THE ETHICS OF INTEGRATING MEDICAL AI INTO RESEARCH, PRACTICE, AND EDUCATION

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4 PRINCIPLES OF BIOMEDICAL ETHICS

- **Autonomy**
- **Beneficence**
- **Non-Maleficence**
- **Justice**

AUTONOMY: SELF-DETERMINATION

"acknowledge that person's right to hold views, to make choices, and to take actions based on personal values and beliefs"

- **Voluntary Participation**
  - No conflict of interest
  - No coercion or undue influence

- **Informed Consent**
  - Capacity to consent
  - Responsibilities of participant & researcher
  - Risks & benefits
  - Confidentiality, privacy & data storage processes

BENEFICENCE

"forms of action intended to benefit other persons."

- obligation to protect persons from harm
- A social/health value, desired outcome
- Maximize benefits and minimize risks
- Ensuring favorable risk-benefit ratio
- To individuals, community, scholarship

Federal Policy for the Protection of Human Subjects ('Common Rule')

Harm or discomfort **not greater** than that "ordinarily encountered in daily life or during routine physical or psychological examinations or tests"

NON-MALEFICENCE

Obligation "not to inflict harm intentionally"

Physical risks

- Bodily contact, side effects, falls

Psychological/emotional risks

- Feeling uncomfortable, embarrassed, upset

Social risks

- Loss of status, privacy and/or reputation

Legal risks

- Apprehension or arrest, subpoenas

EXAMPLES

- **Anonymity**
- Anonymous participant data
- Notions around privacy (person-centered)

- **Confidentiality**
- Security of data (data-centered)
- Who has access to your data
- Safeguards and procedures
- Limitations of confidentiality
- An extension of privacy

JUSTICE

"fair, equitable, and appropriate treatment in light of what is due or owed to persons"

- Historically excluded groups are not exploited
- Fair distribution of the benefits and burdens of research
- To ensure equitable and culturally competent research
- That all populations are included in research designs

What is Vulnerability?

There is no one definition for vulnerability

- Susceptibility to coercion or exploitation
- Increased risk of harm
- Diminished autonomy
- Capacity to protect own interests
- Historically excluded populations (systems of oppression)
- Balance need for protection with benefits of access, knowledge, ownership and protection

Aspects of Vulnerability

- Capacity to participate in research
- Population (mental illness, children, pregnant women)
- Experiences of marginalization and unethical research (e.g., LGBTQ, Indigenous, economically disadvantaged)
- Power differentials between researcher and subject

NUREMBERG CODE (1947)

Nazi Experimentation on Human Subjects

- **Informed Consent**
- **Absence of Coercion**
- **Beneficence**

The NEW ENGLAND
JOURNAL of MEDICINE

BOOK REVIEW

The Nazi Doctors and the Nuremberg Code: Human Rights in Human Experimentation

N Engl J Med 1993; 328:1429-1430 | May 13, 1993 | DOI: 10.1056/NEJM199305133281922

DECLARATION OF HELSINKI (1964)

World Medical Association

(Most Recent Revision: 2013)

- **Respect for the Individual**
- **Right to self-determination**
- **Right to make informed decisions**
- **Privacy & Confidentiality**

Milestone to the IRB Process

INTERNATIONAL JOURNAL OF PHARMACEUTICAL MEDICINE 2000; 14:279-281 279

ORIGINAL ARTICLE

World Medical Association Declaration of Helsinki

Ethical Principles for Medical Research Involving Human Subjects
Adopted by the 18th WMA General Assembly
Helsinki, Finland, June 1964
and amended by the
29th WMA General Assembly, Tokyo, Japan, October 1975
35th WMA General Assembly, Venice, Italy, October 1983
41st WMA General Assembly, Hong Kong, September 1989
48th WMA General Assembly, Somerset West, Republic of South Africa, October 1996
and the
52nd WMA General Assembly, Edinburgh, Scotland, October 2000

A. Introduction

1. The World Medical Association has developed the Declaration of Helsinki as a statement of ethical principles to provide guidance to physicians and other participants in medical research involving human subjects. Medical research involving human subjects includes research on identifiable human material or identifiable data.
2. It is the duty of the physician to promote and safeguard the health of the people. The physician's knowledge and conscience are dedicated to the fulfillment of this duty.
3. The Declaration of Geneva of the World Medical Association binds the physician with the words, 'The health of my patient will be my first consideration,' and the International Code of Medical Ethics declares that, 'A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.'
4. Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.
5. In medical research on human subjects, considerations related to the well-being of the human subject should take precedence over the interests of science and society.
6. The primary purpose of medical research involving human subjects is to improve prophylactic, diagnostic and therapeutic procedures and the understanding of the aetiology and pathogenesis of disease. Even the best proven prophylactic, diagnostic, and therapeutic methods must continuously be challenged through research for their effectiveness, efficiency, accessibility and quality.
7. In current medical practice and in medical research, most prophylactic, diagnostic and therapeutic procedures involve risks and burdens.
8. Medical research is subject to ethical standards that promote respect for all human beings and protect their health and rights. Some research populations are vulnerable and need special protection. The particular needs of the economically and medically disadvantaged must be recognized. Special attention is also required for those who cannot give or refuse consent for themselves, for those who may be subject to giving consent under duress, for those who will not benefit personally from the research and for those for whom the research is combined with care.
9. Research Investigators should be aware of the ethical, legal and regulatory requirements for research on human subjects in their own countries as well as applicable international requirements. No national ethical, legal or regulatory requirement should be allowed to reduce or eliminate any of the protections for human subjects set forth in this Declaration.

