

Ethical Considerations of Innovation in Healthcare

Cecilia Canales, MD, MPH

Disclosure & Funding



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- RCMAR/CHIME Scientist to support work on Perioperative Neurocognitive Disorders. The award is funded by NIA Grant #P30-AG021684 and NCATS Grant #UL1TR001881.
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- Anesthesiology & Perioperative Medicine at UCLA T32 Training Program #T32GM148369



Objectives



- Discuss ethical considerations
 - Equity
 - Regulatory
 - Other considerations
- Review NAM framework

What Ethics?

Exhaustive List

- Privacy and Data Security
- Informed Consent
- Data Ownership
- Bias and Fairness
- Equity
- Accountability and Liability
- Regulation and Governance
- Patient Autonomy
- Unintended Consequences
- Transparency and Explainability





Focus



Equity	Regulatory	Considerations
Access	Privacy	Unintended Consequences
Bias	Security and Ownership	Accountability
Disparities	Governance	Education



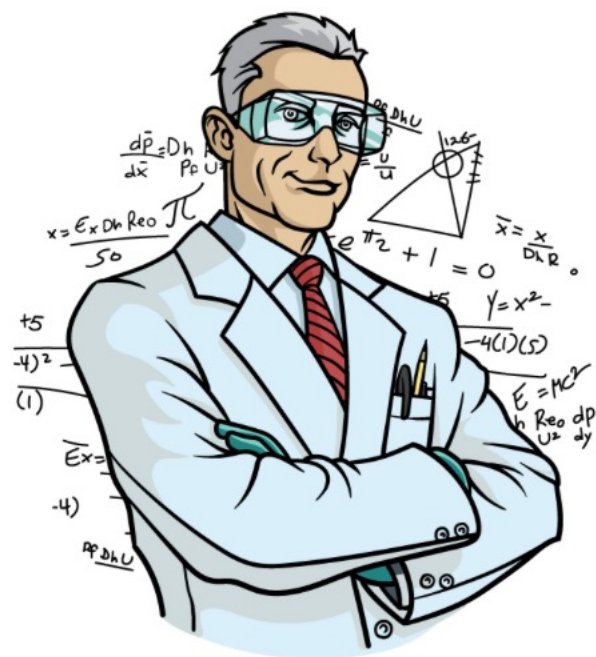
Equity

All Quality Improvement Work is Health Equity Work



NATIONAL ACADEMY OF MEDICINE

Equity



Representation

Gender Shades: Intersectional Accuracy Disparities in Commercial Gender Classification*

Joy Buolamwi
MIT Media Lab
Timnit Gebru
Microsoft Research



Problem

Striking underrepresentation of visual learning images with brown and black skin

- 91.7% of images on google image searches are white/light skin
- 88.6% of images in dermatology textbooks are white/light skin
- 84.3% of images in recommended medical student resources are white/light skin
- In a 2021 cross-continental and cross-specialty analysis only 5% of physicians in a 600-physician study sample were confident in diagnosing skin conditions across skin colors

Fix: Equitable representation of all skin colors in medical education resources

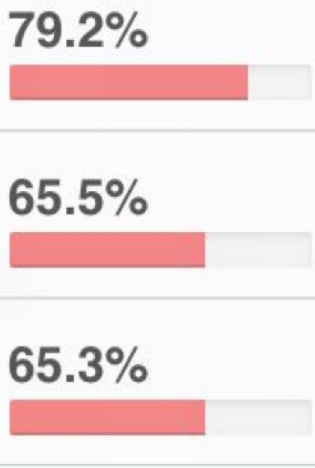
Alaina James, M.D., Ph.D.

University of Pittsburgh School of Medicine/University of Pittsburgh Medical Center

Visual Learning-----



-----Visual Diagnosis



Results

- 3501 images from 41 of the 48 CMSS member journals (26 images were excluded)
- 3475 images meeting our inclusion criteria:
 - 80% (2780) were classified as light/white skin
 - 14.65% (509) were classified as medium/brown skin
 - 5.35% (186) were classified as dark/black skin

Skin color affects the appearance of skin conditions

Type and Gender
www.gendersh

- Infectious Diseases journal had the highest proportion of brown and black images at 47.37% (18/38)
- One journal had the lowest proportion of brown and black images at 0% (0/19)

Representation

A new study shows that Black patients were more likely to have low oxygen levels that were missed by pulse oximeters, translating into as many as 1 in 10 inaccurate readings.



CORRESPONDENCE

Racial Bias in Pulse Oximetry Measurement

[357 Citing Articles](#) [Letters](#)

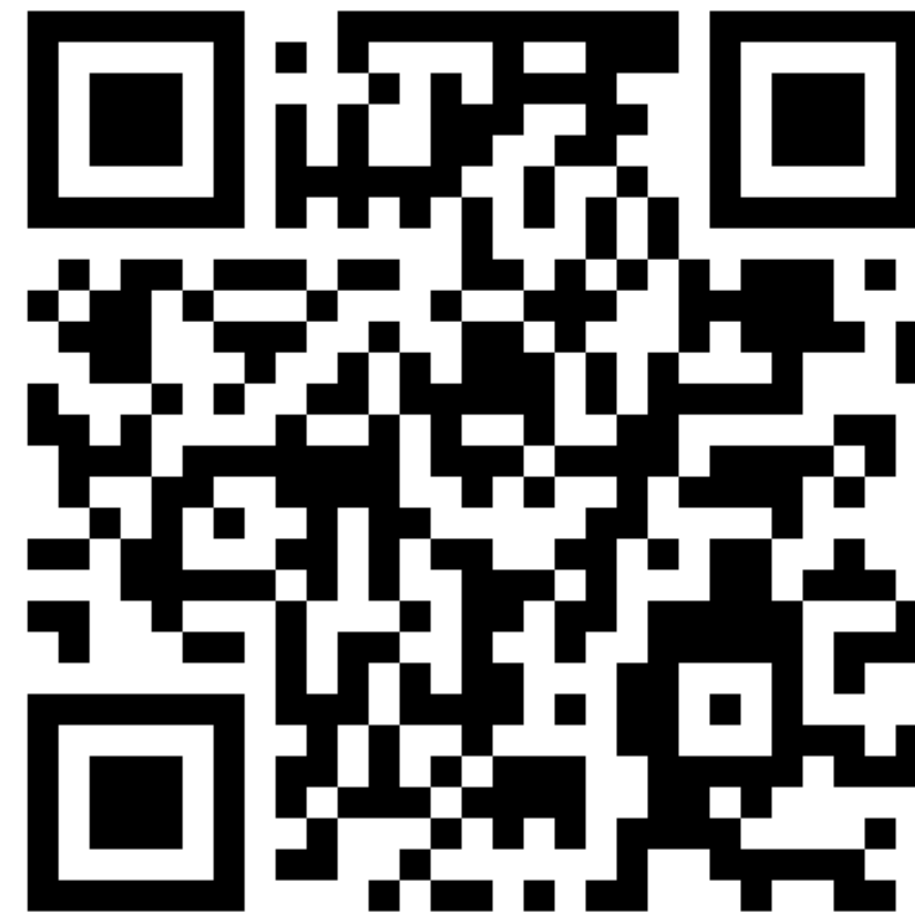
TO THE EDITOR:

December 17, 2020

N Engl J Med 2020; 383:2477-2478

DOI: 10.1056/NEJMc2029240

[Metrics](#)



Representation

This Issue Views **13,978** | Citations **3** | Altmetric **64** | Comments **1**

Viewpoint

January 9, 2023

Pulse Oximeters and Violation of Federal Antidiscrimination Law

Annabel Kupke, BA, BS¹; Carmel Shachar, JD, MPH²; Christopher Robertson, JD, PhD, MA¹

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

JAMA. 2023;329(5):365-366. doi:10.1001/jama.2022.24976

That pulse oximeters have been used in clinical settings for nearly 40 years with little assurance of equitable performance across skin tones is distressing.



