Special Insight on the Ethical & Legal Aspects of Artificial Intelligence

In The Presence Of
His Excellency Lieutenant General Doctor Sheikh
Mohammed Bin Abdullah Al-Khalifa
Chairman of the Supreme Council of Health

2023 MANAMA HEALTH
2nd ROUND Congress & Expo

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MBBS, DPHC, FRCGP, FFPH,FRCP (UK)

Prof of Public Health- Imperial College-London

Family and Community Medicine Consultant

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The 1st

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Peace be upon you and the mercy and blessings of Allah on you all.

Thanks to Allah who guided us to our path, without His guidance we wouldn’t have been guided.

اندبندنت عربية

منذ 4 أسابيع

"قمة سلامة الذكاء الاصطناعي" دقت ناقوس الخطر من أضراره الكارثية

الإثنين، ٦ نوفمبر / تشرين الثاني ٢٠٢٣

الفرق بين العمل والمهنة

- المهنة تقتضي الإتقان
- العمل قد يتولاه غير المتقن

The difference between work and profession

- The work may be undertaken by the inexperienced
- The profession requires mastery

The difference between work and profession

Every profession is a job, but not every job is a profession

The profession requires mastery and precise knowledge

In contrast to work, a person may do work that he is not proficient in, so he cannot be called a professional at.

Why ? ... How ?

Professional ethics or ethics

باب في المحاسبة والمراقبة

تعاليمنا الإسلامية السمحاء

دررٌ نفيسة

كنوز كريمة

إنه

نهجنا في شرعنا العظيم

الإسلام

قَالَ تَعَالَى:

﴿ مَّا فَرَّطْنَا فِي ٱلْكِتَـٰبِ مِن شَيْءٍ ﴾

الأنعام: ٣٨

It is a set of behavioral and ethical rules and etiquette that must accompany a professional person in his profession, towards his work, towards society as a whole, and towards his acts and himself.

Ethics of practicing medicine

حيثما اجتمعت المعرفة والدراية مع الكفاءة
والفاعلية والخبرة المستنيرة نرتقي بإذن الله بالأداء
إلى الامتياز.. كما النجوم في السماء..

قال تعالى:
{وَابْتَغِ فِيمَا آتَاكَ اللَّهُ الدَّارَ
الْآخِرَةَ وَلَا تَنسَ نَصِيبَكَ مِنَ
الدُّنْيَا }

Health System

A health system, health care system, or healthcare system, is the organization of people, institutions, and resources that deliver health care services to meet the health needs of target populations.

Information resources

- **Sound information plays an increasingly critical role in the delivery of modern health care and the efficiency of health systems.**
- **Health informatics – the intersection of information science, medicine and healthcare – deals with the resources, devices, and methods required to optimize the acquisition and use of information in health and biomedicine.**
- **Necessary tools for proper health information coding and management include clinical guidelines, formal medical terminologies, and computers and other information and communication technologies.**
- **The kinds of data processed may include patients' medical records, hospital administration and clinical functions, and human resources information.**

The use of health information lies at the root of evidence-based policy and evidence-based management in health care.

Increasingly, information and communication technologies are being utilized to improve health systems in countries through the standardization of health information; computer-aided diagnosis and treatment monitoring; informing population groups on health and treatment.

A well-functioning health system working in harmony is built on having trained and motivated health workers, a well-maintained infrastructure, and a reliable supply of medicines and technologies, backed by adequate funding, strong health plans and evidence-based policies.

Health systems need to have the capacity to control and address global public health threats such as epidemic diseases and other severe events.

Health systems framework and building blocks

six core components or “building blocks”:

