Artificial Intelligence and Machine Learning, Systems Integration and Interoperability

Ethics, Evidence, and Equity

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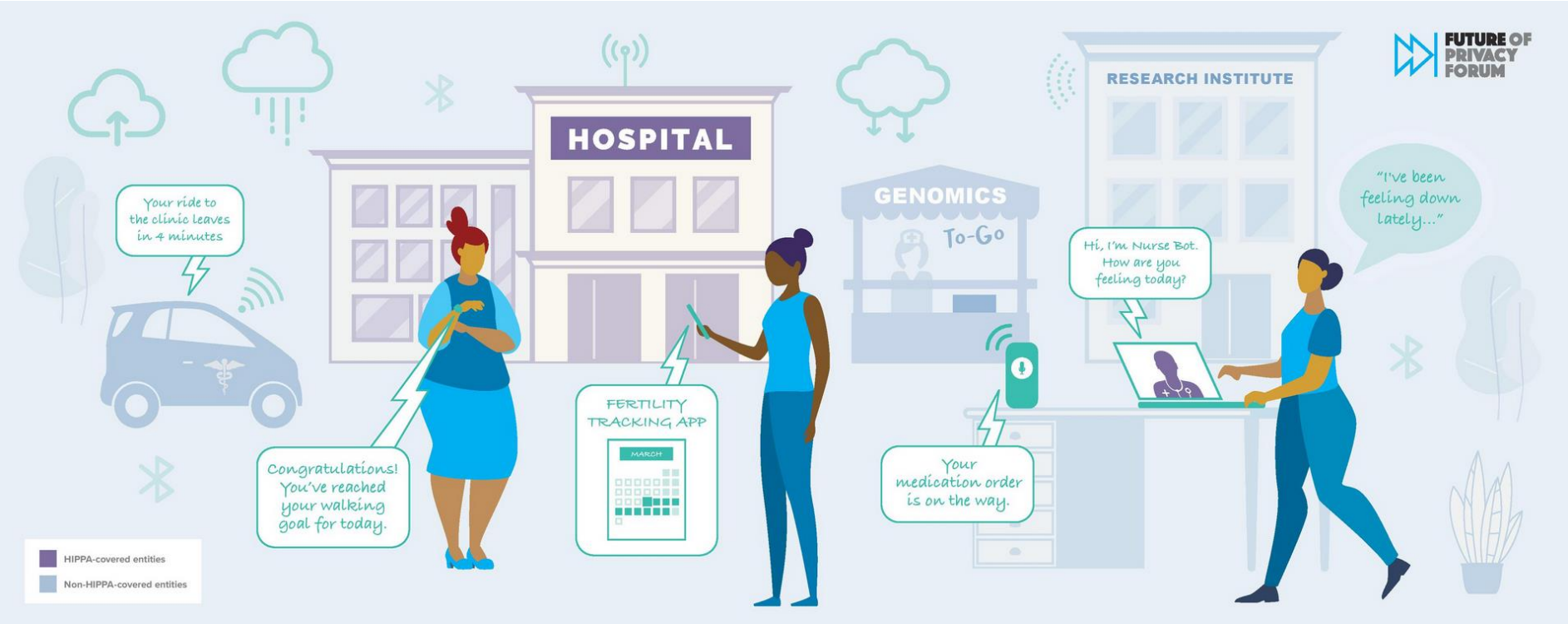
Patient information is everywhere



Our Vision: AI and the Quadruple Aim

Patients' rights are respected, they are empowered to make an informed decision about the use of AI in their care, and research demonstrates that its use improves their clinical outcomes, quality of life and satisfaction.

Health care AI addresses high-priority clinical needs and advances health equity by closing disparities rooted in historical and contemporary injustices and discrimination, benefitting all patients regardless of demographic or socioeconomic factors.

Oversight and regulatory structures account for the risk of harm and benefit posed by health care AI systems. Payment and coverage is conditioned on complying with appropriate laws and regulations, providing appropriate levels of clinical validation and high-quality evidence, and advancing affordability and access.

Physicians are engaged in developing and implementing health care AI tools that augment their ability to provide high-quality clinically validated health care to patients and improve their well-being. Barriers to adoption such as lack of education on AI and liability and payment issues are resolved.