B. Basic principles for all medical research

10. It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject.
11. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and on adequate laboratory and, where appropriate, animal experimentation.

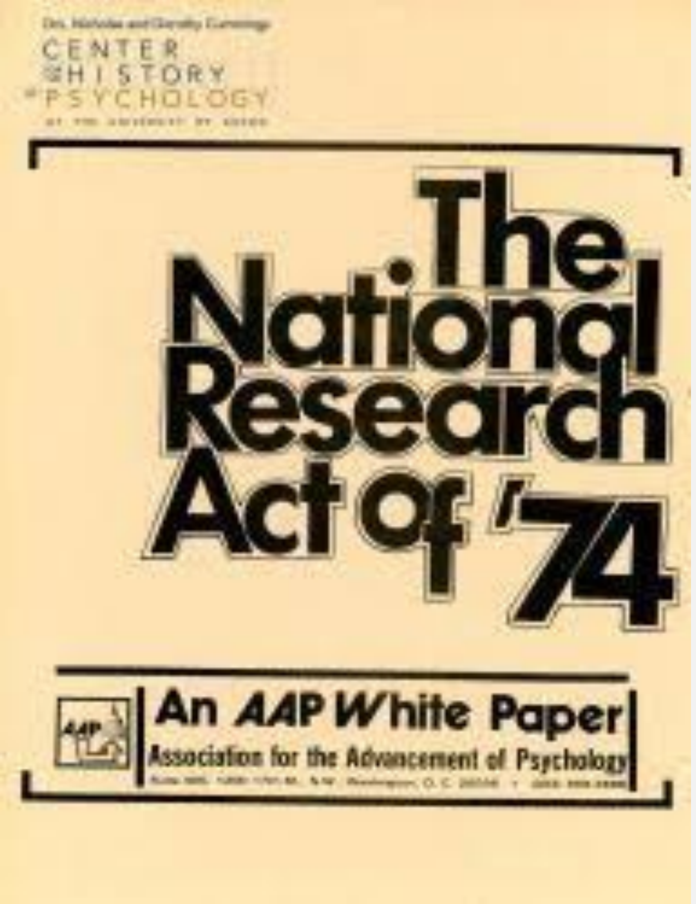
1364-9027 © 2000 LIPPINCOTT WILLIAMS & WILKINS

NATIONAL RESEARCH ACT (1974)

Created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- Guidelines for human subject research
- Oversee and regulate medical experiments
- Formularized regulations through local IRBs

    (Office of Human Research Protections)



CENTER
HISTORY
PSYCHOLOGY

The National Research Act of '74

An AAP White Paper
Association for the Advancement of Psychology

BELMONT REPORT (1978)

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

- *Tuskegee Syphilis Experiment*

- Respect for Persons, Beneficence and Justice
- Informed Consent
- Assessment of Risks & Benefits
- Selection of Subjects

The Belmont Report

Current AI Trends in Healthcare Industry

This slide contains information regarding the current trends that are prevailing in healthcare industry in context to artificial intelligence. The present AI healthcare trends aims in improving overall patient and medical practitioner relationship, reduce clinical services cost.

Patient Centric Approach

- AI assisted high quality care to patients
- Electronic healthcare reports and smartphone apps offers at home health solutions
- Add text here

Data Driven Healthcare

- AI allows data compilation and for clinical purpose- medical research and review
- Detecting effective treatments based on patient's relevant health history data
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Enhanced Healthcare Communication

- AI assisted apps aiding patients to chat with doctors, appointment booking
- Decreased medical errors
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Medical Diagnostic Imaging

