



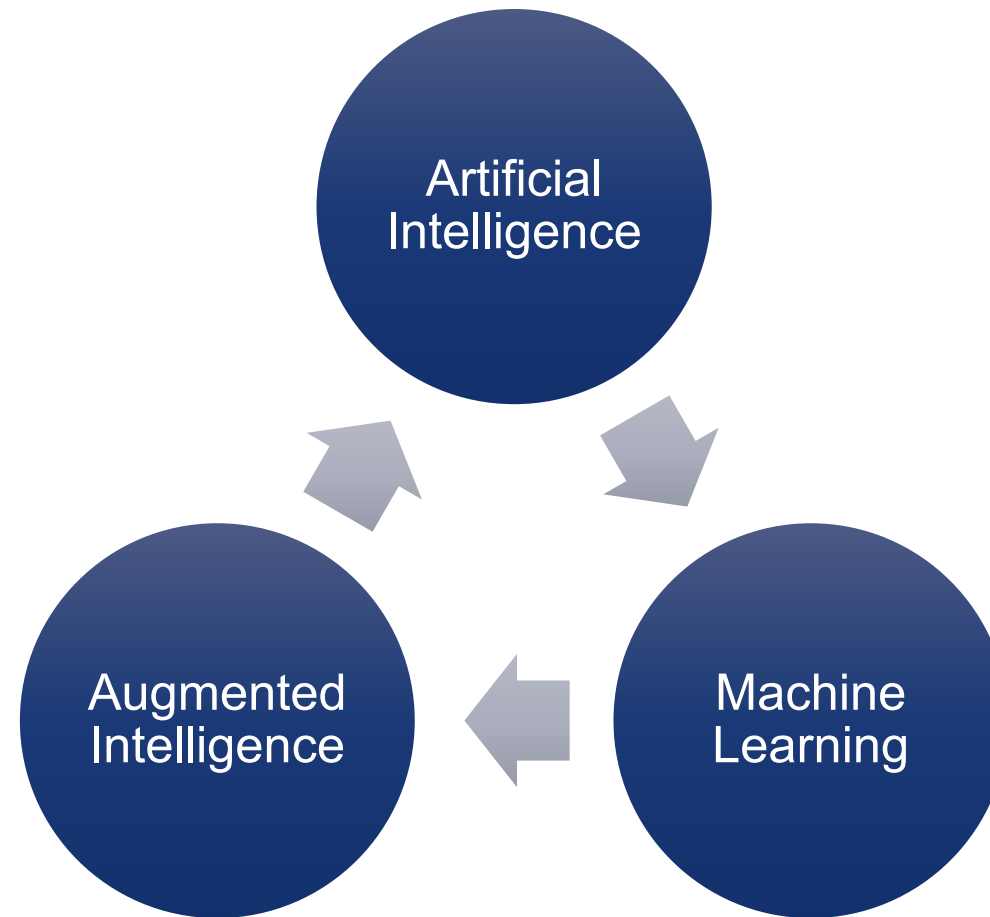
Artificial Intelligence in Health IT – The Good, The Bad, The Ugly (Part 1)

A Joint Clinician Panel with the American Medical Association

The Office of the National Coordinator for
Health Information Technology



Artificial Intelligence in Health IT – The Good, The Bad, The Ugly (Part 1)



Artificial Intelligence in Health IT – The Good, The Bad, The Ugly (Part 1)

- **Andrew Gettinger, MD, Moderator**
 - Chief Clinical Officer, The Office of the National Coordinator for Health IT
- **Danielle Whicher, PhD, MHS**
 - Health Researcher, Mathematica
- **Hassan A. Tetteh, MD, MBA, FACS, FACHE**
 - Health Mission Chief for Warfighter Health, Joint Artificial Intelligence Center, Department of Defense
- **Jesse M. Ehrenfeld, MD, MPH**
 - Chair, Board of Trustees, American Medical Association