(i) service delivery,

(ii) health workforce,

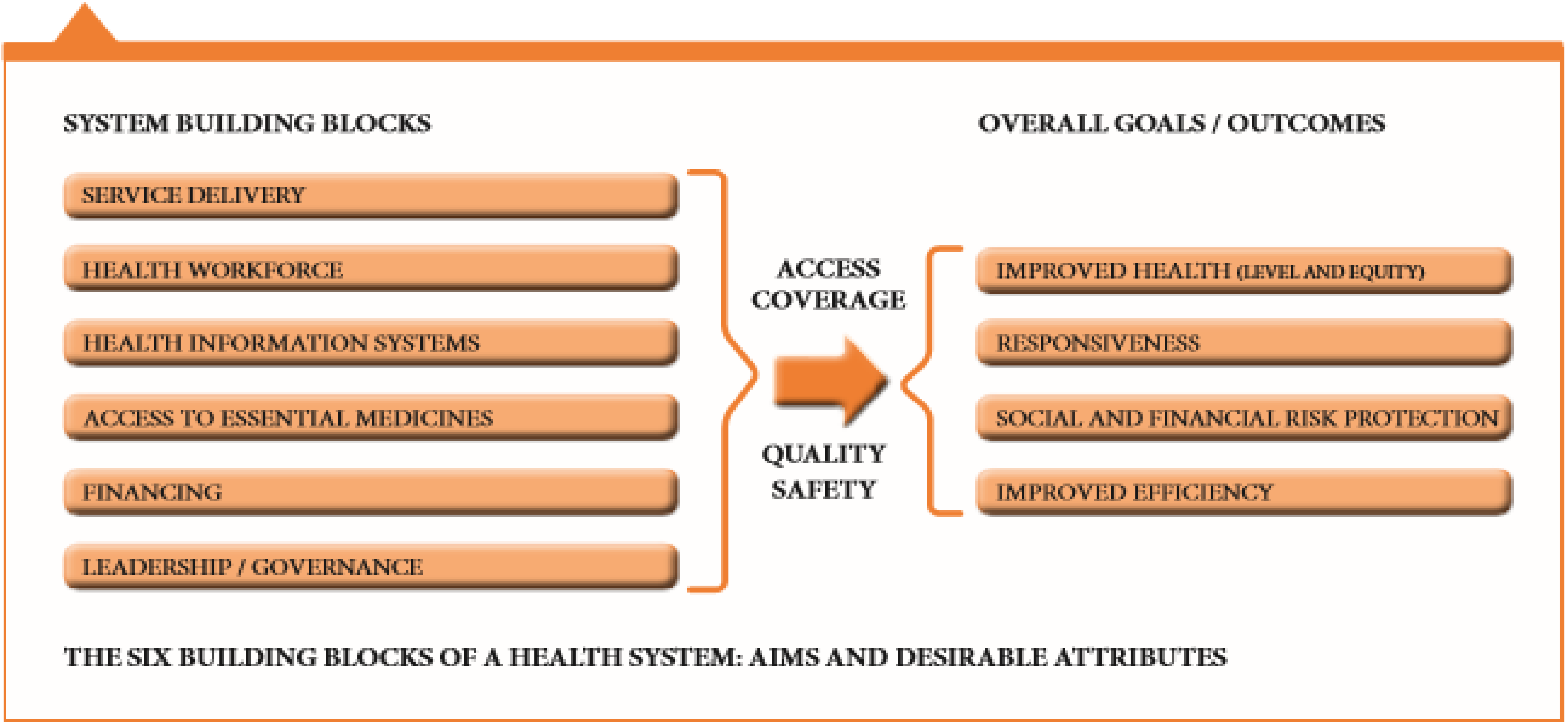
(iii) health information systems,

(iv) access to essential medicines,

(v) financing, and

(vi) leadership/governance.

The WHO Health Systems Framework



SYSTEM BUILDING BLOCKS

- SERVICE DELIVERY
- HEALTH WORKFORCE
- HEALTH INFORMATION SYSTEMS
- ACCESS TO ESSENTIAL MEDICINES
- FINANCING
- LEADERSHIP / GOVERNANCE

ACCESS
COVERAGE

QUALITY
SAFETY

OVERALL GOALS / OUTCOMES

- IMPROVED HEALTH (LEVEL AND EQUITY)
- RESPONSIVENESS
- SOCIAL AND FINANCIAL RISK PROTECTION
- IMPROVED EFFICIENCY

THE SIX BUILDING BLOCKS OF A HEALTH SYSTEM: AIMS AND DESIRABLE ATTRIBUTES

Key characteristics of good service delivery

Good service delivery is a vital element of any health system. Service delivery is a fundamental input to population health status, along with other factors, including social determinants of health. The precise organization and content of health services will differ from one country to another, but in any well-functioning health system, the network of service delivery should have the following key characteristics.

1 **Comprehensiveness: A comprehensive range of health services is provided, appropriate to the needs of the target population, including preventative, curative, palliative and rehabilitative services and health promotion activities.**

2 **Accessibility**: Services are directly and permanently accessible with no undue barriers of cost, language, culture, or geography. Health services are close to the people, with a routine point of entry to the service network at the primary care level (not at the specialist or hospital level). Services may be provided in the home, the community, the workplace, or health facilities as appropriate.

