(1):1-9.

2/20 Week 6 Data “Ownership” and Knowledge Sharing (Part 2): Indigenous Data Sovereignty
Guest: Joseph Yracheta, MS
ZOOM session

1. Please spend some time familiarizing yourself with the Native Biodata Consortium from their website: <https://nativebio.org>
2. Kim Tallbear, *Native American DNA* (esp. Introduction, Chapter 4 and Conclusion)
3. Fox K, *The Illusion of Inclusion: The “All of Us” Research Program and Indigenous Peoples’ DNA*, *NEJM* (2020)
4. Krystal S. Tsosie, Joseph M. Yracheta, Jessica A. Kolopenuk & Janis Geary (2021) We Have “Gifted” Enough: Indigenous Genomic Data Sovereignty in Precision Medicine, *The American Journal of Bioethics*, 21:4, 72-75, DOI: [10.1080/15265161.2021.1891347](https://doi.org/10.1080/15265161.2021.1891347)
5. BROWSE: <https://www.gida-global.org/care>
6. Carroll, S, Garba, I, Figueroa-Rodríguez, O, Holbrook, J, Lovett, R, Materechera, S, Parsons, M, Raseroka, K, Rodriguez-Lonebear, D, Rowe, R, Sara, R, Walker, J, Anderson, J and Hudson, M. 2020. The CARE Principles for Indigenous Data Governance. *Data Science Journal*, 19: XX, pp. 1–12. DOI: <https://doi.org/10.5334/dsj-2020-042>
7. Ruha Benjamin (2009) A Lab of Their Own: Genomic sovereignty as postcolonial science policy, *Policy and Society*, 28:4, 341-355, DOI: [10.1016/j.polsoc.2009.09.007](https://doi.org/10.1016/j.polsoc.2009.09.007)
8. Trinidad et al. Precision medicine research with American Indian and Alaska Native communities: Results of a deliberative engagement with tribal leaders
9. Claw KG, Dundas N, Parrish MS, Begay RL, Teller TL, Garrison NA and Sage F (2021) Perspectives on Genetic Research: Results From a Survey of Navajo Community Members. *Front. Genet.* 12:734529. doi: [10.3389/fgene.2021.734529](https://doi.org/10.3389/fgene.2021.734529)
10. Optional: If you love the NPR show Science Friday, Joseph was a guest on that show...check it out here: <https://www.sciencefriday.com/person/joseph-yracheta/>

2/27 Week 7 Spring Break - No Class

3/5 Week 8 The American Health Care System (or non-system)

OECD Presentations (app. 15 minutes each)

Watch:

1. <https://www.washingtonpost.com/opinions/2021/06/17/best-health-care-systems-world/>
2. <https://www.youtube.com/watch?v=BytzrjEfyfA> (PBS News hour)

Read:

1. <https://www.ispor.org/heor-resources/more-heor-resources/us-healthcare-system-overview/us-healthcare-system-overview-background-page-1>
2. Chapter 14 “Healthcare in four nations “ in: Bodenheimer, Thomas, et al. *Understanding health policy: A clinical approach*. Vol. 2019. McGraw-Hill.
3. McGinnis JM, Foege WH. Actual causes of death in the United States. *Jama*. 1993 Nov 10;270(18):2207-12. (and Optional: Mokdad AH, Marks JS, Stroup DF, Gerberding JL. Actual causes of death in the United States, 2000. *Jama*. 2004 Mar 10;291(10):1238-45.)

MIDTERM EXAM DUE - Friday, 3/8 at 5pm

MODULE 3: The Ethical, Legal and Social Issues of Learning Health Systems: Policy Responses

3/12 Week 9 Quality of Care: Evidence and Policy (TC)
 Guest lecturer Rod Hayward

Pre-reading/listening (subject to change)

1. Anatomy of a Decision *JAMA*. 1990;263(3):441-443.
doi:10.1001/jama.1990.034440030128037 <https://jamanetwork.com/journals/jama/article-abstract/380306>
2. Designing a Practice Policy: Standards, Guidelines, and Options *JAMA*. 1990;263(22):3077-3084.
doi:10.1001/jama.1990.03440220105041 <https://jamanetwork.com/journals/jama/article-abstract/382154>
3. Integrating quality into the cycle of therapeutic development
<https://pubmed.ncbi.nlm.nih.gov/12475447/>

