Big Data, AI, and Health Care, Legal and Ethical Issues

I. Glenn Cohen, JD

James A. Attwood and Leslie Williams Professor, Harvard Law School

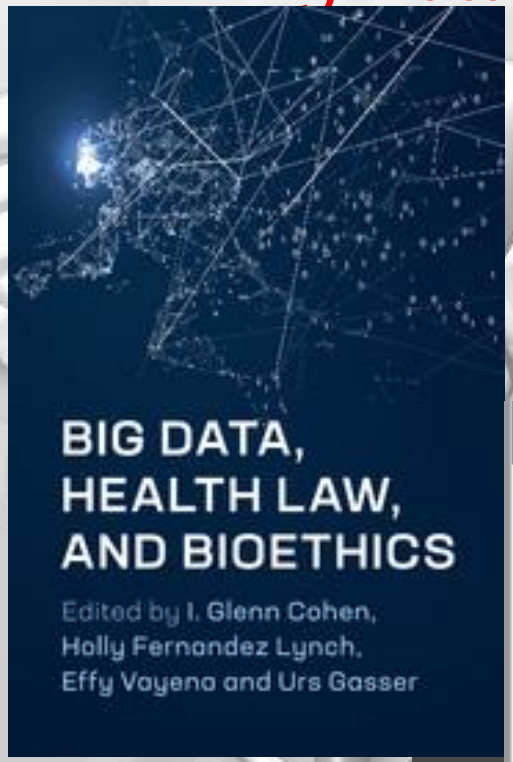
Director, Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics

igcohen@law.harvard.edu

Disclosure

- Will not be promoting unlabeled/unapproved uses of drugs, devices, products, protocols, or therapeutic strategies.
- Serves as a bioethics consultant for Otsuka Pharmaceuticals on digital medicine portfolio.

Big Data, Predictive Analytics, Machine Learning: Promise and Peril



PREDICTIVE ANALYTICS

By I. Glenn Cohen, Ruben Amarasingham, Anand Shah, Bin Xie, and Bernard Lo

The Legal And Ethical Concerns That Arise From Using Complex Predictive Analytics In Health Care

DOI: 10.1377/hlthaff.2014.0048
HEALTH AFFAIRS 33,
NO. 7 (2014): 1139–1147

nature medicine

FOCUS | REVIEW ARTICLE

Privacy in the age of medical big data

W. Nicholson Price II[1,2,3] and I. Glenn Cohen[2,3,4*]

Big data has become the ubiquitous watch word of medical innovation. The rapid development of machine-learning techniques and artificial intelligence in particular has promised to revolutionize medical practice from the allocation of resources to the diagnosis of complex diseases. But with big data comes big risks and challenges, among them significant questions about patient privacy. Here, we outline the legal and ethical challenges big data brings to patient privacy. We discuss, among other topics, how best to conceive of health privacy; the importance of equity, consent, and patient governance in data collection; discrimination in data uses; and how to handle data breaches. We close by sketching possible ways forward for the regulatory system.

Big data has come to medicine. Its advocates promise increased accountability, quality, efficiency, and innovation. Most recently, the rapid development of machine-learning techniques and artificial intelligence (AI) has promised to better [illegible] effectiveness of different interventions, as in the Patient Centered Outcome Research Institute (http://www.pcori.org); and to monitor drug and device safety, as with the Food and Drug Administration

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I. Glenn Cohen (igcohen@law.harvard.edu) is a professor of law and director of the Petrie-Flom Center for Health Law Policy, Biotechnology, and Bioethics, both at Harvard Law School, in Cambridge, Massachusetts.

Ruben Amarasingham is president and CEO of PCCI, a nonprofit research and development corporation, and an associate professor in the Departments of Internal Medicine and of Clinical Sciences at the University of Texas Southwestern Medical Center, both in Dallas.