3 **Coverage**: Service delivery is designed so that all people in a defined target population are covered, i.e. the sick and the healthy, all income groups, and all social groups.

4 **Continuity**: Service delivery is organized to provide an individual with continuity of care across the network of services, health conditions, levels of care, and over the life cycle.

5 **Quality**: Health services are of high quality, i.e. they are effective, safe, centered on the patient’s needs, and given in a timely fashion.

Patient Safety

6 **Person-centredness**: Services are organized around the person, not the disease or the financing. Users perceive health services to be responsive and acceptable to them. There is participation from the target population in service delivery design and assessment. People are partners in their health care.

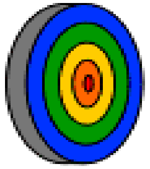
7 **Coordination**: Local area health service networks are actively coordinated, across types of providers, types of care, levels of service delivery, and for both routine and emergency preparedness. The patient's primary care provider facilitates the route through the needed services and works in collaboration with other levels and types of providers. Coordination also takes place with other sectors (e.g. social services) and partners (e.g. community organizations).

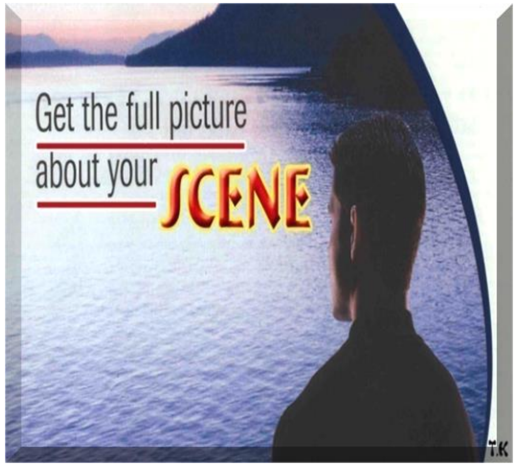
8 **Accountability and efficiency**: Health services are well managed so as to achieve the core elements described above with a minimum wastage of resources. Managers are allocated the necessary authority to achieve planned objectives and held accountable for overall performance and results Assessment includes appropriate mechanisms for the participation of the target population and civil society.

Patient-centered care
الرعاية المتمحورة حول المريض

Quality.. continue

We Need Strategic Plan For PCC In Health





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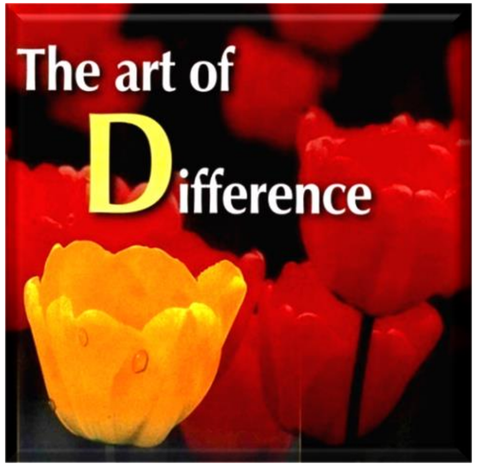
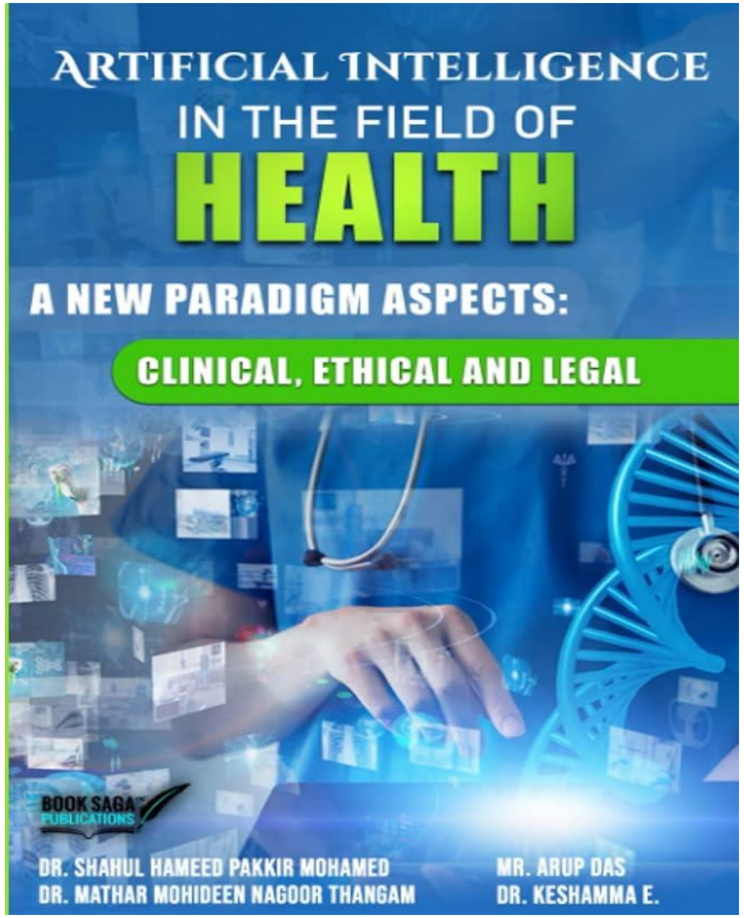