- AI assisted imaging useful for detecting and screening vision threatening eye diseases, serious heart and brain strokes, lesions in lungs and liver
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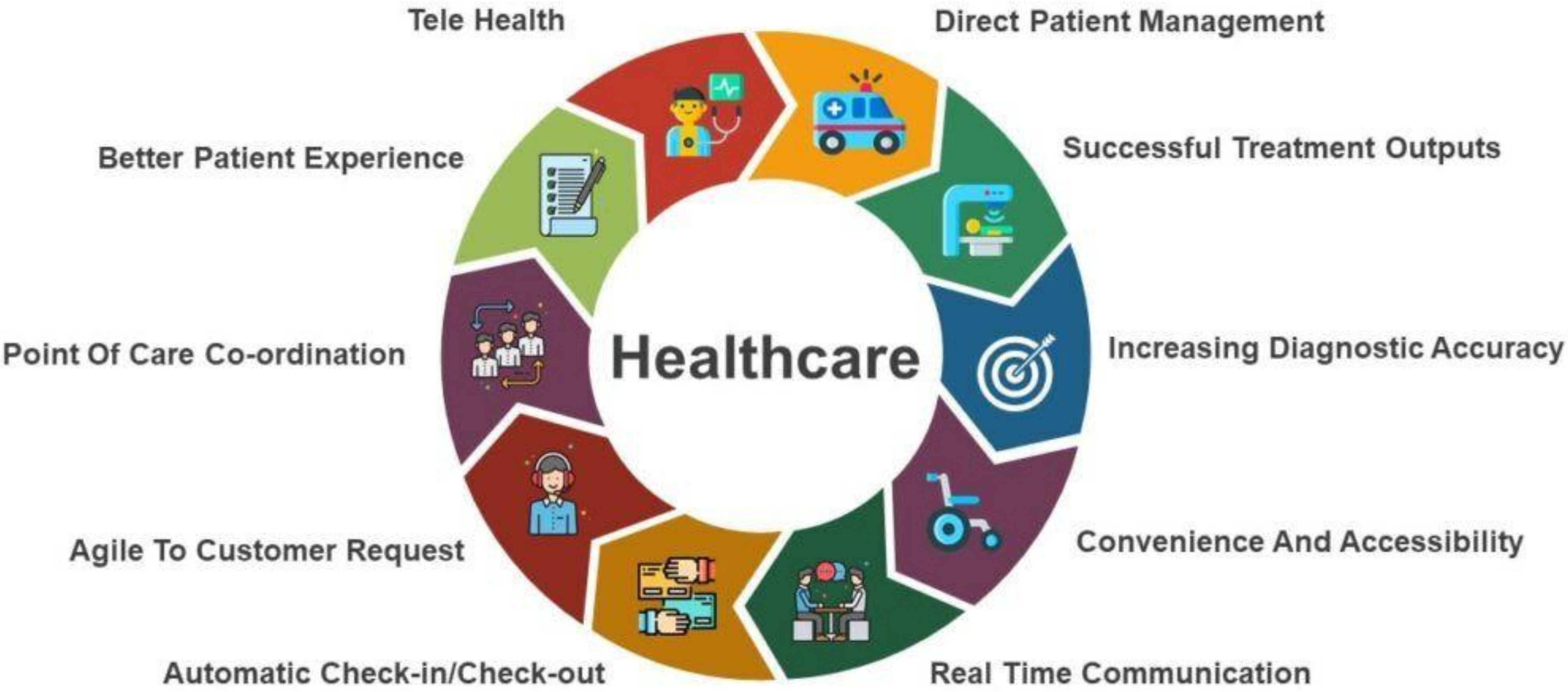


Healthcare

Tele Health

Direct Patient Management

Successful Treatment Outputs

Increasing Diagnostic Accuracy

Convenience And Accessibility

Real Time Communication

Automatic Check-in/Check-out

Agile To Customer Request

Point Of Care Co-ordination

Better Patient Experience

ETHICAL BENEFITS

- Reduce administrative tasks of physicians
- Facilitate workflow
- Accurate and earlier diagnoses and treatment options
- Reduce human error and bias
- AI can be used to predict risk factors
- Can obtain information about social contexts that influence care
- More personalized and value driven care
- Can reach rural or remote communities through eHealth platforms and telehealth
- Older adults, disabled persons

Medical AI Ethics

- Data Ownership (who owns the data; right to ownership)
- Data Protection (confidentiality and privacy; HIPAA)
- Data Sharing
- Accuracy (efficiency, reliability, consistency)
- Transparency (to whom)
- Bias
- Informed Consent (patient autonomy and self-determination)
- Trust (patient-provider)
- Cost (implementation of AI)
- Accountability and Responsibility (of researchers, physicians, developers)
- Legislation and Regulation

Medical AI Ethics And Social Justice

Bias: How do biases influence practice?

Trust: How does AI influence the patient-provider relationship?

Fairness: Who will have access to AI technologies?

Bias of Medical AI

- Humans’ implicit and explicit biases filter into AI algorithms
- Historical exclusion in clinical trials (back to research ethics)
- Biobanks that uphold samples from predominantly white men
- Questions that are normative and do not consider complex, intersectional identities
- Limited knowledge, training
- So how will AI/ML integrate these experiences without prior knowledge?