Petrie-Flom Center launches Project on Precision Medicine, Artificial Intelligence, and the Law (PMAIL)

The project will seek to better understa

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PERSPECTIVE

Machine learning in medicine: Addressing ethical challenges

Effy Vayena, Alessandro Blasimme, I. Glenn Cohen

Published: November 6, 2018 • https://doi.org/10.1371/journal.pmed.1002689

VIEWPOINT

HIPAA and Protecting Health Information in the 21st Century

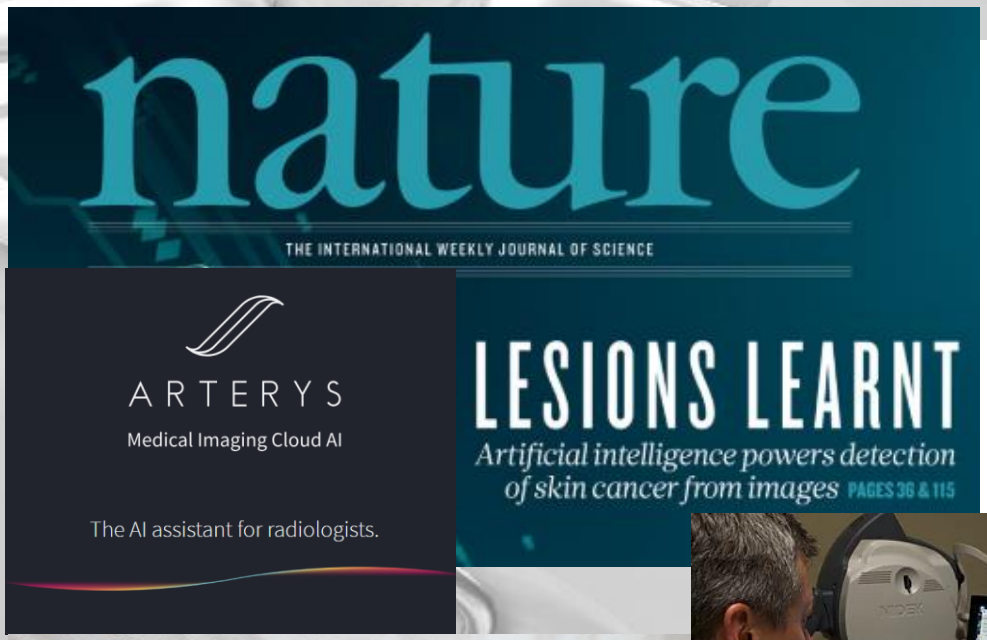
I. Glenn Cohen, JD
Harvard Law School, Cambridge, Massachusetts.

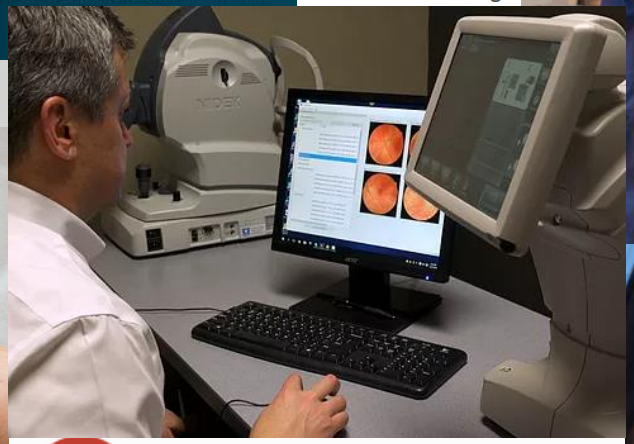
Michelle M. Mello, JD, PhD
Stanford Law School, Department of Health

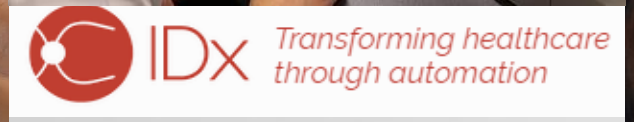
In March 2018, the Trump administration announced a new initiative, MyHealthEData, to give patients greater access to their electronic health record and insurance claims information.[1] The Centers for Medicare & Medicaid Services will connect Medicare beneficiaries with their claims data and increase pressure on health plans and health care organizations to use systems that allow patients to access and send their health information where they like.

ered entities," including clinicians, health care facilities, pharmacies, health plans, and health care clearinghouses—and too onerous in its requirements for patient authorization for release of protected health information. Over time, however, HIPAA has proved surprisingly functional. Particularly after being amended in the 2009 HITECH (ie, the Health Information Technology for Economic and Clinical Health) Act to address challenges arising from electronic