Internalize & Institutionalize in Health System

Artificial intelligence (AI)

- Artificial intelligence (AI), defined as computers that behave in ways that previously were thought to require human intelligence, has the potential to substantially improve health care, help patients, and decrease costs.
- Physicians are experts at acquiring information from different resources. AI can extend this expertise, extracting even more information to make better or entirely new predictions about patients.



ARTIFICIAL INTELLIGENCE
IN THE FIELD OF
HEALTH
A NEW PARADIGM ASPECTS:
CLINICAL, ETHICAL AND LEGAL

BOOK SAGA PUBLICATIONS

DR. SHAHUL HAMEED PAKKIR MOHAMED
DR. MATHAR MOHIDEEN NAGOOR THANGAM
MR. ARUP DAS
DR. KESHAMMA E.

- **Going forward, conclusions about care will be made by human physicians in conjunction with intelligent and autonomous machines. Although the machines will make mistakes, they are likely to make decisions more efficiently and with more consistency than humans and in some instances will contradict human decisions and be proven to be correct. AI will affect investigation interpretation, report generation, result communication, and billing practice.**

- **Artificial intelligence (AI) has enormous potential for strengthening the delivery of health care and medicine and helping all countries achieve universal health coverage. This includes improved diagnosis and clinical care, enhancing health research and drug development, and assisting with the deployment of different public health interventions, such as disease surveillance, outbreak response, and health systems management.**

- **AI could also benefit low- and middle-income countries, especially in countries that may have significant gaps in healthcare delivery and services for which AI could play a role. With the help of AI-based tools, governments could extend healthcare services to underserved populations, improve public health surveillance, and enable healthcare providers to better attend to patients and engage in complex care.**

- **At the same time, for AI to have a beneficial impact on public health and medicine, ethical considerations and human rights must be placed at the center of the design, development, and deployment of AI technologies for health.**

- For AI to be used effectively for health, existing biases in healthcare services and systems based on race, ethnicity, age, and gender, that are encoded in data used to train algorithms, must be overcome. Governments will need to eliminate a pre-existing digital divide in the use of information and communication technologies.

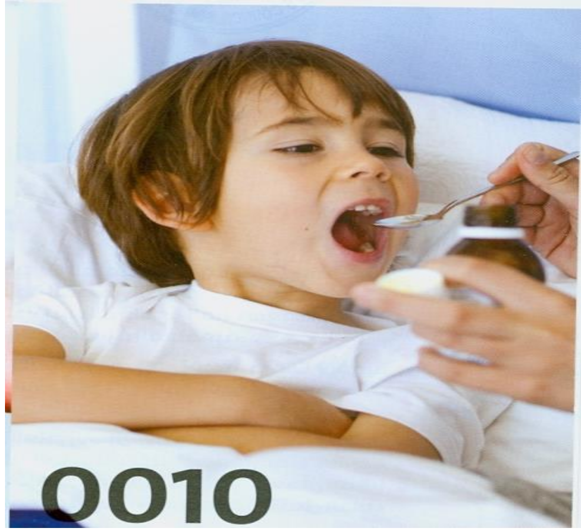
- The proliferation of AI could lead to the delivery of healthcare services in unregulated contexts and by unregulated providers, which might create challenges for government oversight of healthcare. Therefore, appropriate regulatory oversight mechanisms must be developed to make the private sector accountable and responsive to those who can benefit from AI products and services and ensure that private sector decision-making and operations are transparent.

- There are also potential serious negative consequences if ethical principles and human rights obligations are not prioritized by those who fund, design, regulate or use AI technologies for health. AI's opportunities and challenges are thus inextricably linked.