In regards to tort law... *“As for personal injury claims, a dark-skinned patient could argue that a reasonable physician would have sought additional information relevant to oxygen saturation (eg, arterial blood gas testing). Claims against hospitals for failure to provide accurate equipment, or failure to have policies requiring clinicians to assess additional indicators of low oxygen saturation among dark-skinned patients, seem equally plausible”*

Representation

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Viewpoint

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That pulse oximeters have been used in clinical settings for nearly 40 years with little assurance of equitable performance across skin tones is distressing.



HHS Proposed Rule Change... *“If finalized, the rule would arguably create greater enforcement risk for hospitals that continue to use pulse oximeters that perform less accurately on dark-skinned patients.*

Specifically, §92.210 prohibits covered entities from using discriminatory clinical algorithms in health care decision-making.⁷ Although the provision lacks a precise legal definition for “clinical algorithms,” HHS describes them as “tools used to guide health care decision-making,” which can range from simplistic clinical guidelines to complex computer algorithms or decision support interventions.⁷”

COVID-19 e-print

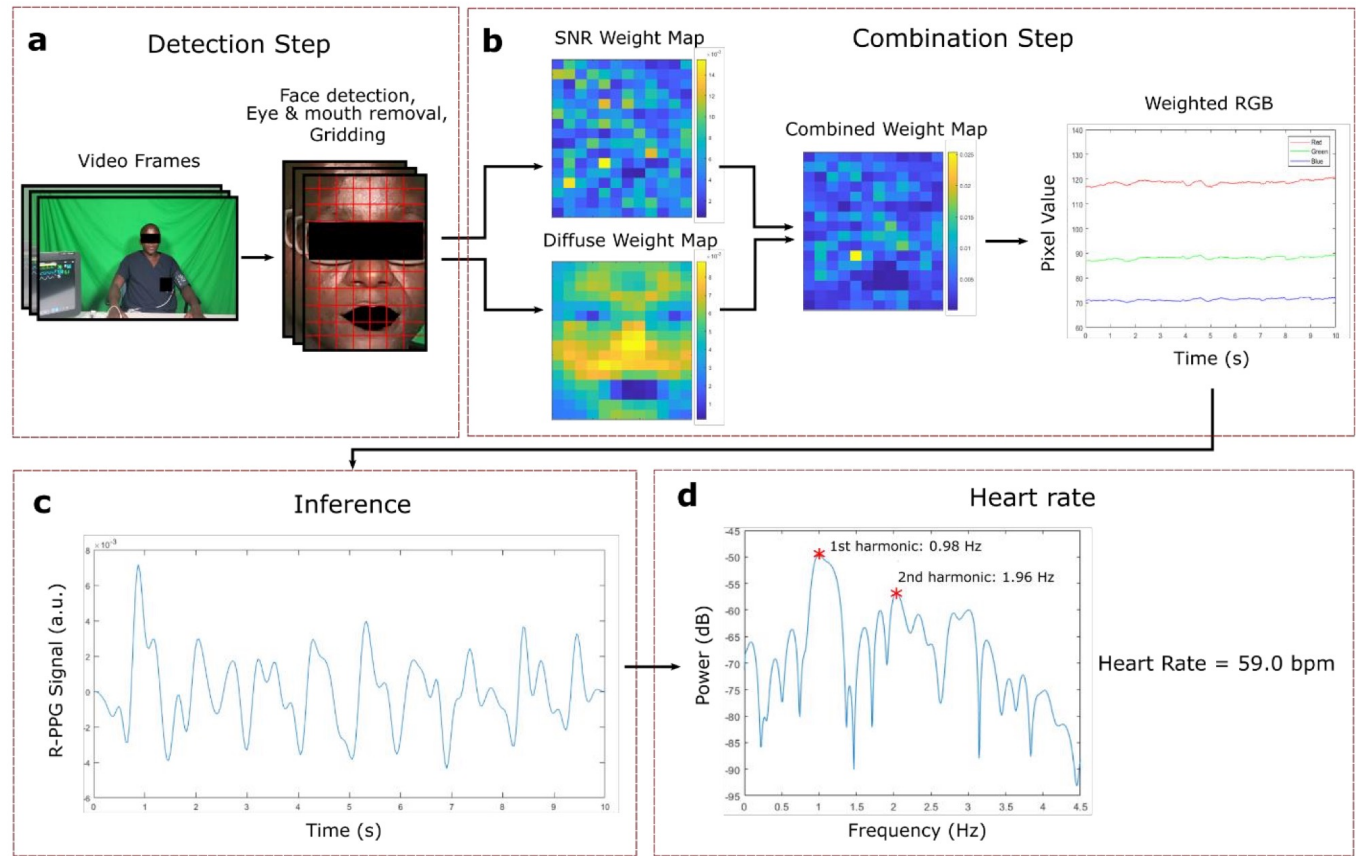
Important: e-prints posted on arXiv are not peer-reviewed by arXiv; they should not be relied upon without context to guide clinical practice or health-related behavior and should not be reported in news media as established information without consulting multiple experts in the field.

[Submitted on 24 Oct 2020 (v1), last revised 9 Dec 2020 (this version, v3)]

Diverse R-PPG: Camera-Based Heart Rate Estimation for Diverse Subject Skin-Tones and Scenes

Pradyumna Chari, Krish Kabra, Doruk Karinca, Soumyarup Lahiri, Diplav Srivastava, Kimaya Kulkarni, Tianyuan Chen, Maxime Cannesson, Laleh Jalilian, Achuta Kadambi