Current and Near Future Applications



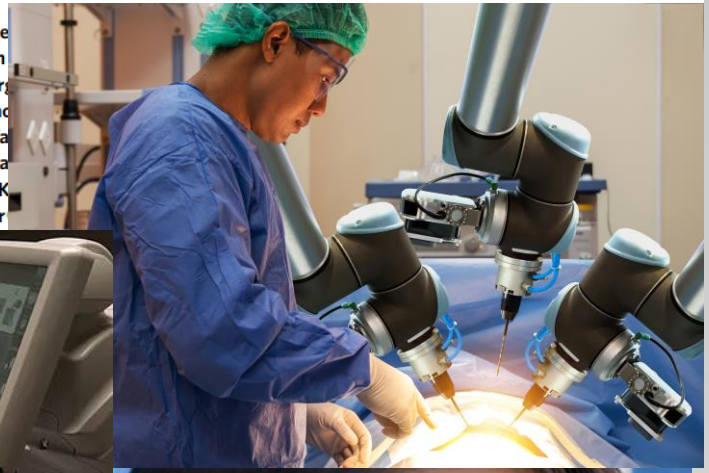




ARTICLES
https://doi.org/10.1038/s41591-018-0107-6
nature medicine

Clinically applicable deep learning for diagnosis and referral in retinal disease

Jeffrey De Fauw[1], Jose
Nenad Tomasev[1], Sam
Daniel Visentin[1], Geor
Faith Mackinder[1], Simo
Karthikesalingam[1], Cía
Catherine Egan[2], Adna
Trevor Back[1], Peng T. K
and Olaf Ronneberger



Two Possible Ways of Dividing the World

Function	**Purpose**
Imaging	Democratizing Expertise
Prognostics	Automating Drudgery
Diagnostics	Optimizing Resources
Treatment	Pushing Frontiers

Suggested by Nicholson Price, U Mich. Law School

Ethics of Building + Implementing Predictive Analytics

Phase 1: Acquiring Data

- Consent
- Data Set Representativeness
- Governance

Phase 2: Building and Validating Model

- Auditing
- Transparency
- Trade Secrecy

Phase 3: Testing Model in Real World Settings

- Notice and Consent for Use on Patients?
- Liability
- Regulator Role

Phase 4: Broad Dissemination

- Equitable Access

Liability

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Potential Liability for Physicians Using Artificial Intelligence

W. Nicholson Price II, JD, PhD[1]; Sara Gerke, Dipl-Jur Univ[2]; I. Glenn Cohen, JD[3]

» Author Affiliations | Article Information

JAMA. Published online October 4, 2019. doi:10.1001/jama.2019.15064

Figure. View Large | Download

Scenario	AI recommendation	AI accuracy	Physician action	Patient outcome	Legal outcome (probable)
1	Standard of care	Correct	Follows	Good	No injury and no liability
2			Rejects	Bad	Injury and liability
3		Incorrect (standard of care is incorrect)	Follows	Bad	Injury but no liability
4			Rejects	Good	No injury and no liability
5	Nonstandard care	Correct (standard of care is incorrect)	Follows	Good	No injury and no liability
6			Rejects	Bad	*Injury but no liability*
7		Incorrect	Follows	Bad	*Injury and liability*
8			Rejects	Good	No injury and no liability

Examples of Potential Legal Outcomes Related to AI Use in Clinical Practice

AI indicates artificial intelligence.

Privacy + Consent

Case: 1:19-cv-04311 Document #: 1 Filed: 06/26/19 Page 1 of 43 PageID #:1

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS, EASTERN DIVISION

MATT DINERSTEIN, individually and on behalf of all others similarly situated, *Plaintiff*, v. GOOGLE, LLC, a Delaware limited liability company, and THE UNIVERSITY OF CHICAGO MEDICAL CENTER, an Illinois not-for-profit corporation, THE UNIVERSITY OF CHICAGO, an Illinois not-for-profit corporation, *Defendants*.	Case No.

CLASS ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff Matt Dinerstein brings this Class Action Complaint and Demand for Jury Trial against Defendants Google, LLC, The University of Chicago Medical Center, and The University of Chicago (collectively referred to as the "University" or "University of Chicago").