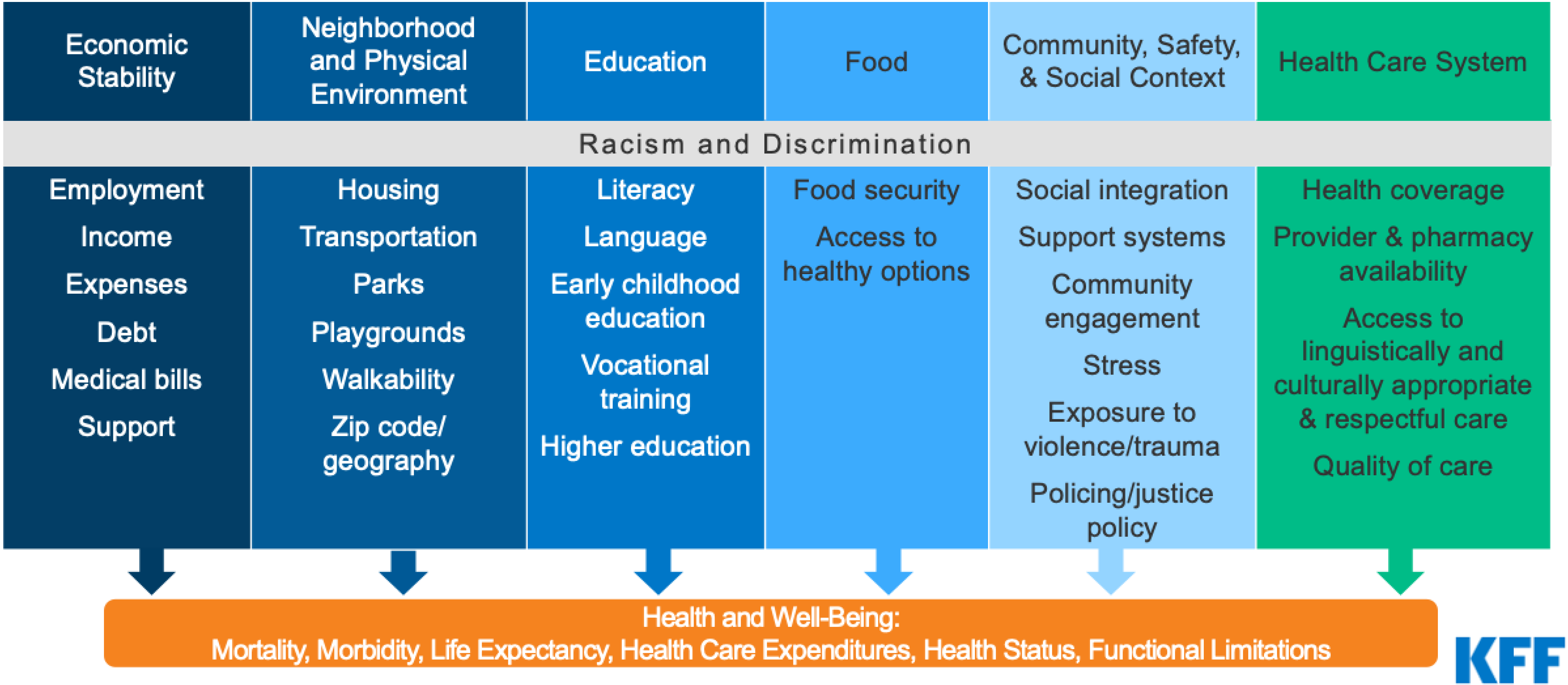
How do we then transition to applying these algorithms to diverse populations?

Intersectionality

- Individuals belong to multiple social categories/ identities
- Interconnectedness of social categorizations (race, class, gender)
- Overlapping experiences of discrimination and privilege