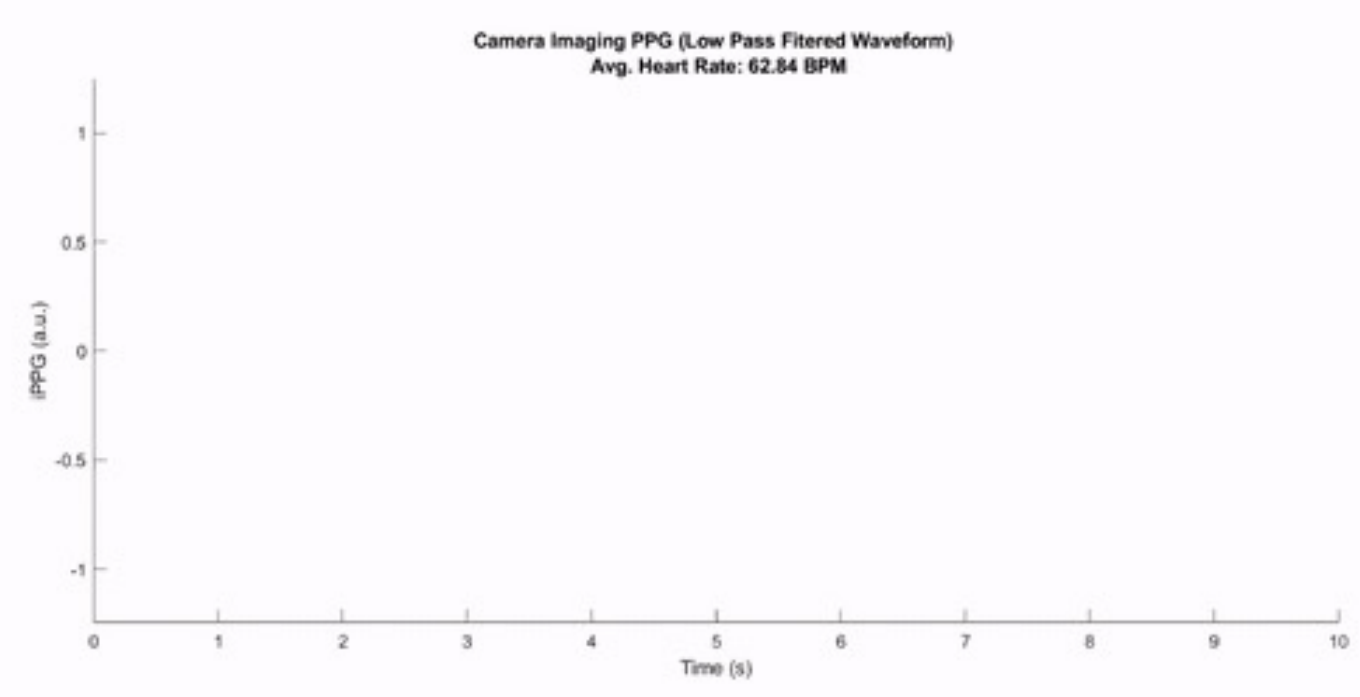
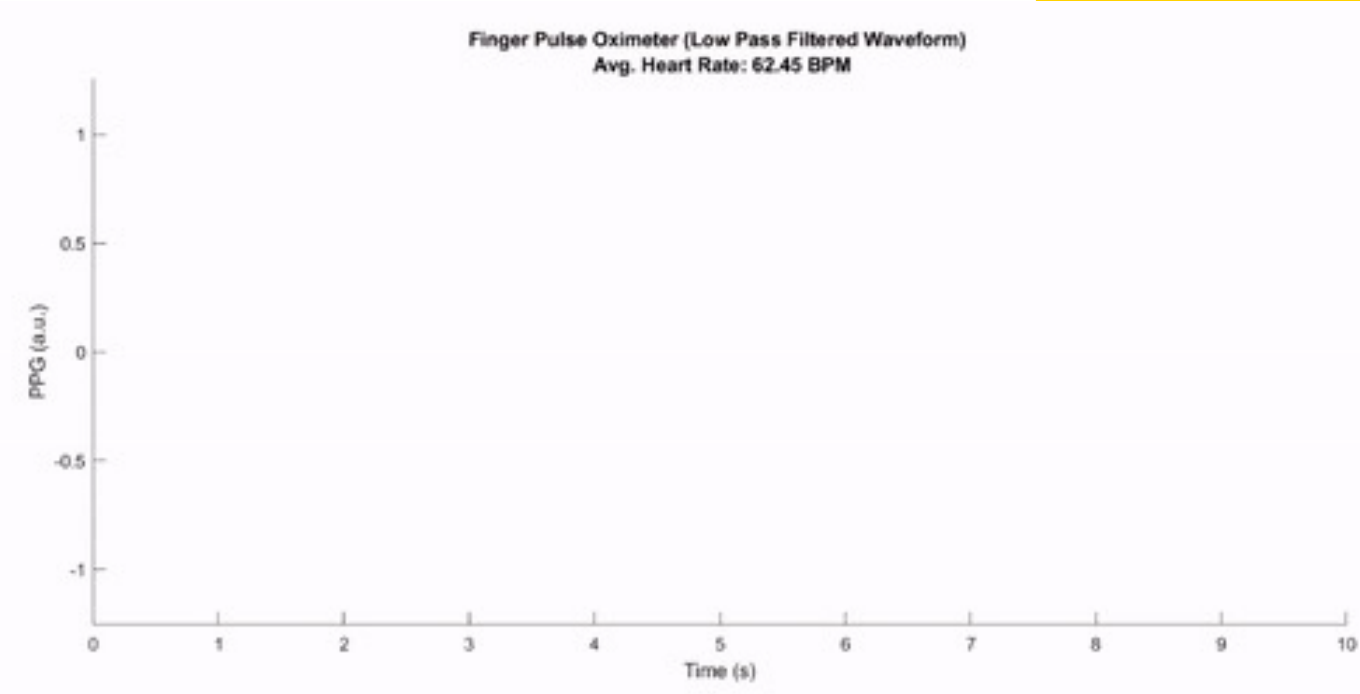
Heart rate (HR) is an essential clinical measure for the assessment of cardiorespiratory instability. Since communities of color are disproportionately affected by both COVID-19 and cardiovascular disease, there is a pressing need to deploy contactless HR sensing solutions for high-quality telemedicine evaluations. Existing computer vision methods that estimate HR from facial videos exhibit biased performance against dark skin tones. We present a novel physics-driven algorithm that boosts performance on darker skin tones in our reported data. We assess the performance of our method through the creation of the first telemedicine-focused remote vital signs dataset, the VITAL dataset. 432 videos (~864 minutes) of 54 subjects with diverse skin tones are recorded under realistic scene conditions with corresponding vital sign data. Our method reduces errors due to lighting changes, shadows, and specular highlights and imparts unbiased performance gains across skin tones, setting the stage for making medically inclusive non-contact HR sensing technologies a viable reality for patients of all skin tones.



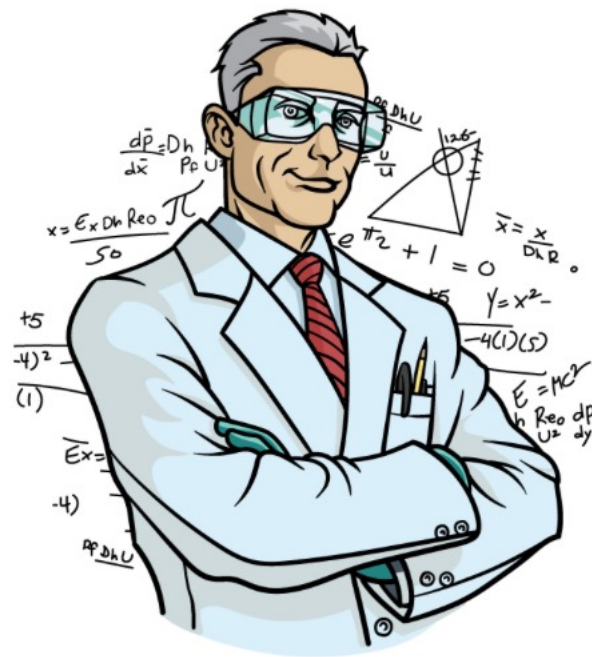
Captured Video



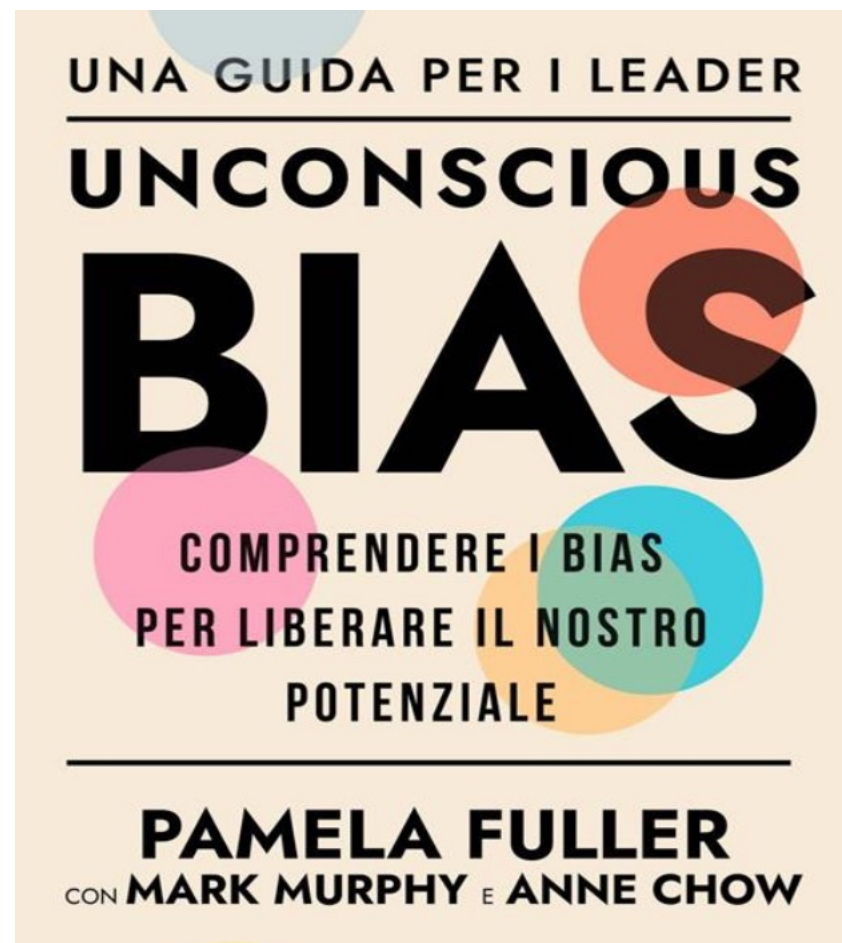
Color Magnified Video



Equity



Representation



Bias

Bias

FEATURED ARTICLES

Science Without Conscience Is but the Ruin of the Soul: The Ethics of Big Data and Artificial Intelligence in Perioperative Medicine