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Viewpoint

August 9, 2019

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Big Data, Big Tech, and Protecting Patient Privacy

I. Glenn Cohen, JD[1]; Michelle M. Mello, JD, PhD[2]

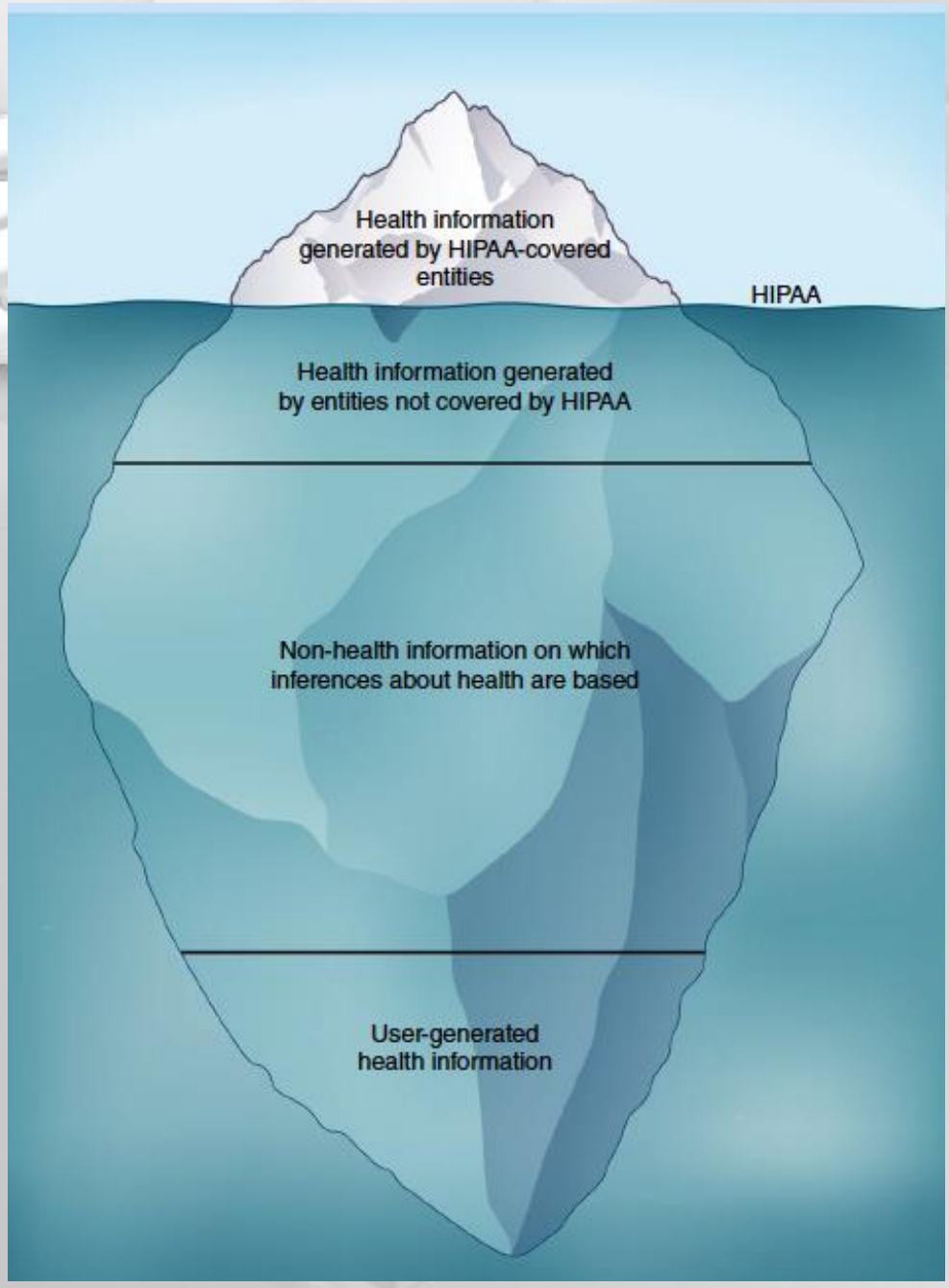
Author Affiliations

JAMA. 2019;322(12):1141-1142. doi:10.1001/jama.2019.11365

Full Text

The market for patient data has never been more active. Technology companies, from startups to giants, are eager to access electronic health record (EHR) data to build the next generation of health-focused products. Medical artificial intelligence (AI) is particularly data-hungry; large, representative data sets hold promise for advancing not only AI companies' growth, but also the health of patients.[1] Companies' overtures to major hospitals about data sharing have highlighted legal and ethical uncertainties as to whether and how to undertake these relationships

Types of Health Data



I. Glenn Cohen & W. Nicholson Price II *Privacy in the Age of Medical Big Data*, **Nature Medicine** (2019)

Thank you!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