Figure 1

Health Disparities are Driven by Social and Economic Inequities

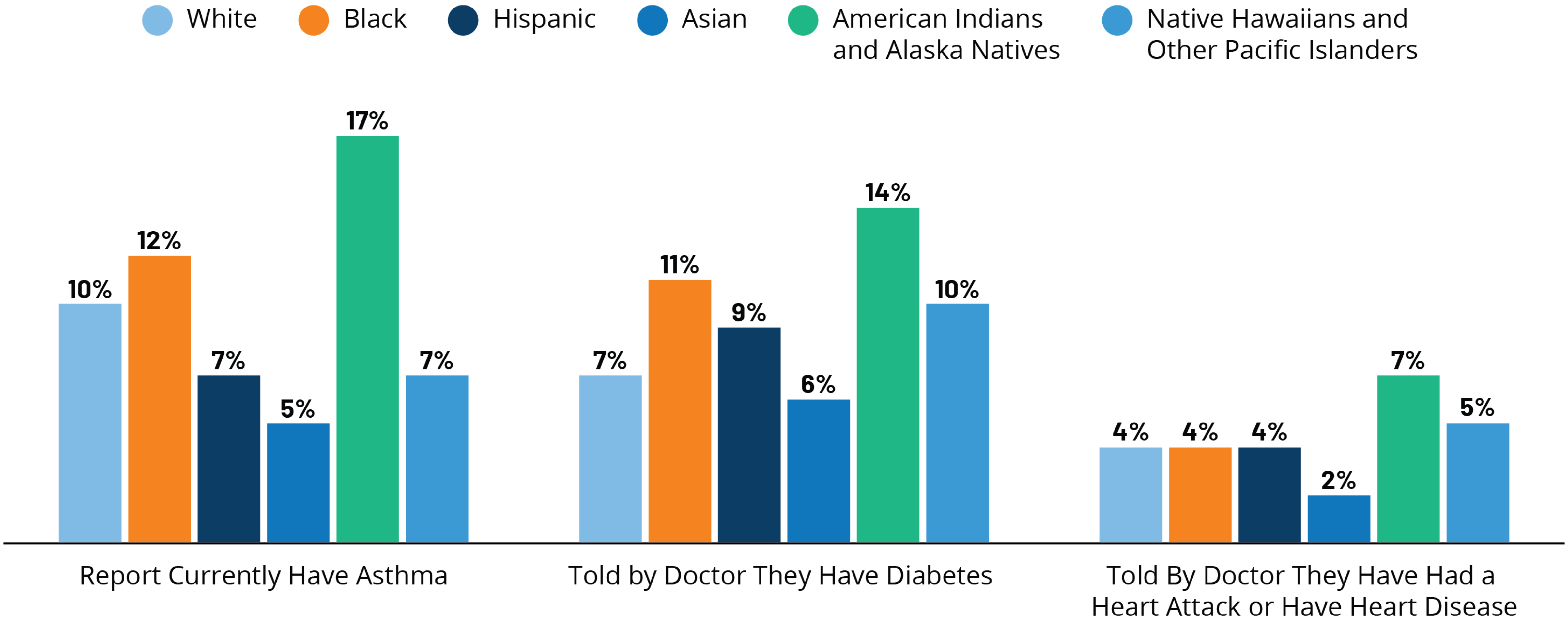


<table>
<tr><th>Economic Stability</th><th>Neighborhood and Physical Environment</th><th>Education</th><th>Food</th><th>Community, Safety, & Social Context</th><th>Health Care System</th></tr>
<tr><td colspan="6">Racism and Discrimination</td></tr>
<tr><td>Employment
Income
Expenses
Debt
Medical bills
Support</td><td>Housing
Transportation
Parks
Playgrounds
Walkability
Zip code/ geography</td><td>Literacy
Language
Early childhood education
Vocational training
Higher education</td><td>Food security
Access to healthy options</td><td>Social integration
Support systems
Community engagement
Stress
Exposure to violence/trauma
Policing/justice policy</td><td>Health coverage
Provider & pharmacy availability
Access to linguistically and culturally appropriate & respectful care
Quality of care</td></tr>
</table>

Health and Well-Being:
Mortality, Morbidity, Life Expectancy, Health Care Expenditures, Health Status, Functional Limitations

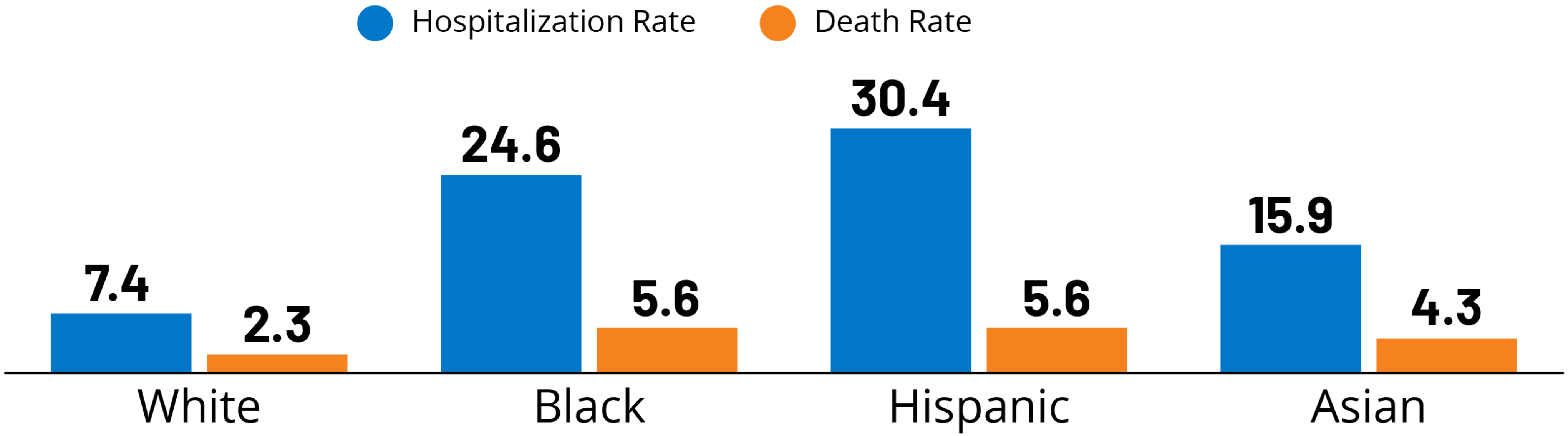
KFF

Percent of Nonelderly Adults with Selected Health Conditions by Race/Ethnicity, 2018



COVID-19 Hospitalization and Death Rates among Active Epic Patients by Race/Ethnicity

Rate per 10,000, as of July 2020



Total Active Patients (millions)	34.1	7.0	5.1	1.4

NOTE: Rates for Black, Hispanic, and Asian patients are statistically significantly different from White patients at the $p<0.05$ level.
Persons of Hispanic origin may be of any race but are categorized as Hispanic; other groups are non-Hispanic.
Data for other racial groups not shown due to insufficient data.
SOURCE: Epic and KFF analysis of Epic Health Record System COVID-19 related data as of July 2020.

So Back to AI….

- With inherent biases related to algorithms that may overlook:

- Diverse health-related experiences
- Social determinants of health
- Health disparities and health inequities
- Actual follow-up and preventative care
- The complexities of care – it is not a single solution