Canales, Cecilia MD, MPH^{*}; Lee, Christine PhD[†]; Cannesson, Maxime MD, PhD^{*}

[Author Information](#) ☺

Anesthesia & Analgesia 130(5):p 1234-1243, May 2020. | DOI: 10.1213/ANE.00000000000004728

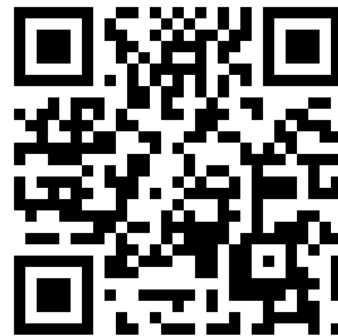
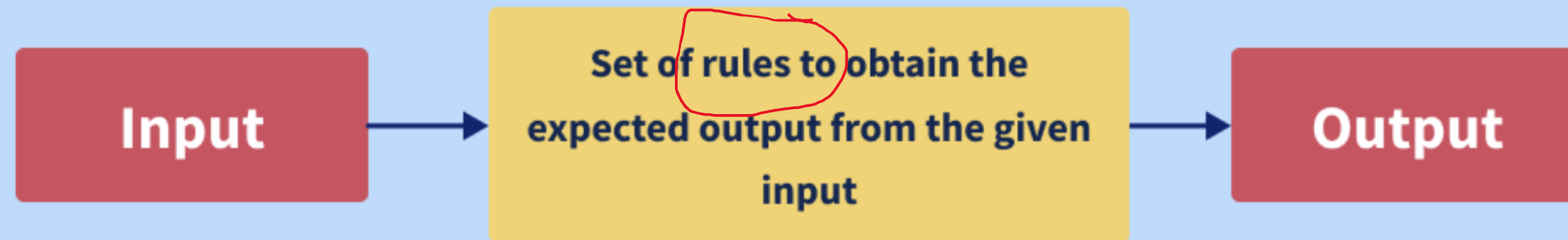


Figure. Ethical questions in AI-dependent health care system. Ethical questions to consider in an AI-dependent health care system, in 4 categories: data stewardship, bias, artificial intelligence implementation, and societal implications. AI indicates artificial intelligence.

- Are AI and ML programs fair?
- Are implicit or explicit bias integrated in to the code?
- Does the training data represent the target population?
- Is there bias in how data gets annotated?
- Are socioeconomic or ethic bias integrated into the system?
- Is there institutional, training or treatment bias?

Bias

What is Algorithm?



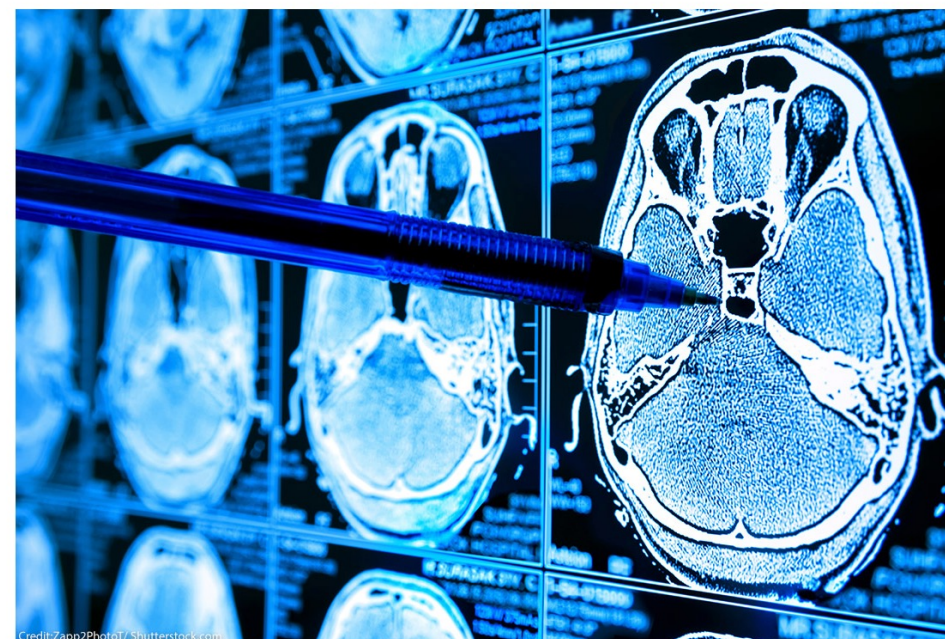
Rules

- Humans
- Experiences
- Unconscious Bias

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Algorithms Are Making Decisions About Health Care, Which May Only Worsen Medical Racism

Unclear regulation and a lack of transparency increase the risk that AI and algorithmic tools that exacerbate racial biases will be used in medical settings.



Science

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HOME > SCIENCE > VOL. 366, NO. 6464 > DISSECTING RACIAL BIAS IN AN ALGORITHM USED TO MANAGE THE HEALTH OF POPULATIONS

RESEARCH ARTICLE

f t in d e

Dissecting racial bias in an algorithm used to manage the health of populations

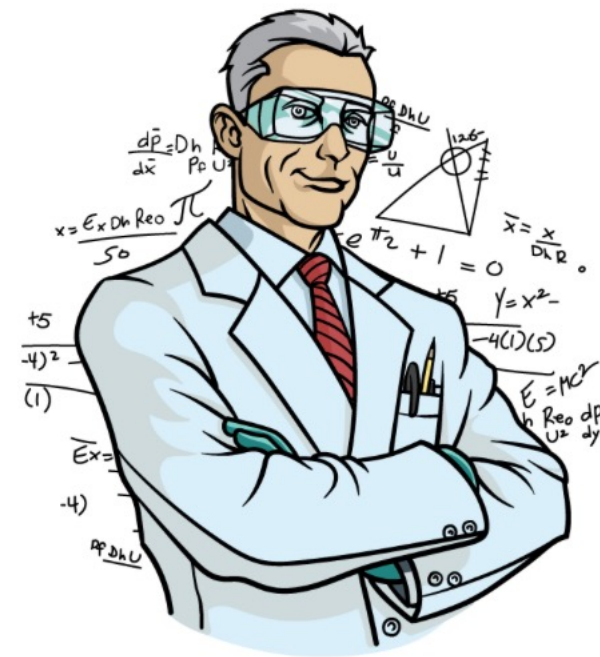
ZIAD OBERMEYER , BRIAN POWERS, CHRISTINE VOGELI, AND SENDHIL MULLAINATHAN [Authors Info & Affiliations](#)

SCIENCE • 25 Oct 2019 • Vol 366, Issue 6464 • pp. 447-453 • DOI: 10.1126/science.aax2342