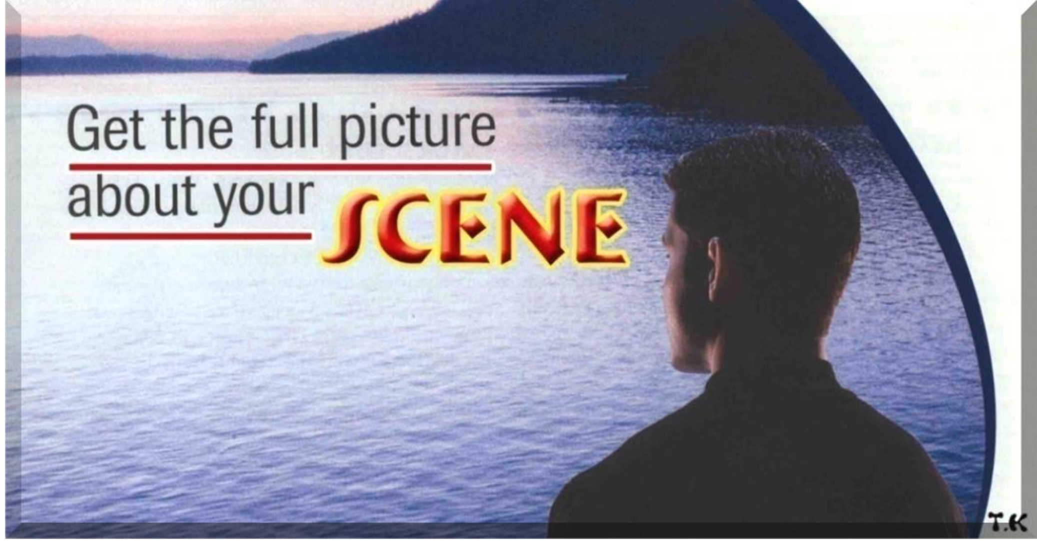
- **AI has the potential to alter professional relationships, patient engagement, knowledge hierarchy, and the labor market.**

- **AI may exacerbate the concentration and imbalance of resources, with entities that have significant AI resources having more “radiology decision-making” capabilities.**

- **AI will infer patterns in personal, professional, and institutional behavior. The value, ownership, use of, and access to medical data have taken on new meanings and significance in the era of AI.**



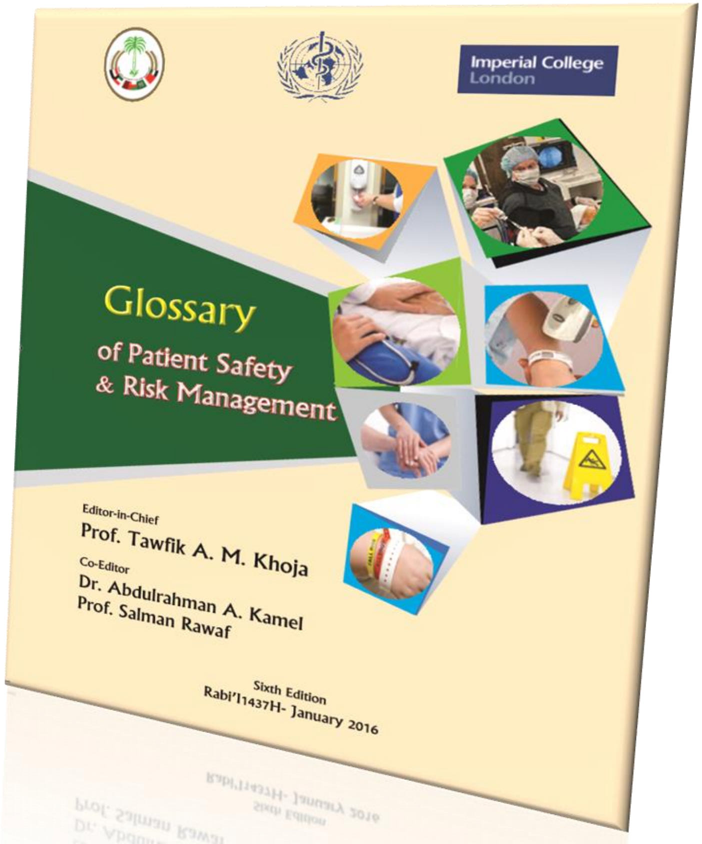
Ethical Principles for Artificial Intelligence in Medicine



PRINCIPLE 1: SAFETY

Although ML and AI have enormous potential, a range of new risks will emerge from ML and AI or through their implementation.