Ethics, Evidence, and Equity Framework

Ethics

Physician practices uphold the fundamental values of medicine.

Evidence

AI products used in practice meet the highest standards for scientific inquiry in design and development; provide clinically relevant evidence of safety and effectiveness.

Health equity

All people live in thriving communities where resources work well, systems are equitable and create no harm, everyone has the power to achieve optimal health, and all physicians are equipped with the consciousness, tools, and resources to confront inequities as well as embed and advance equity within and across all aspects of the health care system.

Translating principles into practice

- Clearly define roles and responsibilities
- Align on best practices, oversight, and accountability
- Engage diverse patient and physician stakeholders throughout the process

RESPONSIBILITY	DEVELOPER	DEPLOYER	PHYSICIAN
PLANNING AND DEVELOPMENT			
Ensure the AI system addresses a meaningful clinical goal	○		○
Ensure the AI system works as intended	○		○
Explore and resolve legal implications of the AI system[1] prior to implementation and agree upon appropriate professional and/or governmental oversight for safe, effective, and equitable use of and access to health care AI	○	○	○
Develop a clear protocol to identify and correct for potential bias	○	○	○
Ensure appropriate patient safeguards are in place for direct-to-consumer tools that lack physician oversight	○		
IMPLEMENTATION AND MONITORING			
Make clinical decisions such as diagnosis and treatment			○
Have the authority and ability to override the AI system			○
Ensure meaningful oversight is in place for ongoing monitoring		○	○
Ensure the AI system continues to perform as intended through performance monitoring & maintenance	○	○	
Ensure ethical issues identified at the time of purchase and during use have been addressed[2]		○	
Ensure clear protocols exist for enforcement and accountability, including a clear protocol to ensure equitable implementation	○	○	○

1. Such as issues of liability or intellectual property

2. Including but not limited to safeguarding patients' and other individuals' privacy interests and preserving the security and integrity of personal information; securing patient consent; and providing patients' access to records"

Guidance for physicians

Does it work?

- The AI system meets expectations for ethics, evidence, and equity. It can be trusted as safe and effective.

Does it work for my patients?

- The AI system has been shown to improve care for a patient population like mine, and I have the resources and infrastructure to implement it in an ethical and equitable manner.

Does it improve health outcomes?

- The AI system has been demonstrated to improve outcomes.

All parties are responsible for ensuring that stakeholders are held accountable for meeting these expectations.

Does it work?

The AI system meets expectations for ethics, evidence, and equity. It can be trusted as safe and effective.

The AI system

- was developed in response to a clearly defined clinical need identified by physicians and it addresses this need;
- was designed, validated, and implemented with the physician's perspective in mind.
- was validated through a process commensurate with its risk.
- has been validated analytically and scientifically. An AI system that diagnoses or treats (i.e., is considerable risk) has been prospectively clinically validated in an appropriate care setting.
- It has been tested for usability by participants who are demographically representative of end users.
- The data and validation processes used to develop the AI system are known (i.e., publicly available).
- It has received FDA approval or clearance (if applicable).

The developer

- has demonstrated that a predictive model predicts events early enough to meaningfully influence care decisions and outcomes.
- has an established commitment to data quality and security.
- has identified and addressed ethical considerations (e.g., an ethical technology assessment).
- has robust data privacy and security processes in place for any patient data collected directly or from practice settings (i.e., for research or monitoring purposes).
- has identified and taken steps to address bias and avoided introducing or exacerbating health care disparities when testing or deploying the AI system, particularly among vulnerable populations.
- has ensured that the characteristics of the training dataset are known, and that the dataset reflects the diversity of the intended patient population, including demographic and geographic characteristics.
- has a transparent revalidation process in place for evaluating updates throughout the AI system's lifecycle.

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- The AI system has been validated in a population and health care setting that reflects my practice.
- Continuous performance monitoring is in place in my practice to identify and communicate changes in performance to the developer
- It can be integrated smoothly into my current practice, will improve care, and will enhance my relationship with patients
- The AI system has been beta tested in different populations prior to implementation to identify hidden bias.

Does it improve health outcomes?

The AI system has been demonstrated to improve outcomes.