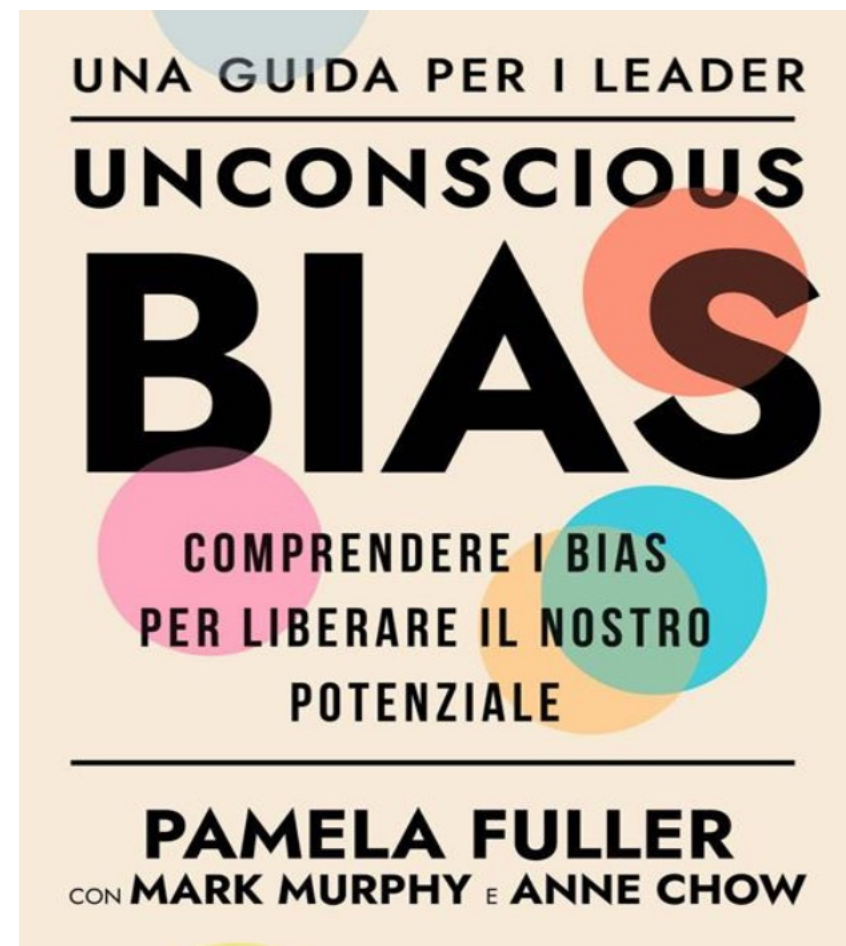
50,203 1,261



Equity



Representation



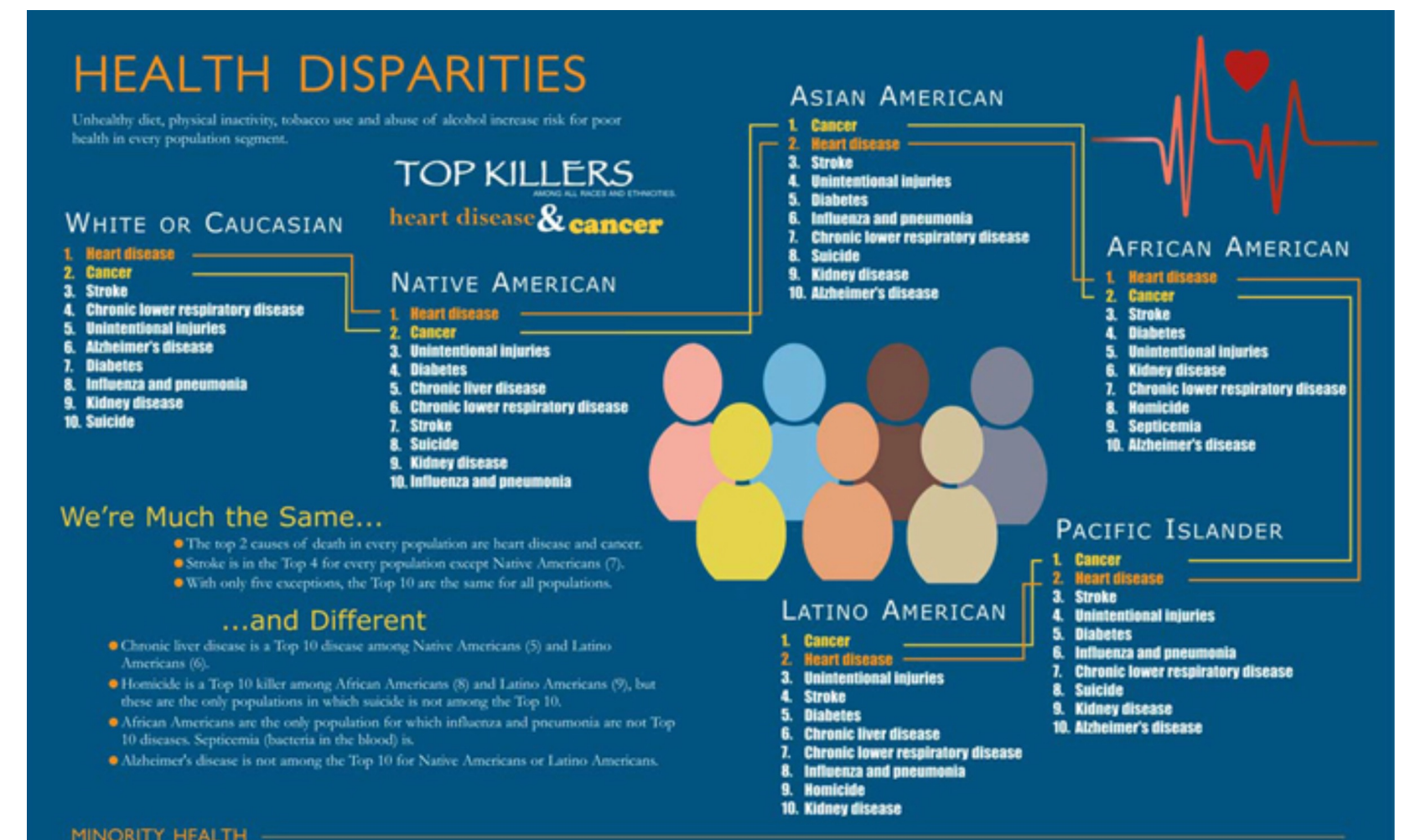
Bias



Health Disparities

Equity

- Cornerstone of innovation
- Improve access
- Reduce health disparities
- Proactive instead of reactive
 - Language
 - Disabilities
 - Race
 - Cultural norms
 - Social determinants of health



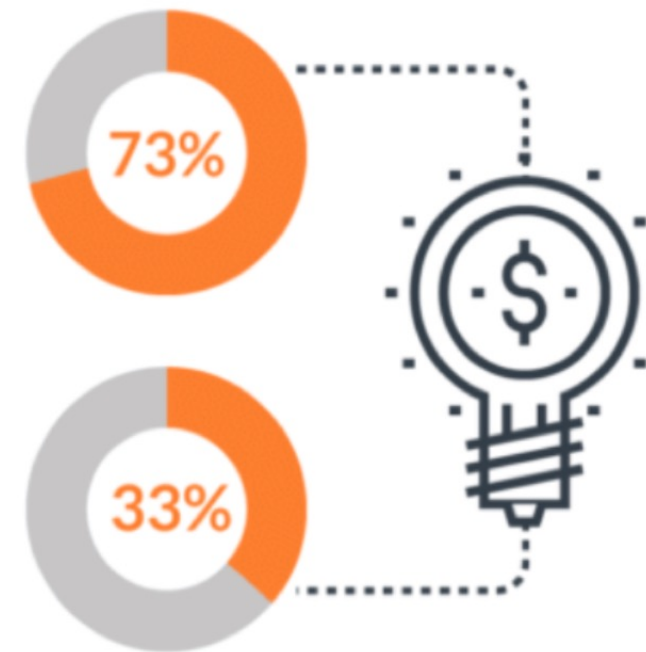
Equity

- Return on Investment

DIVERSITY PAYS

Companies with diverse leadership teams attain **73% more in revenue from innovation** than less diverse companies.¹

Companies with diverse boards and leadership are **33% more likely** to outperform less diverse companies on profitability.