The first and foremost consideration in the development, deployment or utilisation of ML or AI must be patient safety and quality of care, with the evidence base to support this**.**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PRINCIPLE 2: Privacy

- Researchers developing artificial intelligence applications need to carefully consider various aspects of the project, including the settings in which sensing data will be collected, the types of information that could be stored, the inferences that might be drawn from that information, and what design measures might be needed to protect that information, especially given that efforts to deidentify information cannot be as complete as is sometimes imagined.

- Engagement with privacy concerns for AI usage should aim to go beyond basic compliance with relevant laws and address the different values and trade-offs involved in privacy interests.

- Different ethical and regulatory frameworks apply to different types of healthcare activities and stakeholders, which should be considered when developing an AI application. Privacy is a value that presents trade-offs with other values and considerations in a project. Doing a project as research rather than as quality improvement, for example, determines which legal requirements will apply regarding privacy and informed consent.

Privacy is a concept that incorporates a range of rights and obligations meant to protect an individual from unwanted intrusions or interferences into their domain.

In artificial intelligence projects and healthcare settings, there is often a focus on informational privacy, which involves “how and when personal information should be communicated or obtained and what uses of it will be made by others, and encompasses the collection, storage, use, maintenance, dissemination/disclosure, and disposition of personal information.

Data management and liability

Legal Framework

Most states either recognize the provider as the owner of medical information or have no law conferring specific ownership or property rights to the medical record.

Health data are currently exchanged in global marketplaces, with a total value of approximately $11.45 billion in 2016, with expected double-digit growth in the forecast period of 2017–2025.

Although state laws should be in place protecting patient privacy and access to data, from a legal standpoint, clinical data are generally considered to be the property of the provider organization and can be used and sold by the provider organization as long as patient access and privacy protection requirements are met.

Ethical Framework

- The field of ethics involves systematizing, defending, and recommending principles, values, and standards of behavior.
- Ethical behavior is the foundation for the medical profession because it establishes the fiduciary duties of medical professionals and provider organizations.
- By establishing concrete guidelines for using clinical data for research and development, we believe that ethics should drive legal and regulatory frameworks.
- Three general principles that guide the protection of human subjects in biomedical and behavioral research which can be as a general reference to ethical principles:

  - First, ***respect*** *for persons* refers to the notion that individuals have the right to make their own choices about actions that affect them.

  - Second, ***beneficence*** refers to the notion that researchers must do what is in the subject's best interest, including avoiding harming the subject.

  - Third, ***justice*** refers to the notion that the benefits and costs of research and medical care should be distributed and borne in a fair manner.

  - **nonmaleficence**,

  - **physician integrity**.

“knowledge” may reduce human error and fill physician knowledge gaps, especially as technology rapidly advances, which could benefit **beneficence** and **nonmaleficence** for patients and potentially improve physician **competence**.

Physician reliance on inappropriate recommendations without applying clinical reasoning or reviewing best practices compromises **beneficence**, and if recommendations are inappropriate **nonmaleficence.**

Patients may seek medical information from ChatGPT / AI before appointments, which physicians must address. Reliance on language models by physicians or patients poses the risk of minimizing **physician integrity and competency** if patients perceive this technology as being equivalent to physician expertise.

Importantly, ChatGPT currently lacks critical thinking abilities, and therefore, does not truly replicate physicians’ clinical reasoning

ChatGPT’s ability to streamline clinical workflows presents ethical dilemmas for physicians who seek to provide appropriate care but are pressured to evaluate patients quickly.

Rapid patient evaluation by ChatGPT may compromise the humanistic qualities of medicine and cause patients to feel uncared for.

David B. Larson et al, proposed the seven fundamental ethical obligations proposed by Faden et al, summarized in Table.

Six of these obligations are directed to researchers, clinicians, administrators, payers, and purchasers.

Some of these entities are not-for-profit entities, whereas others are for-profit entities, such as hospital networks, managed care organizations, and purchasers.

The seventh obligation, the obligation to "contribute to the common purpose of improving the quality and value of clinical care and health care systems," is directed to patients.