4. Patient-centered performance management: enhancing value for patients and health care systems <https://jamanetwork.com/journals/jama/article-abstract/1710465> [pdf in Files]
5. The Challenge of Integrating eHealth Into Health Care: Systematic Literature Review of the Donabedian Model of Structure, Process, and Outcome <https://www.jmir.org/2021/5/e27180/>
6. How NICE guidance and quality standards can help you <https://www.nice.org.uk/about/what-we-do/into-practice/resources-help-put-guidance-into-practice/how-guidance-standards-help-you#:~:text=NICE%20guidance%20provides%20recommendations%20across,about%20how%20to%20measure%20progress.>
7. Performance Measurement in Search of a Path <https://www.nejm.org/doi/full/10.1056/NEJMe068285> [pdf in Files]

**3/19 Week 10 ELSI & Policy of LHS - Governing the LHS; AI, ML and Algorithms (Everywhere)
Guest Speaker: Paige Nong
ZOOM session**

1. O'Neil C. Weapons of math destruction: How Big Data Increases Inequality and Threatens Democracy (2016)
Introduction
Chapter 1 + 1 other chapter to be assigned
Conclusion
2. Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Dissecting racial bias in an algorithm used to manage the health of populations. Science. 2019 Oct 25;366(6464):447-53.
3. Lavertu A, Vora B, Giacomini KM, Altman R, Rensi S. A New Era in Pharmacovigilance: Toward Real-World Data and Digital Monitoring. Clinical Pharmacology & Therapeutics. 2021 Jan
4. Murray et al. Discrimination By Artificial Intelligence In A Commercial Electronic Health Record A Case Study, Health Affairs, Jan 31, 2020, 10.1377/forefront.20200128.626576
5. Ferryman K Addressing health disparities in the Food and Drug Administration's artificial intelligence and machine learning regulatory framework, JAMIA 27(12), 2020, 2016–2019

RECOMMENDED: Artificial Intelligence (AI) and Machine Learning (ML) in Medical Devices: Executive Summary for the Patient Engagement Advisory Committee. FDA. October 22, 2020. <https://www.fda.gov/media/142998/download>

3/26 **Week 11** **ELSI of LHS: Public-Private Partnerships, HIE and Health Data Exchange**

Guest Speaker: Jody Platt, MPH, PhD

ZOOM session

1. **Watch:** Kayte Spector-Bagdady, LHS Collaboratory "A Double-Edged Sword" Genetic Data Sharing and Implications for the LHS (Media Gallery)
2. Respecting Autonomy And Enabling Diversity: The Effect Of Eligibility And Enrollment On Research Data Demographics. (2021) Kayte Spector-Bagdady, et al.
3. Governing secondary research use of health data and specimens: the inequitable distribution of regulatory burden between federally funded and industry research, Kayte Spector-Bagdady

4/2 **Week 12 LHS Case Study - The Veterans Administration - Health Data Uses to Reduce Disparities and Promote Health Care Equity**

Guest Speaker: Justin M. List, MD, MAR, MSc, FACP

ZOOM session

Theme: "Promoting equity in health systems and the policies that influence the equitable delivery of care in health systems"

1. [Addressing Veteran Health-Related Social Needs: How Joint Commission Standards Accelerated Integration and Expansion of Tools and Services in the Veterans Health Administration - PubMed \(nih.gov\)](#)
2. [From HRO to HERO: Making Health Equity a Core System Capability - PubMed \(nih.gov\)](#)
3. [The Quintuple Aim for Health Care Improvement: A New Imperative to Advance Health Equity | Health Disparities | JAMA | JAMA Network](#)
4. [Achieving Health Care Equity Requires a Systems Approach - ScienceDirect](#)

5. [Bringing the Equity Lens to Patient Safety Event Reporting - Joint Commission Journal on Quality and Patient Safety](#)
6. Browsing the link here as well: [The Health Equity Roadmap | Equity \(aha.org\)](#)

Module 4 - Final Presentations

4/9	Week 13	PUTTING IT ALL TOGETHER: STUDENT PAPERS/ PRESENTATIONS
4/16	Week 14	STUDENT PAPERS/ PRESENTATIONS/(continued)
4/23	Week 15	STUDENT PAPERS/ PRESENTATIONS/(continued)
4/26		Final Paper Due to Canvas by 5pm