Trust in Medical AI

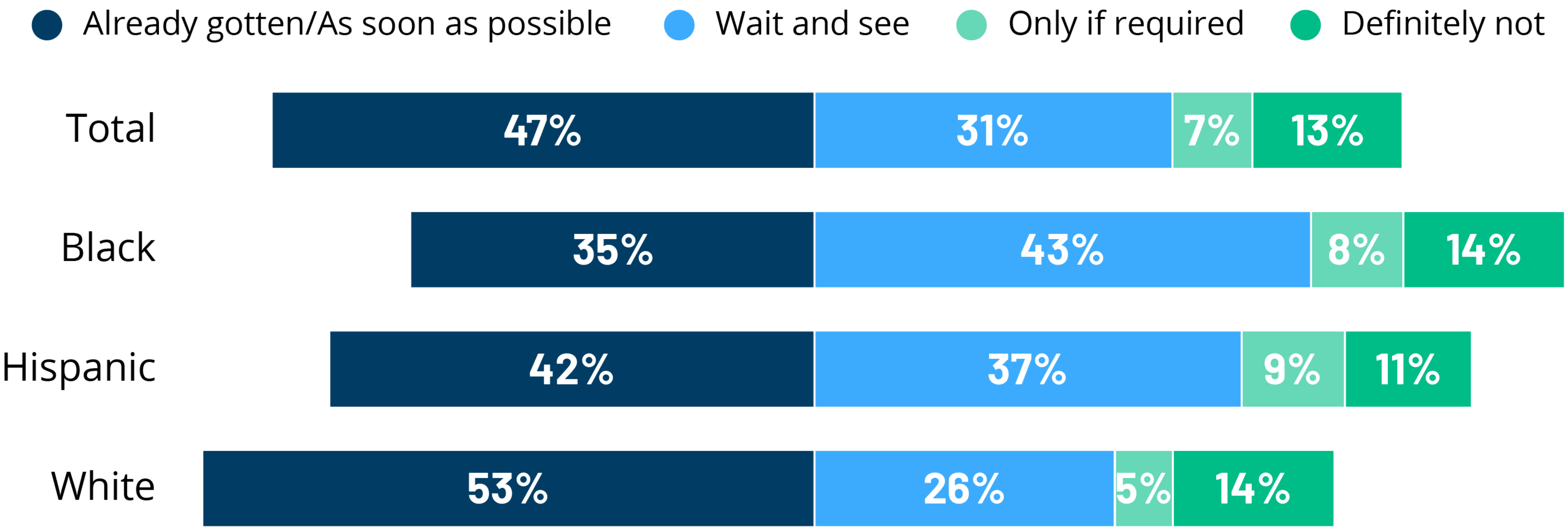
- Bias of AI stems from bias of providers
- Distrust in healthcare, fears of discrimination, avoidance of care
- Lack of training and education
- LGBTQIA+ persons, people of color, disabled persons (e.g.)
- Will bias of AI further distrust in healthcare?
- We know that physician-provider trust is KEY to preventative care
- We see this with vaccine hesitancy

Two Issues:

(1) AI/ML may reduce provider autonomy – lessen relationship

(2) The bias of AI/ML may further distrust prior to the office visit

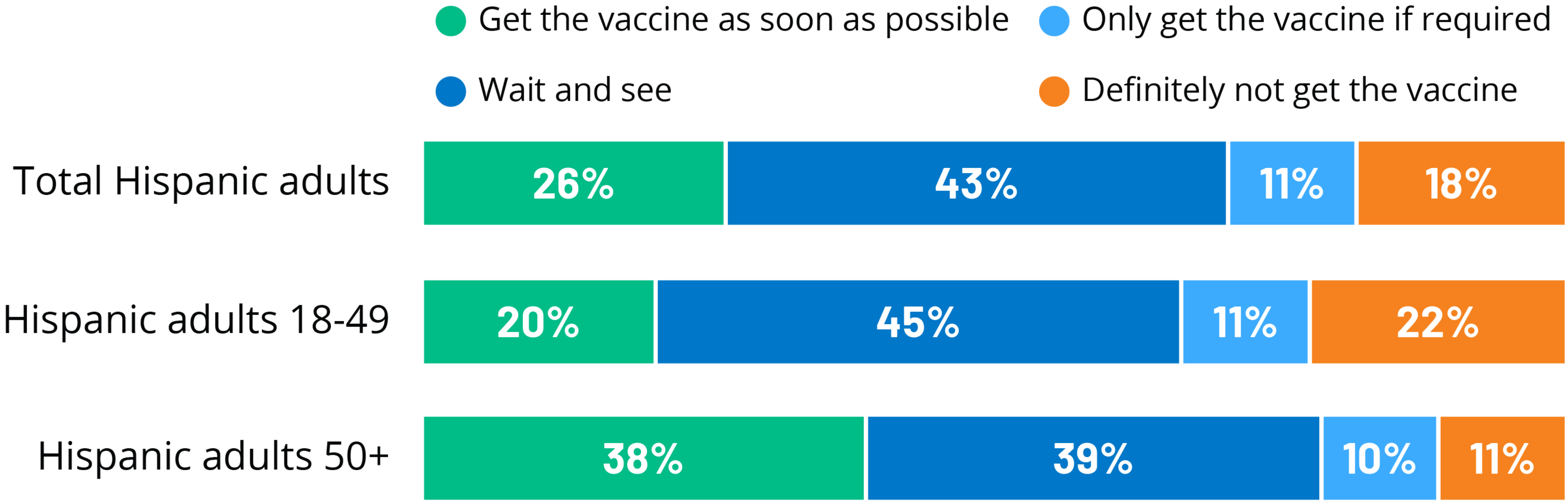
Black, Hispanic Adults Most Likely To Want To "Wait And See" Before Getting a COVID-19 Vaccine



Percent who say they will get a COVID-19 vaccine:

Larger Share Of Younger Hispanic Adults Express Vaccine Hesitancy

When a vaccine for COVID-19 is approved and widely available to anyone who wants it, do you think you will…?