Source: McKinsey & Company, <https://www.mckinsey.com/business-functions/organization/our-insights/delivering-through-diversity>

Regulatory

- Privacy
- Data security
- Data ownership
- Governance



Regulatory

- Privacy
 - Consent
 - Harm

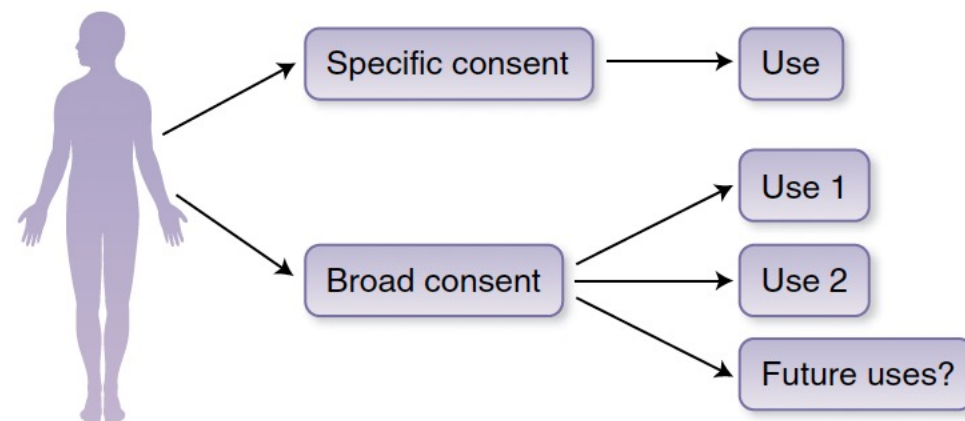


Fig. 1 | Consent models for health data. Specific consent allows individuals to control each specific use of their data. In broad consent, individual give blanket consent for all uses of their data.

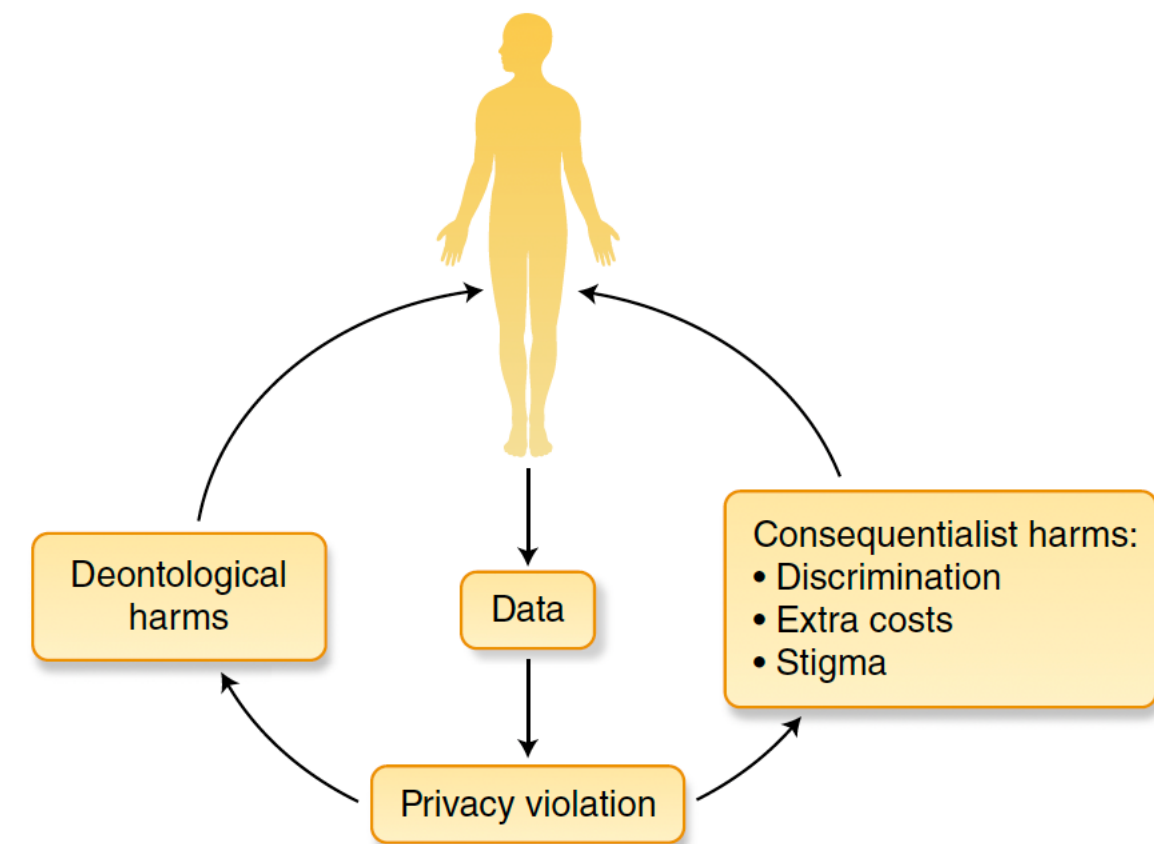
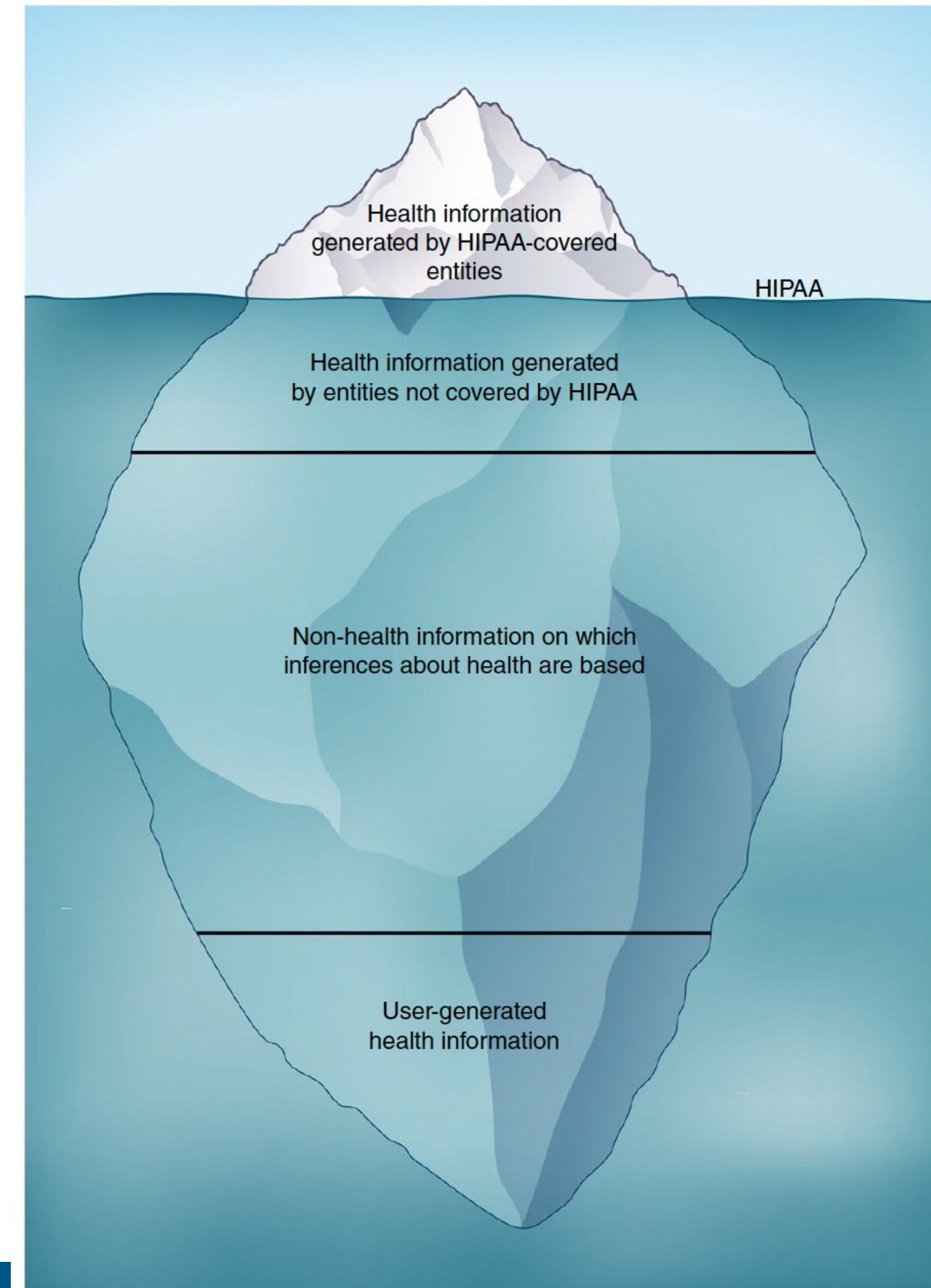


Fig. 3 | Potential harms to the individual if data is breached. The types of harm that can befall an individual once their data is leaked.