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Danielle M. Whicher

Mathematica Policy Research

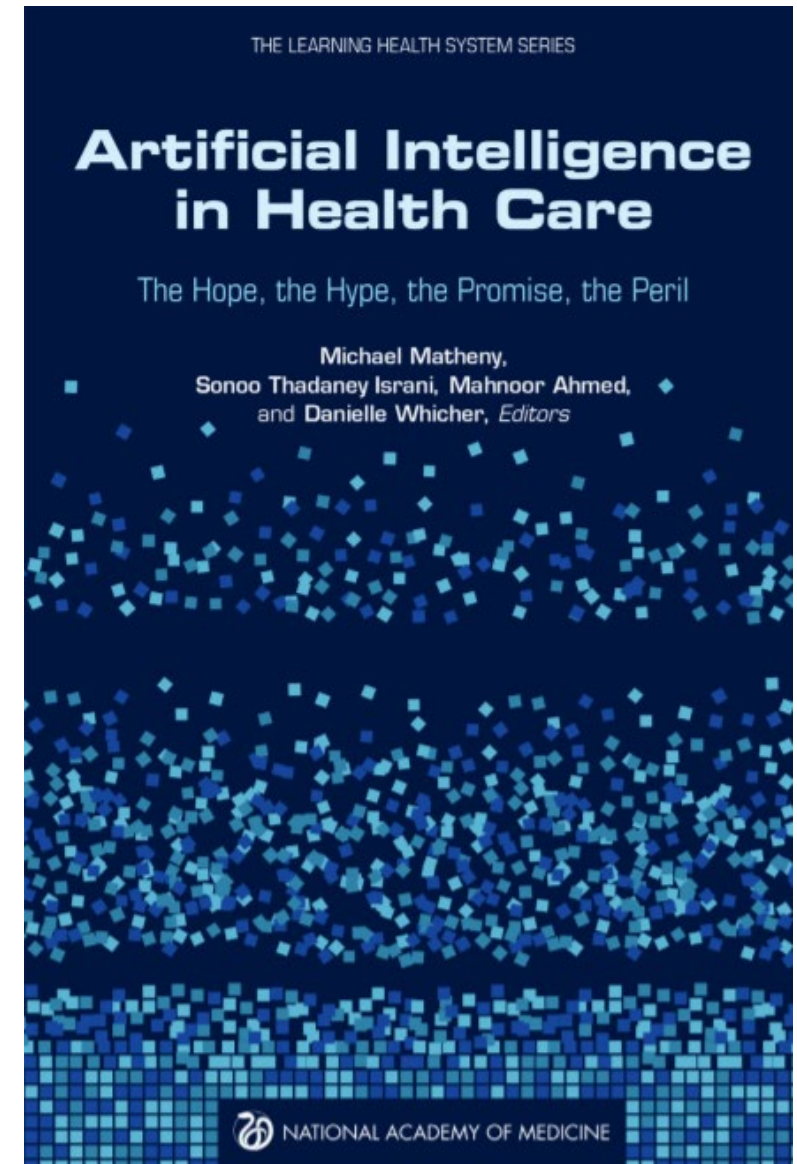
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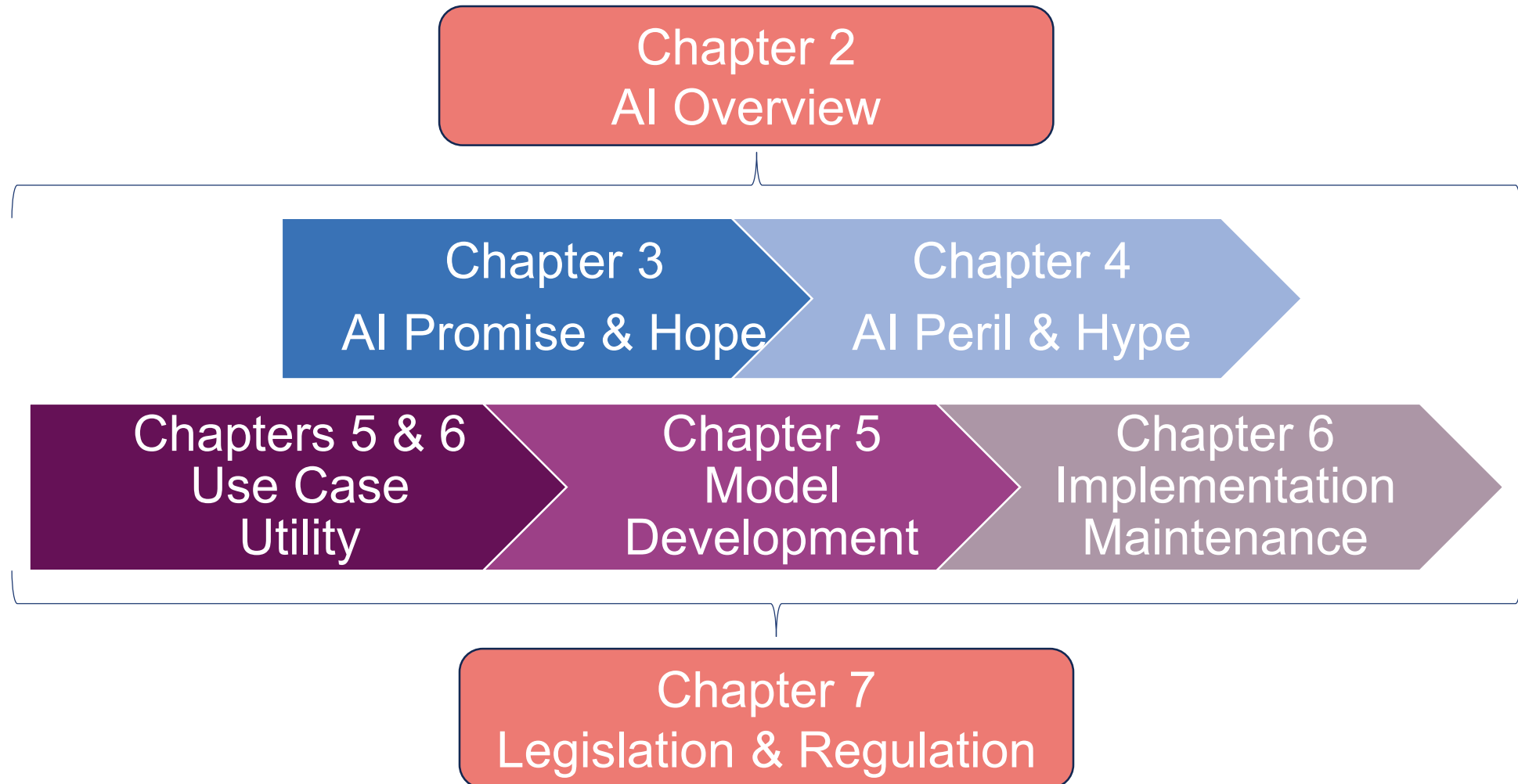
NAM Publication Aims and Audience

- Develop a reference document for *model developers, clinical implementers, clinical users, and regulatory and policy makers* to:
 - understand the strengths & limitations of AI/ML
 - promote the appropriate use of these methods & technologies in healthcare
 - highlight areas of future work needed to facilitate the broader use of AI/ML in healthcare

<https://nam.edu/artificial-intelligence-special-publication/>



NAM Publication Conceptual Organization



Health Care AI Applications

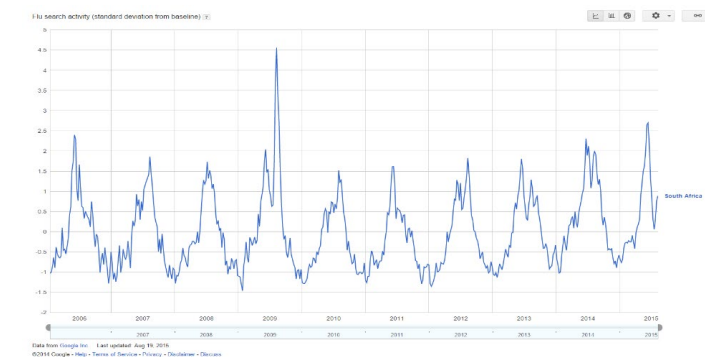
- Patients and families
 - Self management of chronic diseases
 - Assistance for people with cognitive disabilities
- Clinical care teams
 - Diagnosis and risk assessment
 - Personalize treatment plans
 - Information retrieval and visualization



Health Care AI Applications

- Health systems/hospital administration
 - Patient scheduling
 - Identifying fraudulent claims
 - Prior authorization

- Public health
 - Disease surveillance
 - Monitoring air pollution



Key Considerations Moving Forward

- **Health care data:** data access, bias, standardization, reporting of data quality, and patient privacy
- **Transparency:** data transparency versus algorithmic transparency depends on factors such as risk, performance, and user trust and liability
- **Level of automation:** near term focus on augmented intelligence
- **Regulatory environment:** environment is evolving; the goal should be balancing innovation with appropriate oversight/protection
- **Training and education:** for clinical users, AI developers, and other relevant stakeholders
- **Deployment environments:** system need a robust and mature underlying information technology (IT) governance strategy



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Jesse M. Ehrenfeld, M.D., M.P.H., FAMIA, FASA