How will medical AI impact the trustworthy relationship to strengthen preventative care?

How will AI/ML consider the complex lived experiences?

Fairness in Medical AI – Health Care Settings

- Who will have access to AI/ML developments?
- Less resourced hospital settings (community hospitals) that are predominantly utilized by historically excluded populations?
- 1 out of 5 people use a community hospital
- Large highly resourced academic medical centers

Fairness in Medical AI

2021 – Pew Research Report:

7% of Americans (23 million people) do not use the Internet

23% do not have access to broadband connection at home

27% do not own a laptop or desktop

44% of households with incomes below $30,000 don't have broadband

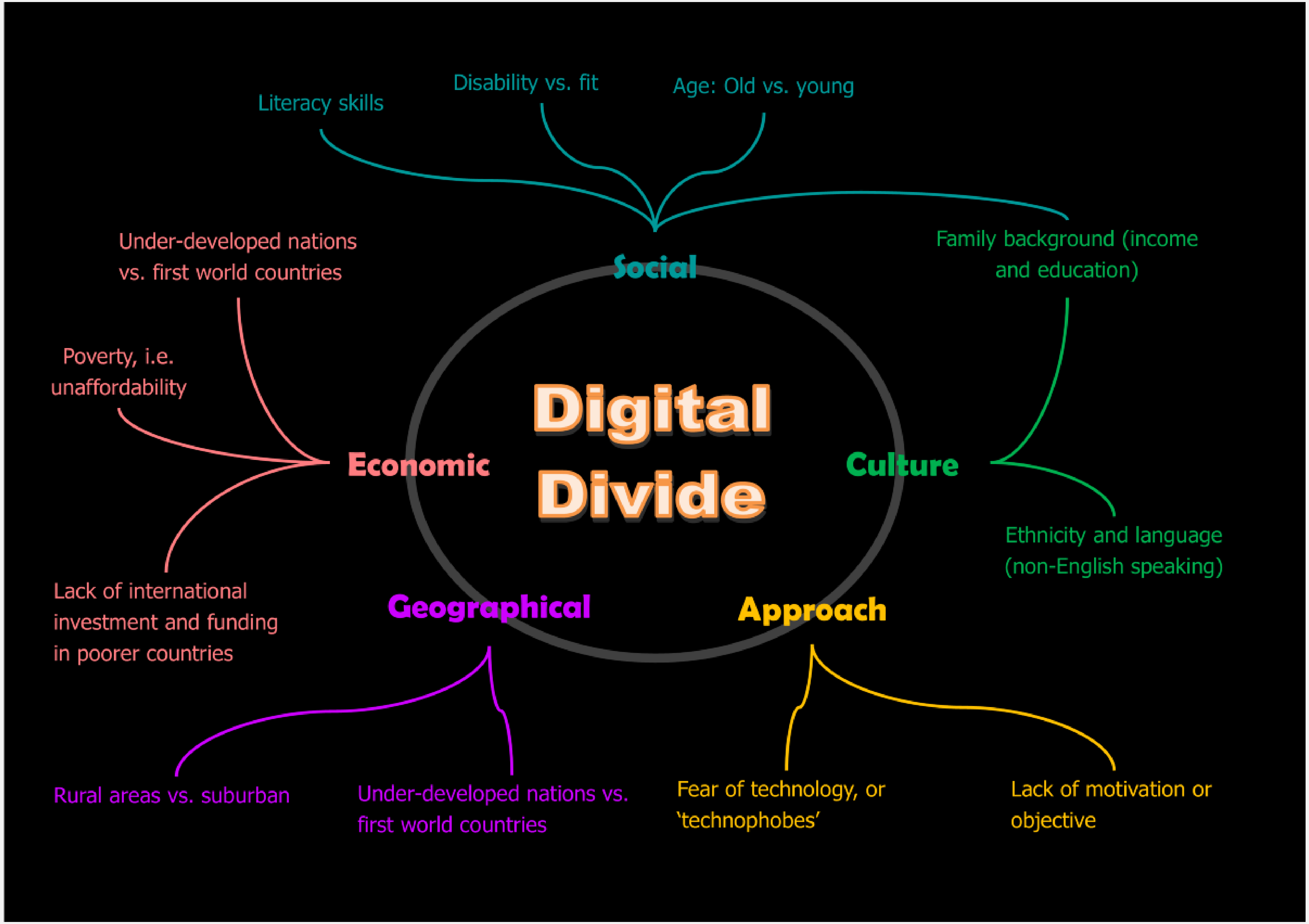
40% of schools lack broadband connections

60% of health care facilities outside metropolitan areas

Fairness in Medical AI – Patient-Centered Care

- Issues connected to the digital divide
- The digital divide: technology, internet access, digital literacy

- Cost for companies and cost to individuals (classism)
- Seniors who report chronic health conditions, disability, or physical limitations that prevent them from full utilization (ageism)
- AI may have restrictions for those living with disabilities (ableism)



Digital Divide

Social

- Literacy skills
- Disability vs. fit
- Age: Old vs. young
- Family background (income and education)

Culture

- Ethnicity and language (non-English speaking)

Approach

- Fear of technology, or 'technophobes'
- Lack of motivation or objective

Geographical

- Rural areas vs. suburban
- Under-developed nations vs. first world countries

Economic

- Under-developed nations vs. first world countries
- Poverty, i.e. unaffordability
- Lack of international investment and funding in poorer countries