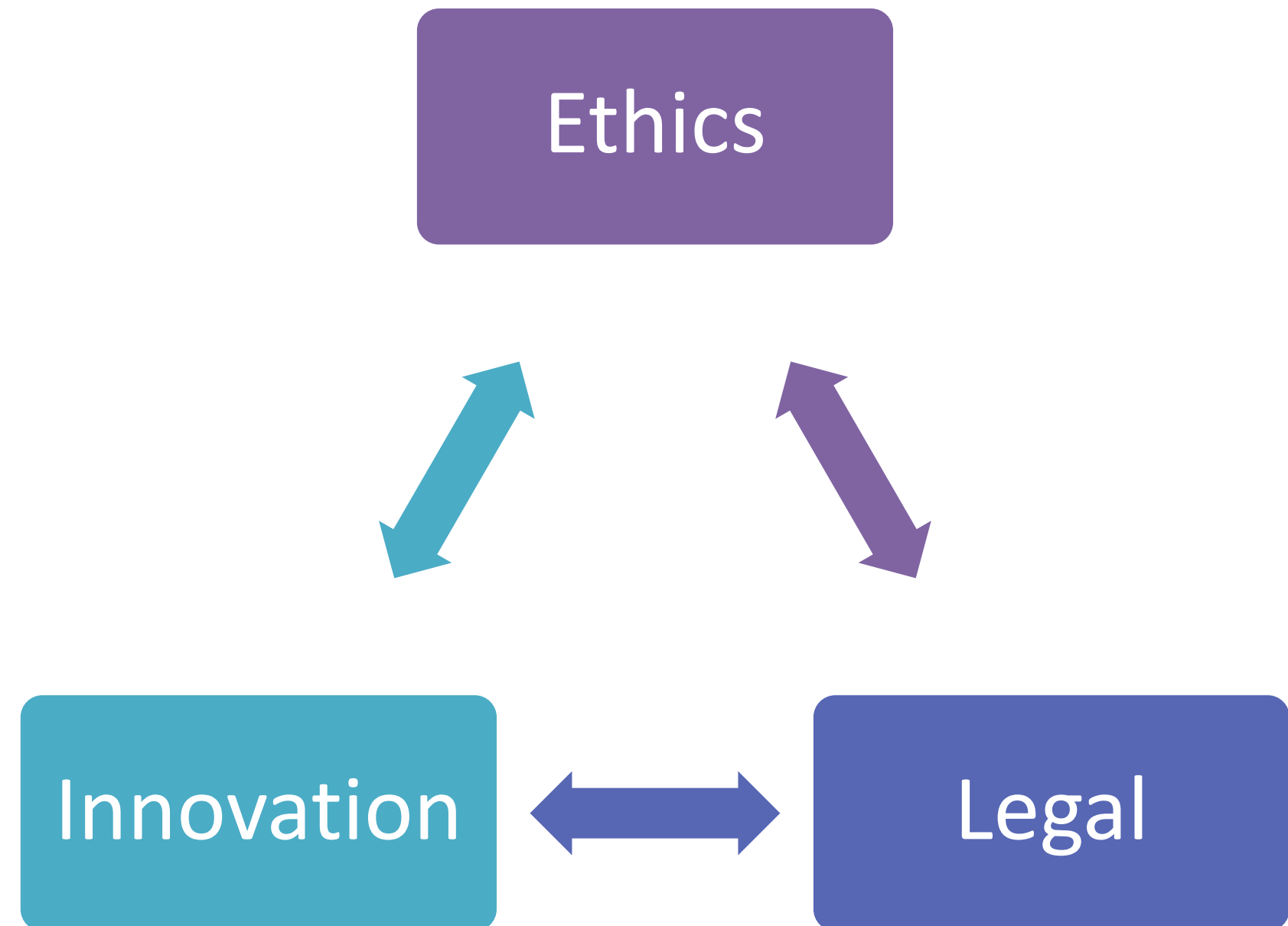
Regulatory

- Data security
 - Beyond hospital data
- Patient/Provider autonomy



Regulatory

- Governance
- Data ownership
- Data stewardship



Accountability

- Moral and legal accountability



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Artificial Intelligence in Health Care: Benefits and Challenges of Technologies to Augment Patient Care

GAO-21-7SP

Published: Nov 30, 2020. Publicly Released: Nov 30, 2020.

REVIEW article

Front. Artif. Intell., 30 May 2022
Sec. Medicine and Public Health

Volume 5 - 2022 | <https://doi.org/10.3389/frai.2022.879603>

This article is part of the Research Topic

Explainable Artificial Intelligence for Critical Healthcare Applications

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Transparency of AI in Healthcare as a Multilayered System of Accountabilities: Between Legal Requirements and Technical Limitations



Anastasiya Kiseleva^{1,2*}



Dimitris Kotzinos^{2†}



Paul De Hert^{1†}




Clicking Away Consent: Establishing Accountability and Liability Apportionment in Direct-to-Consumer Healthcare Artificial Intelligence

[Stephanie L. Lee](#)



The Ethics of Big Data and Artificial Intelligence in Perioperative Medicine: Is Unregulated AI Already at the Bedside?

Hailey Ivanson^{1,2} · Brannon Altenhofen¹ · Maxime Cannesson¹ · Cecilia Canales¹ 

Accepted: 11 June 2023

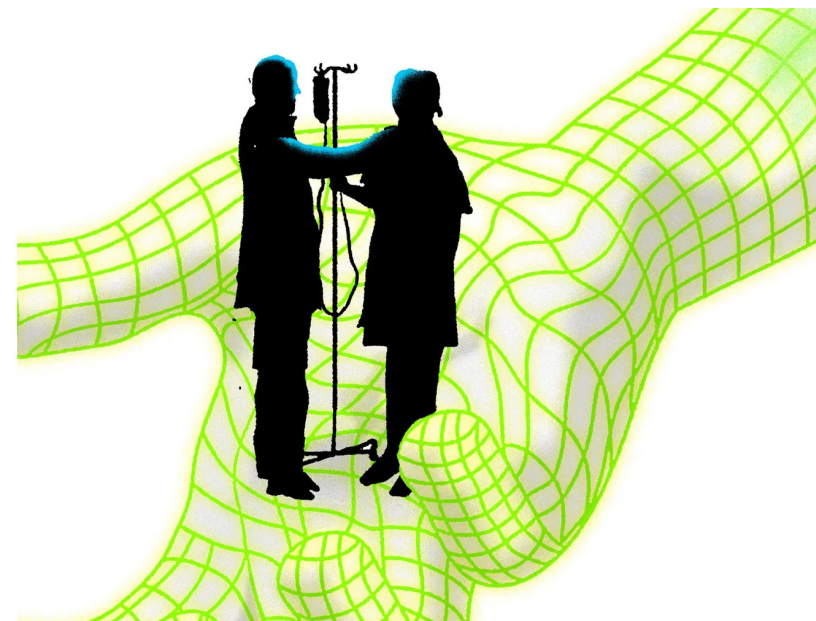
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Unregulated AI at the bedside?

When Doctors Use a Chatbot to Improve Their Bedside Manner

Despite the drawbacks of turning to artificial intelligence in medicine, some physicians find that ChatGPT improves their ability to communicate empathetically with patients.



Healthcare, Language Processing, Machine Learning

How Well Do Large Language Models Support Clinician Information Needs?

Stanford experts examine the safety and accuracy of GPT-4 in serving curbside consultation needs of doctors.