@DoctorJesseMD

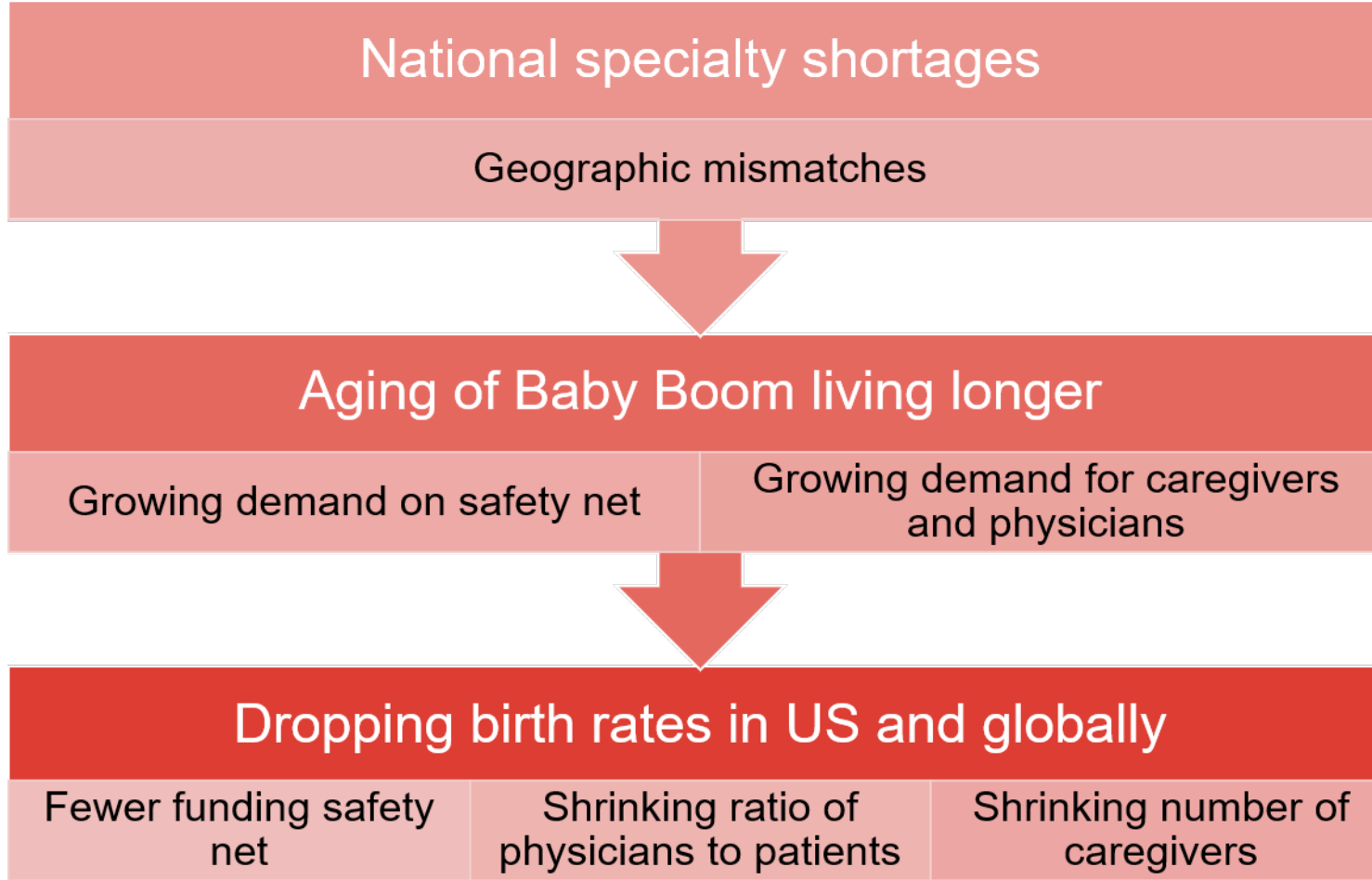
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No ordinary trends....



Physician
burn-out

Overwhelmed
with data

Overall
technology
without
emphasis on
user-centered
design

AMA Policy Development

- Learnings from 2016 survey of 1300 physicians
 - Physicians are optimistic about digital medicine tools.
 - Physicians have the greatest enthusiasm for the clinical benefit and work efficiencies provided by digital tools.
- 2017 AMA Board of Trustees adopts advocacy principles on health care AI
- 2018 AMA House of Delegates adopts policy on Health Care Augmented Intelligence (AI)
 - Rapidly evolving systems should augment and scale the capabilities of physicians, the broader health care team, and patients in **achieving the quadruple aim in health care**.
- Specifically, AI systems should:
 - Enhance the patient experience of care and outcomes;
 - Improve population health;
 - Reduce overall costs for the health care system while increasing value; and
 - Support the professional satisfaction of physicians and the health care team.

AI In General

- **Augmented Intelligence (AI)** is an alternative conceptualization that focuses on AI's assistive role, emphasizing the fact that its design enhances human intelligence rather than replaces it.
- **Machine Learning (ML)** is a part of the discipline of artificial intelligence and refers to constructing algorithms that can make accurate predictions about future outcomes. Machine learning can be supervised or unsupervised.
- When thinking about AI, you must ask “what type of AI systems are we discussing?”

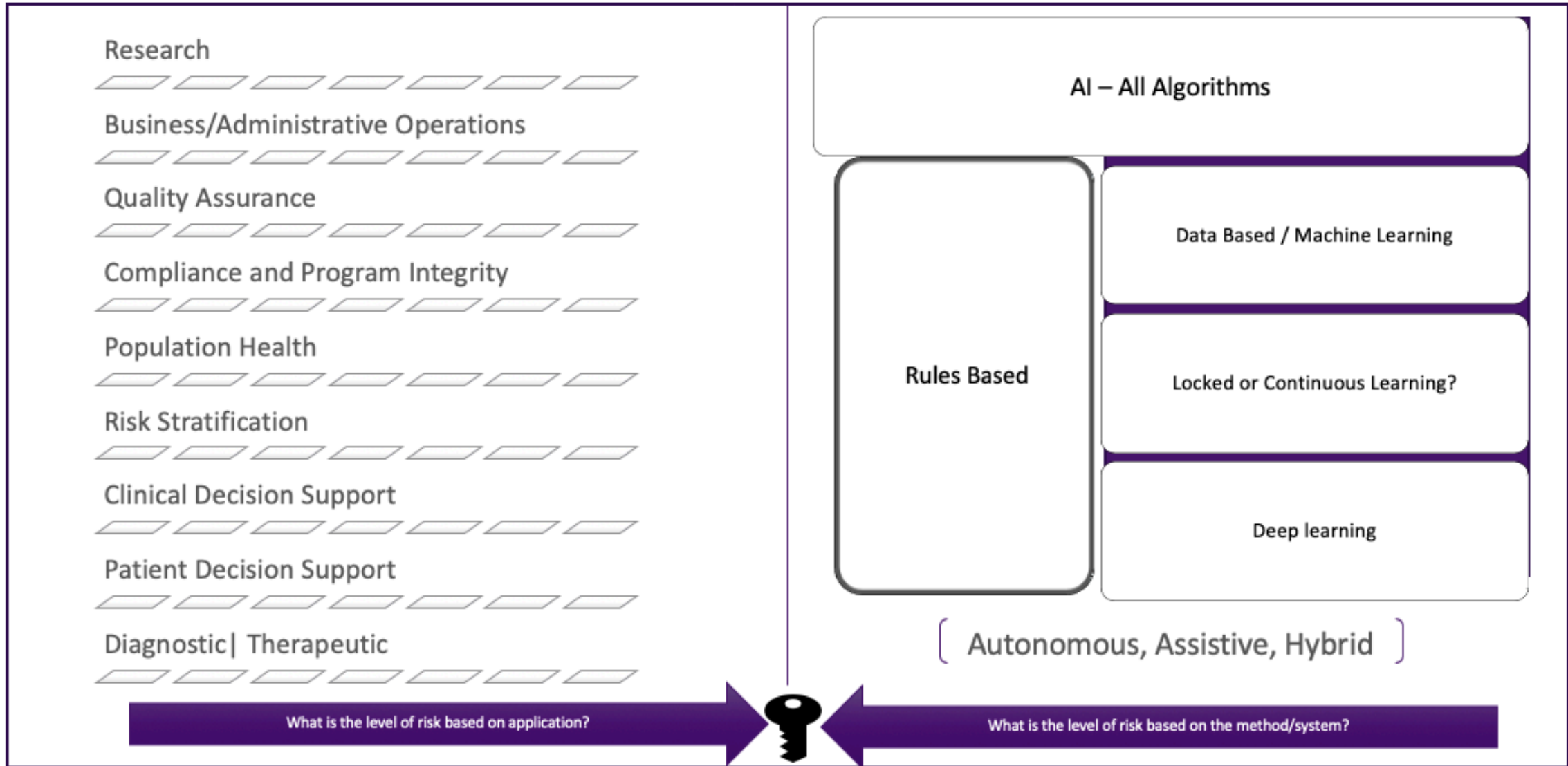
Key Attributes for AI in Health Care – AMA policy

- AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it
 - Keeping with best practices in user-centered design
 - AI systems must be based on risk of harm and benefit accounting for a host of factors
 - Is explainable
 - Clinically validated
 - Conforms to leading standards for reproducibility
 - Address bias and avoids introducing or exacerbating health care disparities
 - Safeguards patients' and other individuals' privacy interests
-
- Rapidly evolving systems should augment and scale the capabilities of physicians, the broader health care team, and patients in **achieving the quadruple aim in health care.**

AI In Health Care - Opportunities

- Office and hospital automation – patient scheduling, order entry, chat bots, voice recognition, etc.
- Diagnosis – analyze all the known data about the patient and produce insights
- Treatment – analyze the diagnosis and all other known data and produce best practice treatments, perhaps even comparing to “patients like me” data
- Additional time for physicians to spend with patients to focus on their health
- Improve patient experience and aid behavioral change and treatment compliance

There is not a single health care AI system, application, or method, but many. Systems may use one or more methods and likely have different risk profiles and benefits:



AMA Resources

- Additional AI resources available from AMA: <https://www.ama-assn.org/amaone/augmented-intelligence-ai>



3 ways medical AI can improve workflow for physicians

The real promise of health care AI is to enhance the work of physicians, not to replace them. Discover three ways AI may improve physicians' workflow.



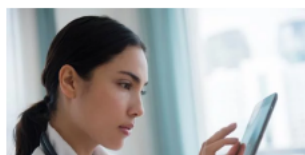
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Unlocking the potential of digital health care

Evolving technologies could lead to great advances in health care, but it is important ensure that they don't intensify pre-existing disparities.



Health care AI holds promise, but physicians' perspective needed

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While AI can be a boon to health care efficiency, it is essential to maintain transparency and include physicians early in the development process.



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AMA policy on augmented intelligence

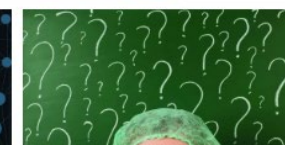
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Review AMA discussion of key health care AI topics and policy.



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The Office of the National Coordinator for
Health Information Technology

Contact ONC

Andrew Gettinger, MD

Andrew.Gettinger@hhs.gov

@ag1



Phone: 202-690-7151



Health IT Feedback Form:

<https://www.healthit.gov/form/healthit-feedback-form>



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Artificial Intelligence in Health IT – The Good, The Bad, The Ugly (Part 2)

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Should the AI space be regulated?

Precision Regulation for Artificial Intelligence

By Ryan Hagemann, IBM Policy Lab co-Director (Washington, DC) & Jean-Marc Leclerc, IBM Policy Lab co-Director (Brussels)

Among companies building and deploying artificial intelligence, and the consumers making use of this technology, trust is of paramount importance. Companies want the comfort of knowing how their AI systems are making determinations, and that they are in compliance with any relevant regulations, and consumers want to know when the technology is being used and how (or whether) it will impact their lives.

62% of Americans and 70% Europeans prefer a precision regulation approach for technology, with less than 10% in either region supporting broad regulation of tech. 85% of Europeans and 81% of Americans support consumer data protection in some form, and 70% of Europeans and 60% of Americans support AI regulation.

As outlined in our Principles for Trust and Transparency, IBM has long argued that AI systems need to be transparent and explainable. That's one reason why we supported the OECD AI Principles, and in particular the need to "commit to transparency and responsible disclosure" in the use of AI systems.

Principles are admirable and can help communicate a company's commitments to citizens and consumers. But it's past time to move from principles to policy. Requiring disclosure — as appropriate based on use-case and end-user — should be the default expectation for many companies creating, distributing, or commercializing AI systems. In an earlier Policy Lab essay, we articulated a disclosure requirement for law enforcement use-cases of facial recognition technology. Something similar should be required of AI more generally in order to provide the public with appropriate assurances that they are being

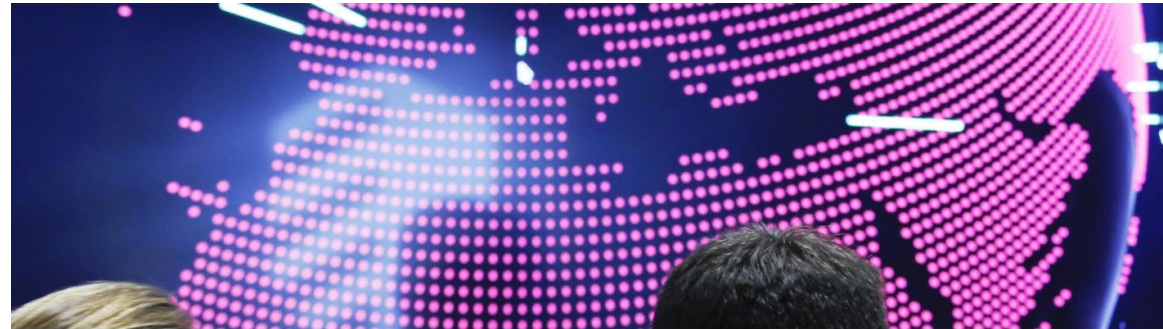
treated fairly and equitably by AI-based determinations in sensitive use-cases.

That is why today we are calling for precision regulation of AI. We support targeted policies that would increase the responsibilities for companies to develop and operate trustworthy AI. Given the ubiquity of AI — it touches all of us in our daily lives and work — there will be no one-size-fits-all rules that can properly accommodate the many unique characteristics of every industry making use of this technology and its impact on individuals. But we can define an appropriate risk-based AI governance policy framework based on three pillars:

- **Accountability** proportionate to the risk profile of the application and the role of the entity providing, developing, or operating an AI system to control and mitigate unintended or harmful outcomes for consumers.
- **Transparency** in where the technology is deployed, how it is used, and why it provides certain determinations.
- **Fairness and security** validated by testing for bias before AI is deployed and re-tested as appropriate throughout its use, especially in automated determinations and high-risk applications.

Wisely, the OECD AI Principles suggest a solid accountability bedrock for this framework, arguing that "[g]overnments should promote a policy environment that supports an agile transition from the research and development stage to the deployment and operation stage for trustworthy AI systems." This implicit recognition

Bloomberg



Photographer: Luke MacGregor/Bloomberg

IBM Proposes Artificial Intelligence Rules to Ease Bias Concerns

By [Ben Brody](#) and [Olivia Carville](#)

January 21, 2020, 4:00 AM EST

IBM Policy Lab

ibm.com/policy 1



Google CEO: 'Artificial intelligence needs to be regulated'

BY EMILY BIRNBAUM - 01/21/20 12:43 PM EST



Photographer: Greg Nash

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- **A. Zach Hettinger, MD, MS, FACEP, FAMIA**
 - Director of Cognitive Informatics, MedStar National Center for Human Factors in Healthcare
- **Sonoo Thadaney Israni, MBA**
 - Executive Director, Stanford Presence Center, School of Medicine, Stanford University



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@DoctorJesseMD

Chair, Board of Trustees

American Medical Association

No ordinary trends....