IMPLICATIONS

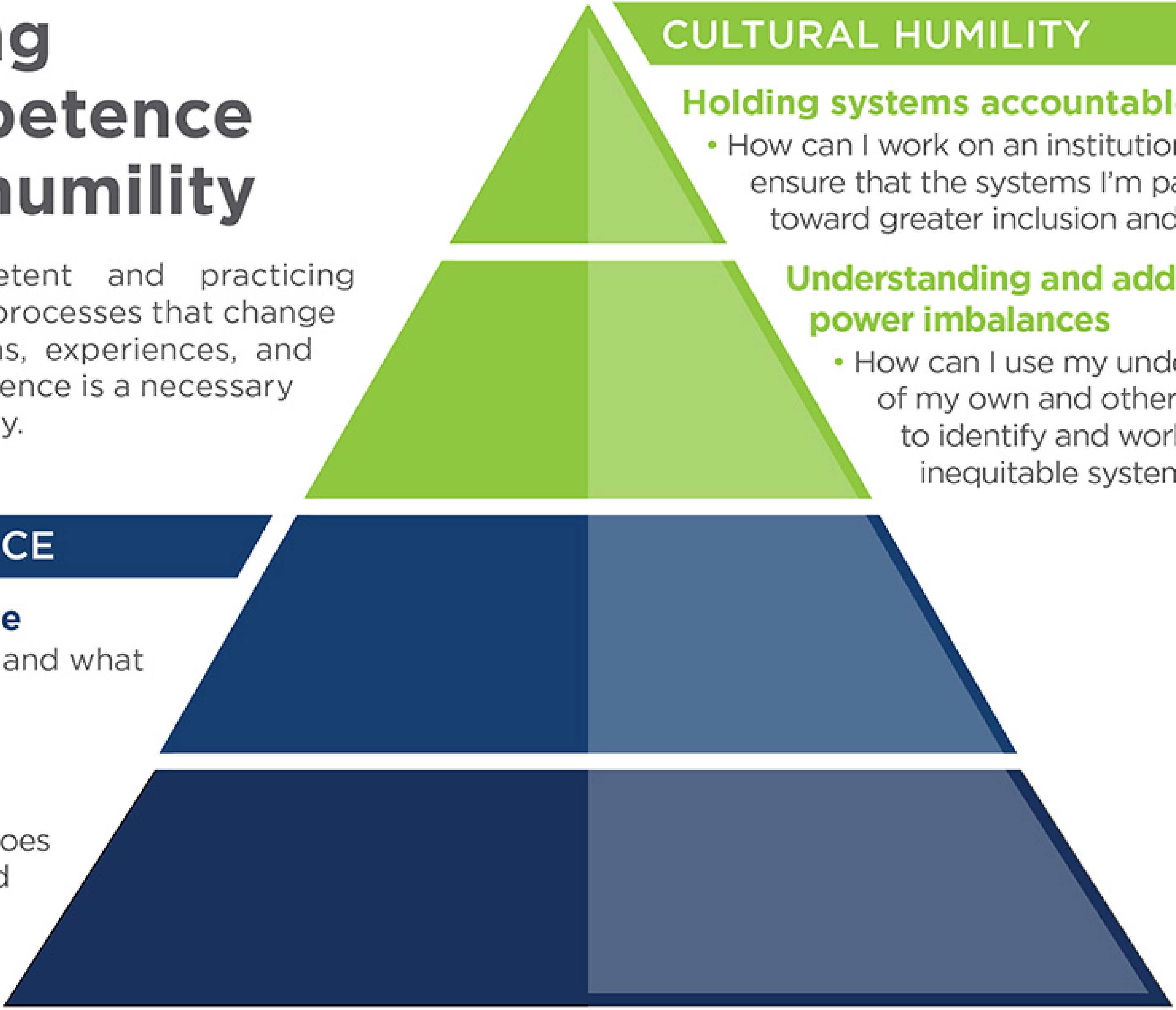
- Training on public health and health equity
- Social determinants of health conversations
- Diversity in bioethics, in AI/ML developers, in healthcare
- Community advisory boards
- Collaboration of AI with patient-centered care

Cultural Humility In Medical AI

- Developing trust, familiarity and mutual respect
- Capacity building
- Stages & Types of Informed Consent
- Data Collection Approaches and Methods
- Community-Based Research
- Context-specific resources
- CABs: Community Advisory Boards
- Dissemination Practices & Knowledge Mobilization

Understanding cultural competence and cultural humility

Becoming culturally competent and practicing cultural humility are ongoing processes that change in response to new situations, experiences, and relationships. Cultural competence is a necessary foundation for cultural humility.



CULTURAL HUMILITY

Holding systems accountable

- How can I work on an institutional level to ensure that the systems I'm part of move toward greater inclusion and equity?

Understanding and addressing power imbalances

- How can I use my understanding of my own and others' cultures to identify and work to disrupt inequitable systems?

CULTURAL COMPETENCE

Gaining cultural knowledge

- What are other cultures like, and what strengths do they have?

Developing cultural self-awareness

- What is my culture, and how does it influence the ways I view and interact with others?

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Q&A

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