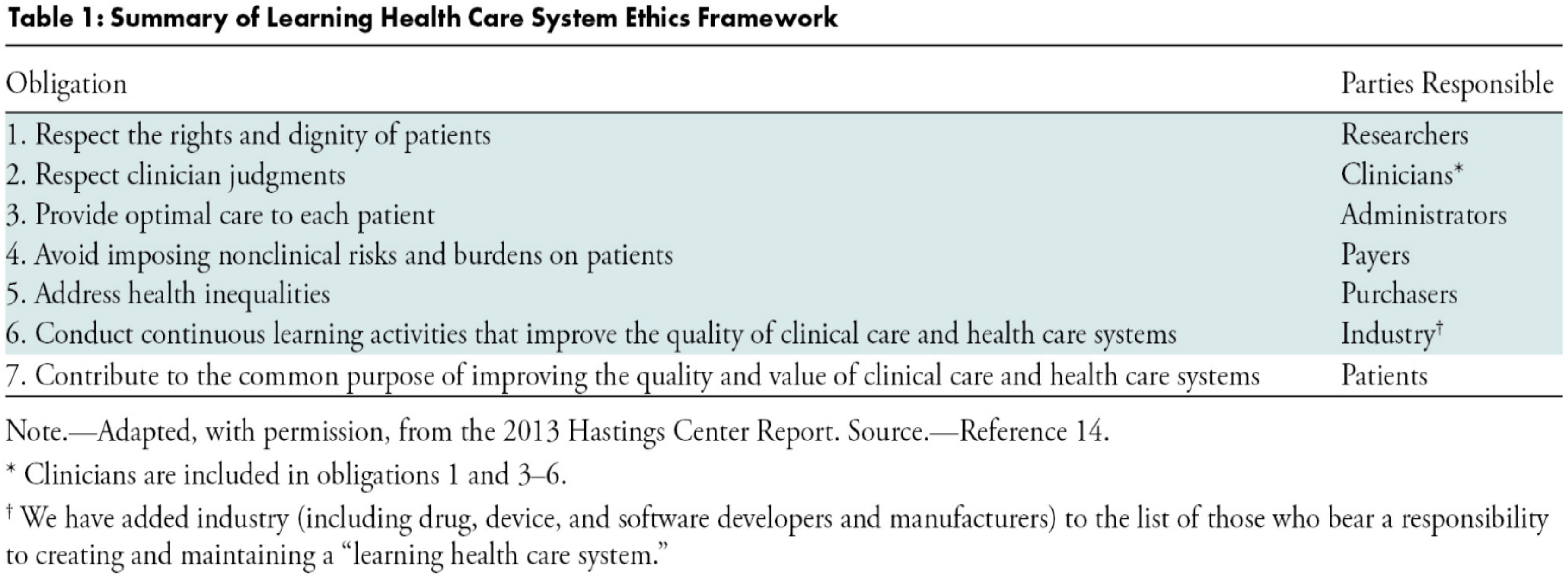

Table 1: Summary of Learning Health Care System Ethics Framework

Obligation	Parties Responsible
1. Respect the rights and dignity of patients	Researchers
2. Respect clinician judgments	Clinicians*
3. Provide optimal care to each patient	Administrators
4. Avoid imposing nonclinical risks and burdens on patients	Payers
5. Address health inequalities	Purchasers
6. Conduct continuous learning activities that improve the quality of clinical care and health care systems	Industry†
7. Contribute to the common purpose of improving the quality and value of clinical care and health care systems	Patients

Note.—Adapted, with permission, from the 2013 Hastings Center Report. Source.—Reference 14.

* Clinicians are included in obligations 1 and 3–6.

† We have added industry (including drug, device, and software developers and manufacturers) to the list of those who bear a responsibility to creating and maintaining a "learning health care system."

The Value of Data

- Because clinical data have value to society, the public has an interest in safeguarding and promoting their use for beneficial purposes. Because of this public interest, once the primary purpose of clinical care has been fulfilled, we believe it is the moral obligation of those who participate in the health care system to treat clinical data as a form of public good, to be used to improve the care of future patients.

- Therefore, from the perspective of beneficence at the population level, we believe it would be unethical to refrain from using clinical data to develop tools that have the potential to benefit others.

- Clinical data are simply a conduit to viewing fundamental aspects of the human condition. It is not the data that are of primary interest, but rather the underlying physical properties, phenomena, and behaviors that they represent.

- Because this valuable resource is developed incidentally, a construct is needed to determine what ethical principles should govern it. All parties must ensure that all knowledge derived from the data will be used for beneficial purposes. It is in the public’s interest to ensure that all who have access to this resource adhere to these ethical obligations.