Mar 31, 2023 | Dev Dash, Eric Horvitz, Nigam Shah



Education

- New roles that health professionals must assume in delivering care:
 - **Evaluator:** Being able to evaluate when a technology is appropriate for a given clinical context and what inputs are required for meaningful results
 - **Interpreter:** Interpretation of knowledge and skills with a reasonable degree of accuracy including knowing potential sources of error, bias, or clinical inappropriateness
 - **Communicator:** Communication of results and underlying process in a way that patients and other health professionals can understand
- Competencies for understanding AI in a broader professional context:
 - **Stewardship:** Be a responsible steward for patient data to ensure basic trust between provider and patient
 - **Advocacy:** Understand the risks around data security and privacy—health care providers must be equipped to advocate for the development and deployment of ethical and equitable systems

NEW PUBLICATION

Toward Equitable Innovation in Health and Medicine: A Framework



Advances in biomedical science, data science, engineering, and technology are leading to high-pace innovation with potential to transform health and medicine. These innovations simultaneously raise important ethical and social issues, including how to fairly distribute their benefits and risks. The National Academies of Sciences, Engineering, and Medicine, in collaboration with the National Academy of Medicine, established the Committee on Creating a Framework for Emerging Science, Technology, and Innovation in Health and Medicine to provide leadership and engage broad communities in developing a framework for aligning the development and use of

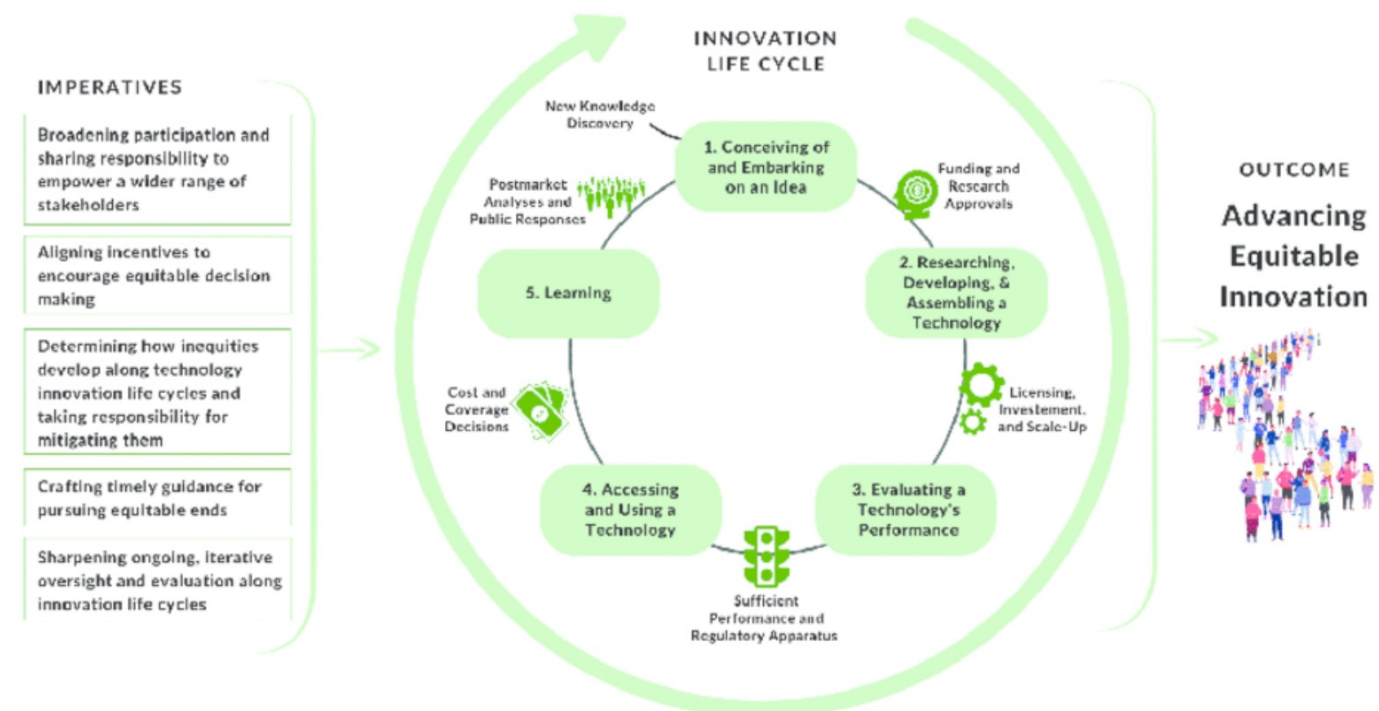


FIGURE S-1 The governance framework for aligning emerging science, technology, and innovation in health and medicine with ethical principles, emphasizing alignment with equity. The five imperatives (*left*) should be used to guide choices and actions depicted in a simplified conceptual model of the innovation life cycle (*center*) to support the desired outcome of advancing equitable innovation (*right*).

Framework

Recommendation	Actions	Desired Outcomes
Establish a National Vision and Priority Setting Body (Recommendation 1)	<ul style="list-style-type: none"> Foster leadership and coordination to align innovation with ethical principles that include equity. Convene a multistakeholder, cross-sectoral Equity in Biomedical Innovation Task Force. Build public and professional awareness of the role of equity in emerging science, technology, and innovation in health and medicine. 	<ul style="list-style-type: none"> A U.S. innovation system that translates emerging science and technology into innovative applications while addressing the needs of the system's full range of users and reducing health inequities. A set of initial priorities and goals for better aligning equity with innovation in health and medicine. New partnerships, synergies, and collaborations that increase the alignment of innovation with equity.
Reorient the Culture of Innovation (Recommendation 2)	<ul style="list-style-type: none"> Incorporate equity as a principle in required ethics training and practice. Where appropriate, require investigators to address equity associated with proposed work, including community engagement plans. Incorporate ethics and equity more fully into technology licensing and investment practices, including through equity-focused provisions. Require study designs and results to reflect a diverse range of anticipated postmarket users and contexts. 	<ul style="list-style-type: none"> Integration of ethical concerns, including stakeholder needs and values, into the formulation and conduct of research, decisions on funding and investments, and regulation and performance assessment. Policies and practices that recognize the importance of aligning technology development and use with equity.

Recommendation	Actions	Desired Outcomes
Incentivize Equity (Recommendation 3)	<ul style="list-style-type: none"> Draw on available governance levers to incentivize stakeholders to incorporate ethics and equity-focused assessments more fully into the process of emerging science, technology, and innovation in health and medicine. Based on the results of such assessments, incentivize stakeholders to make decisions and take action to address misalignments that arise. 	<ul style="list-style-type: none"> Governance of emerging science, technology, and innovation in health and medicine that addresses barriers to effective alignment with equity and supports actions and accountability to mitigate misalignments and inequities within and across institutions and actors.
Expand Participation in innovation (Recommendation 4)	<ul style="list-style-type: none"> Identify best practices and lessons for engaging with underserved and marginalized communities throughout the innovation life cycle. Where relevant to the research, identify aims and methods and establish sustained, bidirectional partnerships with affected and traditionally underrepresented communities. Incorporate policies and practices that recognize and value a community's contributions to and participation in research. Support the capacity of underserved and marginalized communities to engage in innovation. 	<ul style="list-style-type: none"> Practices and tools for addressing decision making across the innovation life cycle. Substantive participation in the innovation system from a wider range of users and communities, driven by enhanced trust, engagement, and capacity.
Develop Equity Science (Recommendation 5)	<ul style="list-style-type: none"> Catalyze the development of equity science and the validation of qualitative and quantitative methods, metrics, and benchmarks. Develop associated data collection and reporting systems and data quality standards. Adopt resulting equity science methods, metrics, and benchmarks to assess and monitor technology implications. 	<ul style="list-style-type: none"> An expanded set of evidence-based methods, metrics, and benchmarks for assessing the alignment of emerging science, technology, and innovation with equity while supporting informed decision making and action throughout the technology life cycle.
Create and Promote Context-Relevant Equity Playbooks (Recommendation 6)	<ul style="list-style-type: none"> Develop and disseminate specific guidance targeted to particular roles in the technology life cycle, types of inequity, or particular areas of emerging science and technology. 	<ul style="list-style-type: none"> Enhanced implementation of a governance framework for aligning emerging science, technology, and innovation with equity through actionable guidance on key questions, practices, and strategies in specific contexts.

A Look Forward

- Technology will evolve
- Equity at the center, not an afterthought
- Engage stakeholders
- Incorporate education



THANK YOU!

Questions?

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