National specialty shortages

Geographic mismatches

Aging of Baby Boom living longer

Growing demand on safety net

Growing demand for caregivers and physicians

Dropping birth rates in US and globally

Fewer funding safety net

Shrinking ratio of physicians to patients

Shrinking number of caregivers

Physician burn-out

Overwhelmed with data

Overall technology without emphasis on user-centered design

AMA policy on AI

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 - AI's role in enhancing patient care, improving population health, reducing overall costs, increasing value and the support of professional satisfaction for physicians.
 - Rapidly evolving systems should augment and scale the capabilities of physicians, the broader health care team, and patients in **achieving the quadruple aim in health care**.
- Specifically, AI systems should:
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- Improve patient experience, and aid behavioral change and treatment compliance

AI In Health Care - Challenges

- Data structure, integrity, privacy and security
- Demonstrate that AI can reduce costs, deliver the quadruple aim, support the patient-physician relationship, and/or alleviate administrative burden
- Implement and integrate AI into clinical practices and patient care
- Susceptibility to training bias
- Questions as to who will benefit and who may lose
- AI-enabled products that will likely not be FDA-regulated (e.g., administrative-type functions) or otherwise exempt from FDA regulation

Additionally, AI opportunities and challenges lead to questions physicians will need to confront:

- What evidence is needed to demonstrate value, utility, and trust? To whom?
- Oversight for AI benefits and risks, and how to communicate these to the public?
- How can patient and clinician expectations be managed, and concerns allayed?
- User/consumer education and training?
- Integration into clinical workflows?
- How will risk be allocated, given the “black box” nature of many AI systems?

Liability

- Innovators/vendors/manufacturers/health systems should not inappropriately shift risk downstream.
- Those best positioned to have knowledge of AI risks are best positioned to minimize harm.
- Protections should be established for the clinically appropriate use and reliance on healthcare AI.
- Where regulatory oversight is limited, black-box, proprietary AI without explainability should be subject to strict liability.

Oversight/regulation

- Healthcare AI presents unique opportunities to advance patient and consumer health; so too will it potentially present new and novel harms to patient and consumer safety.
- Oversight of healthcare AI should be risk based. Categorization of risk should be based on intended use as well as reasonably expected use.
- The AMA supports FDA's efforts to create a new pathway to FDA approval/clearance and recognizes the challenges the agency faces in working through this process. However, any new oversight structure must ultimately ensure patient safety.
- There will be a tremendous amount of technologies coming forward and an incredibly uncertain regulatory oversight structure to ensure safety—this poses challenges for everyone.
- We strongly urge government agencies to collaborate closely on issues of regulation of AI-enabled products.

Data integrity, bias and privacy

- Health care AI systems must account for a host of factors, including efficacy, equity and taking steps to address bias
- Will consumers...
 - Know how their data may be used, by whom, and if solutions or services are being derived from their data?
 - Control how their information is accessed, used, and disclosed by entities collecting data?
 - Know whether their health data will be used to develop and/or train machines or algorithms?
 - Be protected from discrimination, stigma, and exploitation occurring during collection of data and deployment of the AI/ML?
- Health data should not be used to discriminate against individuals, including creation of “risk scores” that could hinder patients and their families from receiving health, disability, or life insurance.

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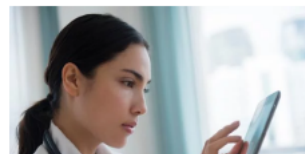
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AI in Healthcare: Hope, Hype, Promise, Peril

Sonoo Thadaney Israni

Executive Director, Presence (a Stanford Medicine Center), Stanford University

presence.
The Art & Science of Human Connection.



The Office of the National Coordinator for
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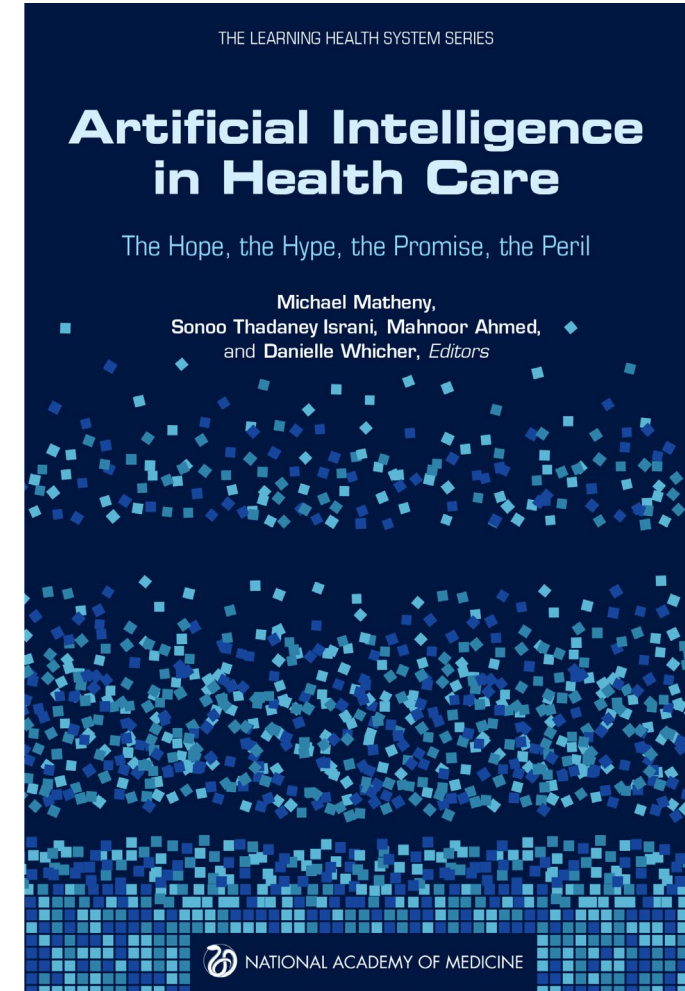
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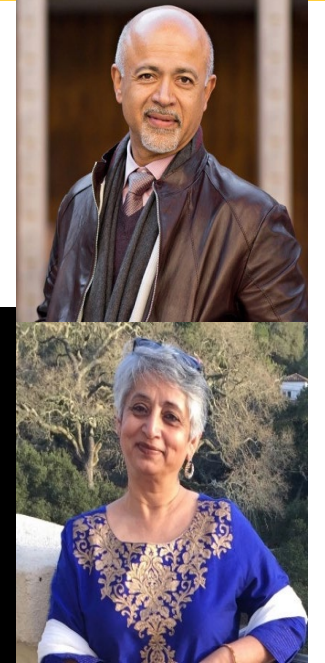


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Presence champions the human experience in medicine.

Being present is essential to the well-being of both patients and caregivers, and it is fundamental to establishing trust in all human interactions. Being present is integral to the art and the science of medicine and predicates the quality of medical care.