- Clinical performance and patient experience data demonstrate its positive impact on health outcomes, including quality of life measures, through qualitative and quantitative research methods.
- The AI system maximizes benefits and minimizes harm to patients, with particular attention to potential impacts on historically marginalized communities.
- The AI system improves patient well-being and experience, as defined by a diverse patient population.
- The AI system adds value to the physician–patient relationship, enabling patient-centered care.
- If the AI system only improves patient outcomes for specific populations, this limitation is transparent.
- Barriers to access are found and addressed to improve outcomes for all patients who can benefit.

Health Equity and CPT®

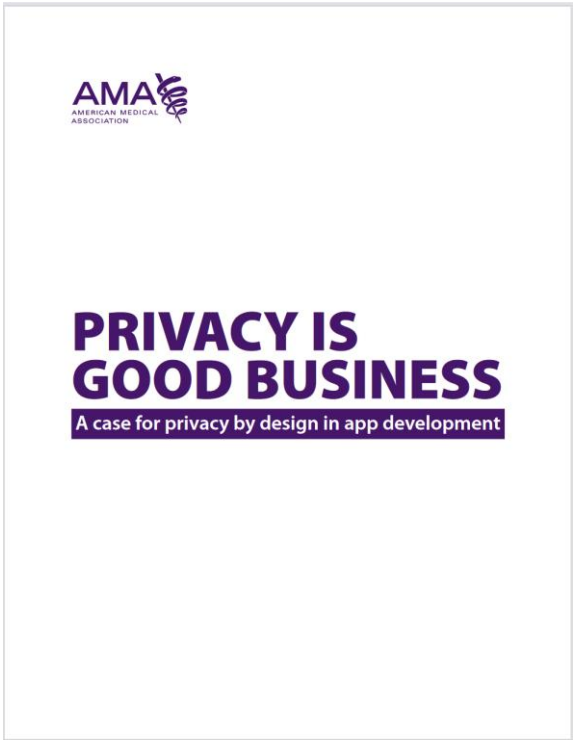
- **Disparate outcomes** in chronic conditions persist among distinct and intersecting marginalized populations
- **Vision: Increased contextual knowledge** across disciplines and organizations **informs physicians and others and improves health outcomes.**
- **How: Address inequities** in innovation (eg, differential access to technologies; variations in adoption and use; algorithmic biases) **that impact health outcomes**
  - Cast a wider net to engage new entrants to participate in CPT® (advisors; innovators)
- **Opportunity: View inequities as a catalyst** for developing innovative solutions to reduce social inequalities and improve outcomes
  - Rapid response to vaccine and testing advances during the COVID-19 pandemic
  - Support changes in telehealth and remote care technology
  - Create and disseminate AI taxonomy → nomenclature (CPT®) reflects the changes

AMA Privacy Principles

- Consumers are increasingly aware of and concerned about their lack of control over data.
- It is time to shift responsibility for privacy from the consumer to the company holding the data, with particular attention to harm mitigation.
  - Promote individuals' confidence in the systems we establish to help keep people safe and healthy.
  - Encourage uptake of innovative technologies.
  - Help ensure that steps we take now will not unfairly and disproportionately impact marginalized populations down the road.
- Available here: https://www.ama-assn.org/system/files/2020-05/privacy-principles.pdf

New AMA Resource for App Developers

- App developers are often unaware of or lack the guidance needed to utilize industry best practices for data privacy.
- Resource focuses on **privacy by design**
  - Business case for privacy
  - How privacy controls advance equity
  - Checklist for developers translating AMA Privacy Principles
- Available here: https://www.ama-assn.org/system/files/privacy-principles-by-design.pdf



Introducing *In Full Health*

What is *In Full Health*?

The *In Full Health* initiative seeks to provide a **framework** for shared understanding and a **community** for stakeholders committed to **learning and action** to center equity within their health innovation investment, development, and purchasing efforts.

Who is invited to join the *In Full Health* Learning & Action Community?

- Asset allocators investing in health innovation funds
- Funders of health innovation companies
- Developers of health innovation products & services
- Purchasers of health innovation solutions
- Influencers of health innovation

InFullHealth.org

Physicians' powerful ally in patient care