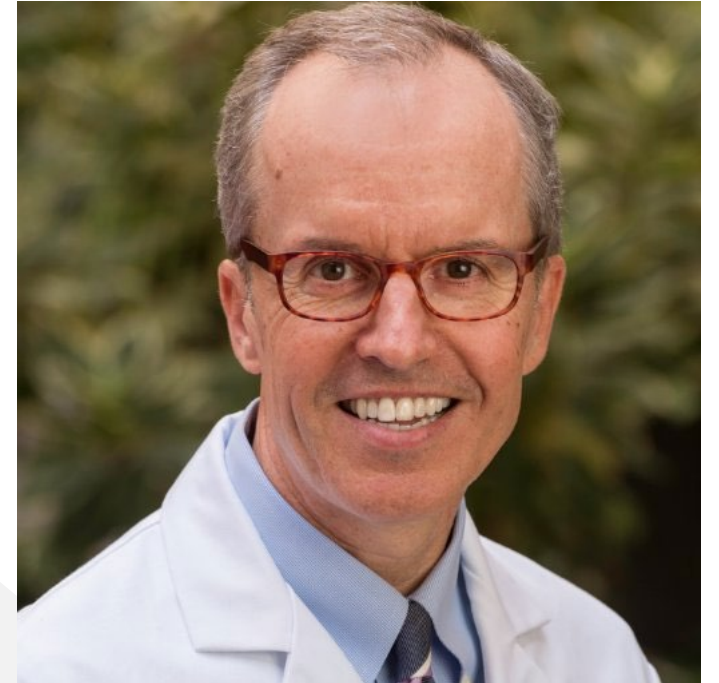
“Humans were always far better at inventing tools than using them wisely.”

Yuval Noah
Harari

21 Lessons
for the

“Will AI ever replace radiologists?
I say the answer is no—
but radiologists who use
AI will replace
radiologists who don’t.”

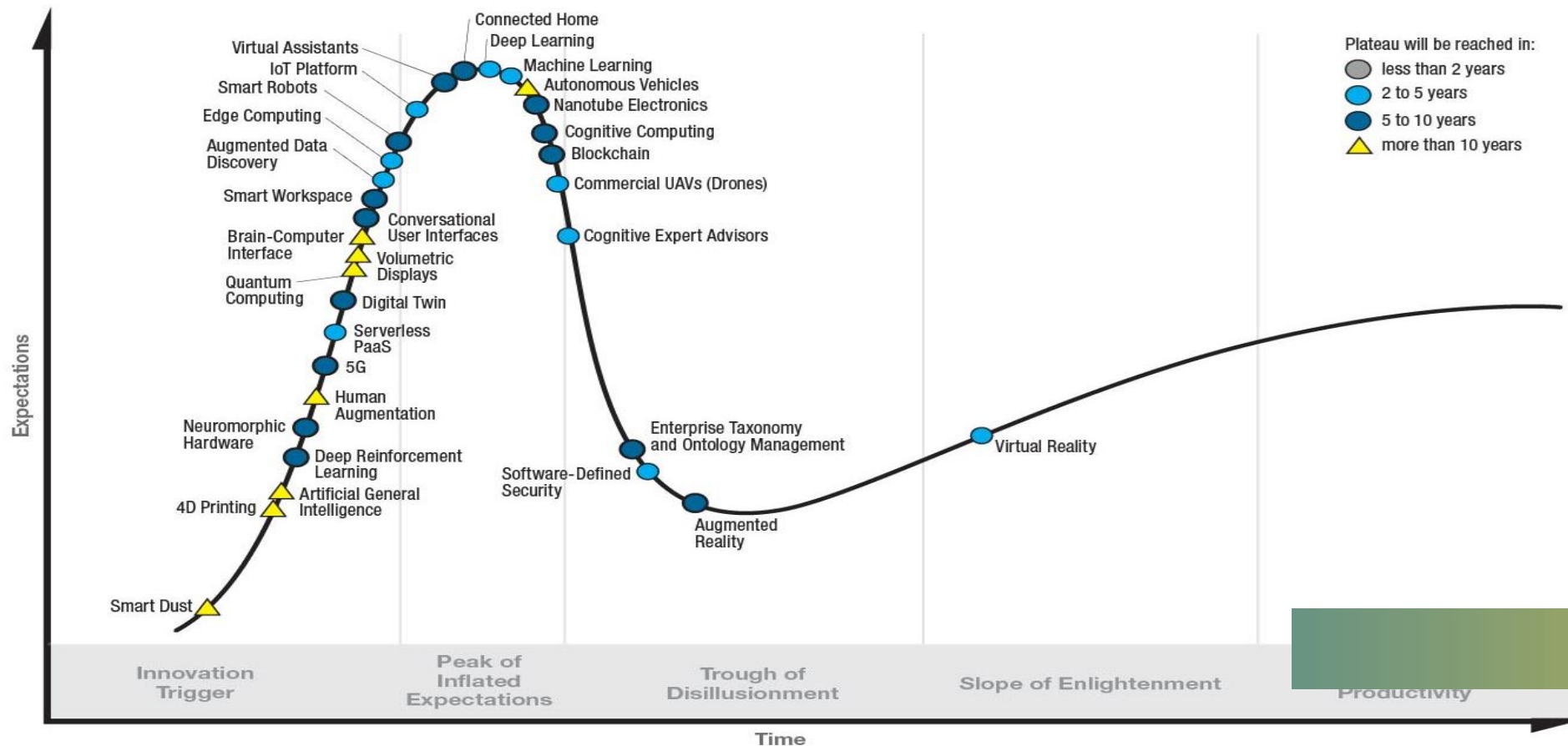
Curtis P. Langlotz, MD, PhD

Professor of Radiology and Biomedical
Informatics



Gartner Hype Cycle

Jonathan H Chen, Steven M Asch,
Machine Learning and Prediction in Medicine
Beyond the Peak of Inflated Expectations,
New England Journal of Medicine (2017)



THE DATA SCIENCE HIERARCHY OF NEEDS

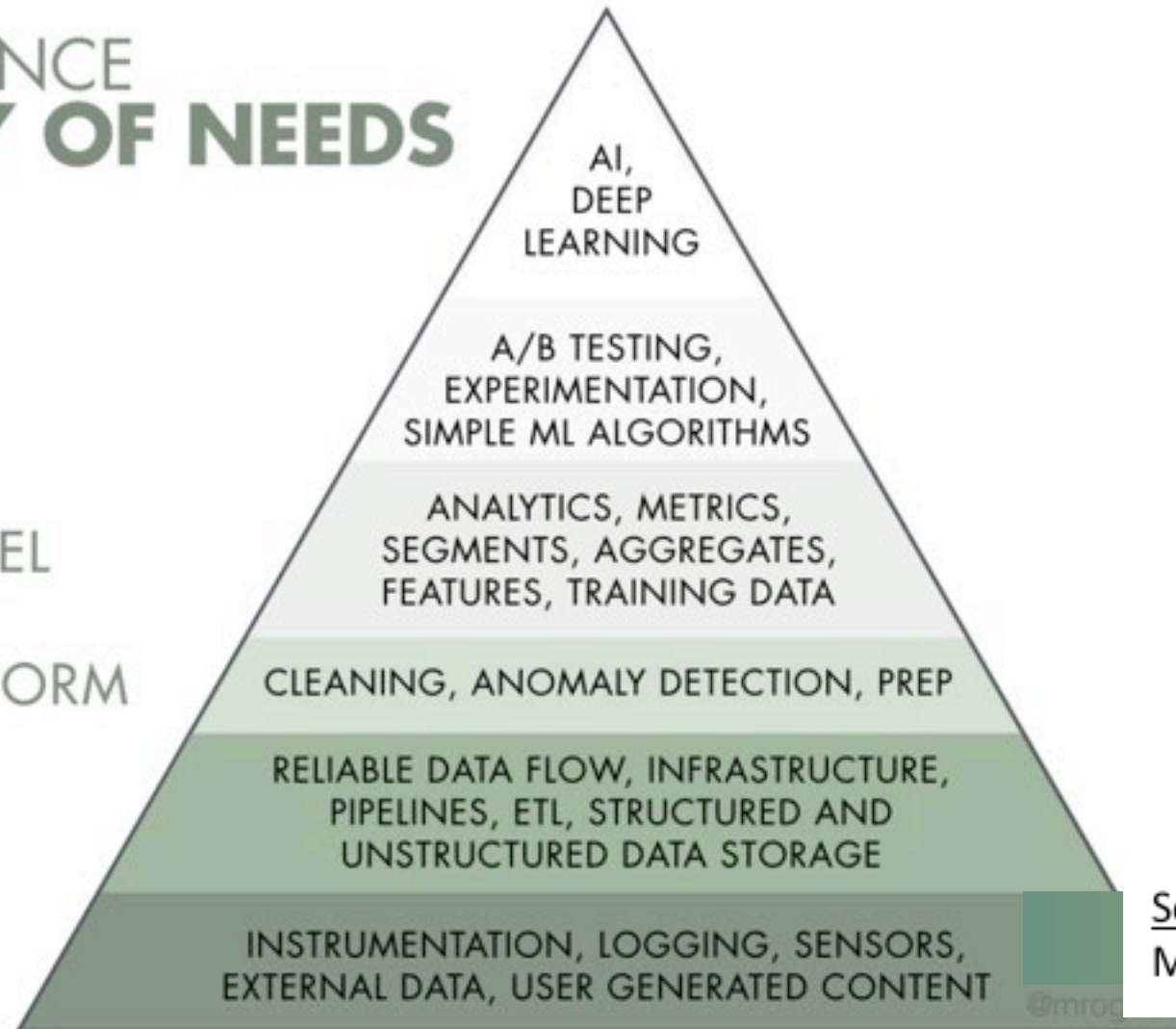
LEARN/OPTIMIZE

AGGREGATE/LABEL

EXPLORE/TRANSFORM

MOVE/STORE

COLLECT



Source: Monica Rogati's
Medium post "The AI Hierarchy of Needs"

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AI needs population representative data or GIGO

AI-triggered Healthcare Inequity



WIRED

Privacy Confidentiality
Privilege

**“AI Could Reinvent Medicine—Or
Become a Patient's Nightmare**

The Mayo Clinic will store health data in Google's cloud and use its AI expertise to unearth insights. But Google has made mistakes before...”

A *Sunday Times* bestseller

**THE AGE OF
SURVEILLANCE
CAPITALISM**

THE FIGHT FOR A
HUMAN FUTURE
AT THE NEW
FRONTIER OF POWER

**SHOSHANA
ZUBOFF**

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This Issue

Views 26,223 | Citations 11 | Altmetric 100

Viewpoint



July 17, 2018

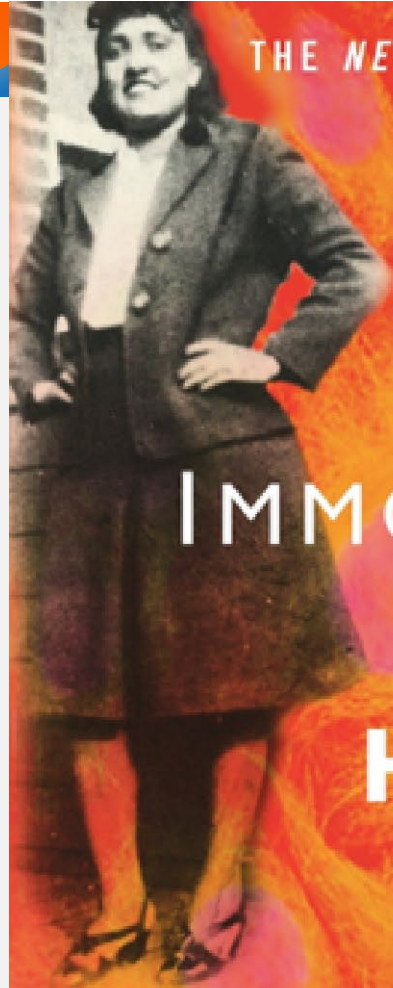
HIPAA and Protecting Health Information in the 21st Century

I. Glenn Cohen, JD¹; Michelle M. Mello, JD, PhD²

[Author Affiliations](#) | [Article Information](#)

JAMA. 2018;320(3):231-232. doi:10.1001/jama.2018.5630

THE NEW YORK TIMES BESTSELLER



THE
IMMORTAL LIFE
OF
HENRIETTA
LACKS

Doctors took her cells without asking.
Those cells never died.
They launched a medical revolution
and a multimillion-dollar industry.
More than twenty years later, her children found out.
Their lives would never be the same.

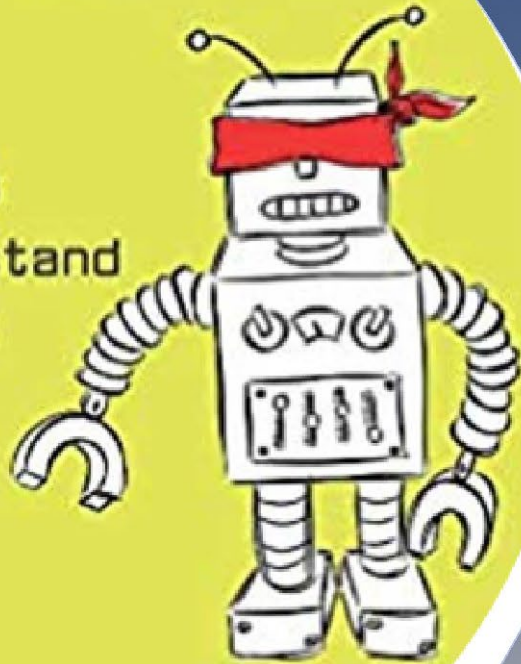
Privacy
Confidentiality
Privilege

“Digital HeLa?”

*Research Ethics for De-identified Big
Data" (work in progress)*

ARTIFICIAL UNINTELLIGENCE

How
Computers
Misunderstand
the World



MEREDITH BROUSSARD

Appropriate AI in
health CARE

Techno-chauvinism

We Can. Should we?

Appropriate AI in health CARE

Man told he's
going to die by
doctor on
video-link
robot



Unintended consequences



more empowered to demand justice." —NAOMI KLEIN

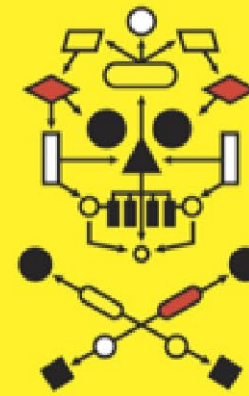
Unintended
consequences

**AUTOMATING
INEQUALITY**

HOW HIGH-TECH TOOLS PROFILE,
POLICE, AND PUNISH THE POOR



**WEAPONS OF
MATH DESTRUCTION**



HOW BIG DATA INCREASES INEQUALITY
AND THREATENS DEMOCRACY

CATHY O'NEIL

MORAL

CRUMPLE

ZONES

Viewpoint

October 4, 2019

JAMA Network™

Potential Liability for Physicians Using Artificial
Intelligence

Unintended consequences

**Moral Crumple Zones:
Agency & Accountability
in Human-AI Interaction**

with MADELEINE CLARE ELISH, Data & Society



Framework for implementing AI via lens of human rights values

What do we value?

How are we each responsible?

We can, but should we?

What does
Human Centered mean?
To humans, for humans, by humans?

How do we define progress,
quality of life, well-being?

Who knows, who decides, who
decides who decides?
– Shoshana Zuboff
The Age of Surveillance Capitalism

Source: Mathaney, M., S. Thadaney, M. Ahmed, and D. Whicher, editors. Forthcoming (2019). Artificial Intelligence and Health Care: The Hope, the Hype, the Promise, and the Perils. Washington, DC: National Academy of Medicine. Reprinted with permission from Judy Estrin. Based on a slide Estrin shared at The Future of Human-Centered AI: Governance Innovation and Protection of Human Rights Conference, Stanford University, April 16, 2019.

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NEWS · 24 OCTOBER 2019 · UPDATE 26 OCTOBER 2019

Millions of black people affected by racial bias in health-care algorithms

Study reveals rampant racism in decision-making software used

Quintuple Aim

“That which is
measured, improves.”

Karl Pearson
Statistician & founder of mathematical
statistics

Source: Mathaney, M., S. Thadaney, M. Ahmed, and D. Whicher, editors.
Forthcoming (2019). Artificial Intelligence and Health Care: The Hope, the Hype,
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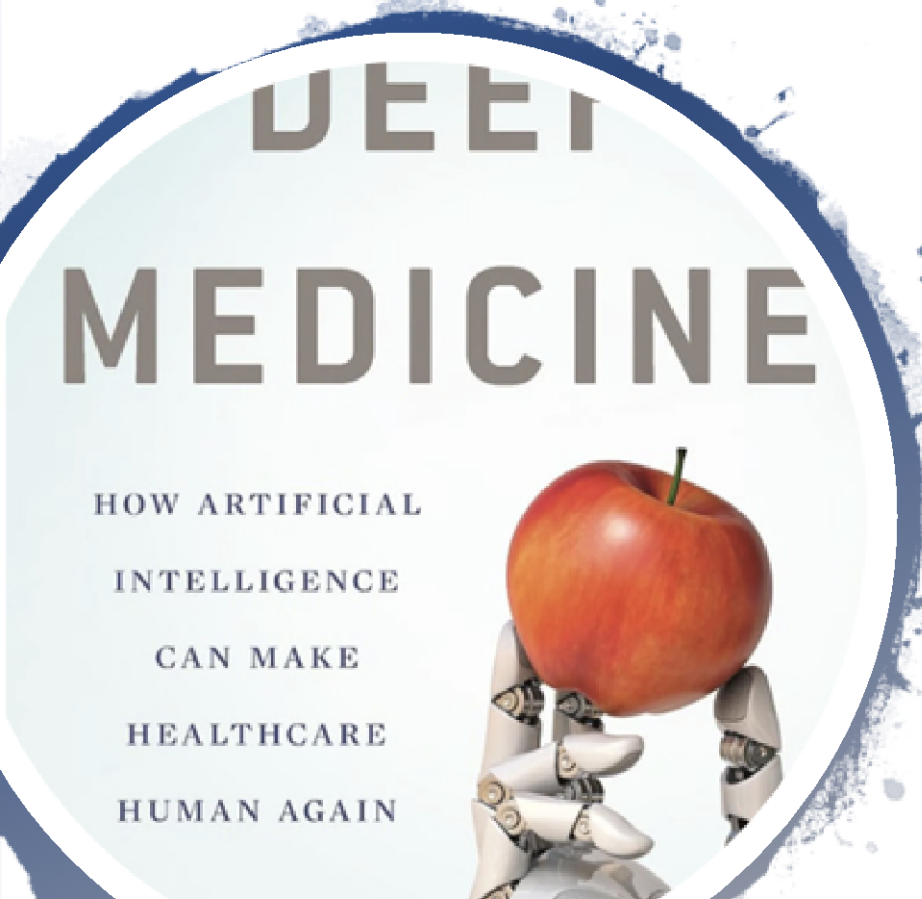


“We need sufficient regulatory scrutiny so that we don’t have debacles like that of Theranos, a company that claimed it could perform comprehensive lab tests from just a few drops of blood.

Technology that is not subject to such scrutiny doesn’t deserve our trust, nor should we ever allow it to be deeply integrated into our work.”

Abraham Verghese, MD





“If you’ve ever experienced deep pain, you know how lonely and isolating it is, how no one can really know what you are feeling, the anguish, the sense of utter despair. You can be comforted by a loved one, a friend or relative, and that certainly helps. But it’s hard to beat the boost from a doctor or clinician you trust and who can bolster your confidence that it will pass, that he or she will be with you no matter what. That you’ll be okay.

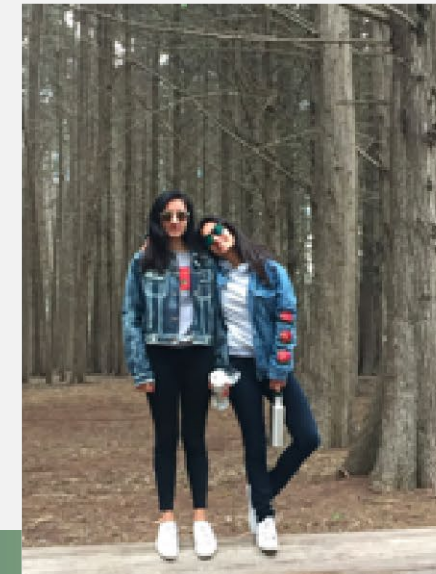
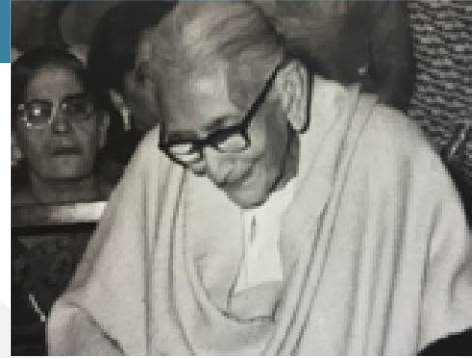
That’s the human caring we desperately seek when we are sick.

That’s what AI can help restore.

We may never have another shot like this.

Let’s take it.” **Eric Topol, MD**

Moving Forward



This is personal

Thank you!



Sonoo Thadaney Israni, MBA
Executive Director, Stanford University
Presence Center (Stanford Medicine)
AI hype and risks

Sonoo Thadaney Israni, MBA
Executive Director, Stanford University
Presence Center (Stanford Medicine)

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