The Value of Data

- Healthcare data are among the most sensitive data that can be held about an individual. Patient data must not be transferred from the clinical environment at which care is provided without the patient’s consent, approval from an ethics board, or where otherwise required or permitted by law. Where data are transferred or otherwise used for AI research, they must be de-identified such that the patient’s identity cannot be reconstructed.

A patient’s data must be stored securely and in line with relevant laws and best practices.

- Because clinical data have value to society, the public has an interest in safeguarding and promoting their use for beneficial purposes. Because of this public interest, once the primary purpose of clinical care has been fulfilled, we believe it is the moral obligation of those who participate in the health care system to treat clinical data as a form of public good, to be used to improve the care of future patients.
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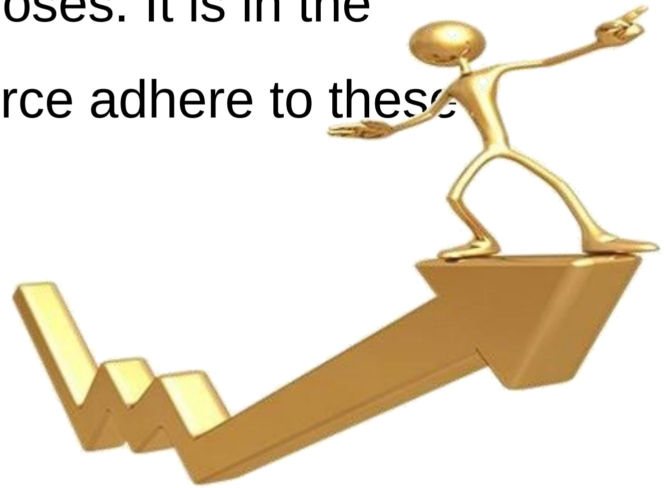


إذا رفضت كل ما هو دون مستوى القمة فإنك دائما تصل إليها
سومرت موم

The Role of Third Parties, Including Industry

- ✓ **In an ideal world, no financial transactions would be involved in the use of clinical data for the clinical research and development and distribution of AI models. However, resources are required to develop, implement, and maintain knowledge and models derived from the clinical data. The expectation of a financial return drives these investments in algorithm development and implementation.**

- ✓ **The necessity of financing AI algorithm development sets up a potential conflict between ethical principles and market forces, with associated questions. First, who should be allowed to profit from the data? Second, how can we ensure that data are used appropriately?**

Obligation to Use Data Appropriately

The concept that all who participate in the delivery of care take upon themselves the same fiduciary obligations as those of medical professionals is a key principle of the Learning Health Care Ethics Framework.

According to this framework, provider organizations that acquire and maintain clinical data do not own them per se, but rather serve as stewards of the data to maintain, protect, and use the data for appropriate purposes. In other words, no one “owns” the data in the traditional sense—not even the patients themselves. Rather, all who interact with or control the data must help ensure that the data are used for the benefit of future patients and society, including AI developers.

The fiduciary responsibility is to patients, in protecting privacy, as well as to society, which has an interest in improving health care. Everyone who is granted access to clinical data similarly becomes a data steward, including for-profit AI algorithm developers.

Considerations of individual privacy also differ between knowledge derived from a single individual versus that derived from a large number of individuals.

Provider organizations may need to share clinical data with outside entities to develop generalizable models, for two reasons:
- First, many provider organizations lack the capability to develop AI models themselves.
- Second, the aggregation of clinical data from multiple institutions may markedly enhance the value of the data.

- Sharing clinical data with outside entities is consistent with this ethical framework if the following conditions are met:

❑ 1. Individual privacy is carefully safeguarded at all times.
❑ 2. The receiving organization willingly accepts the same fiduciary responsibilities of data stewardship as the original provider organization. This includes agreeing that no attempt will be made to re-identify any individual from the data.
❑ 3. The sharing and receiving organizations both strictly adhere to an agreement specifying the purposes for which the data will be used.
❑ 4. The receiving organization agrees to not share the data further without the consent of the original provider organization.

PRINCIPLE 3: AVOIDANCE OF BIAS

AI is limited by its algorithmic design and the data they have access to, making it prone to bias. As a rule, AI trained on greater volumes and varieties of data should be less biased. Moreover, bias in algorithmic design should be minimized by involving a range of perspectives and skill sets in the design process and by considering how to avoid bias.

The data on which AI is based should be representative of the target patient population on which the system or tool is being used. The characteristics of the training data set and the environment in which it was tested must be clearly stated when marketing an AI tool to provide transparency and facilitate implementation in appropriate clinical settings.

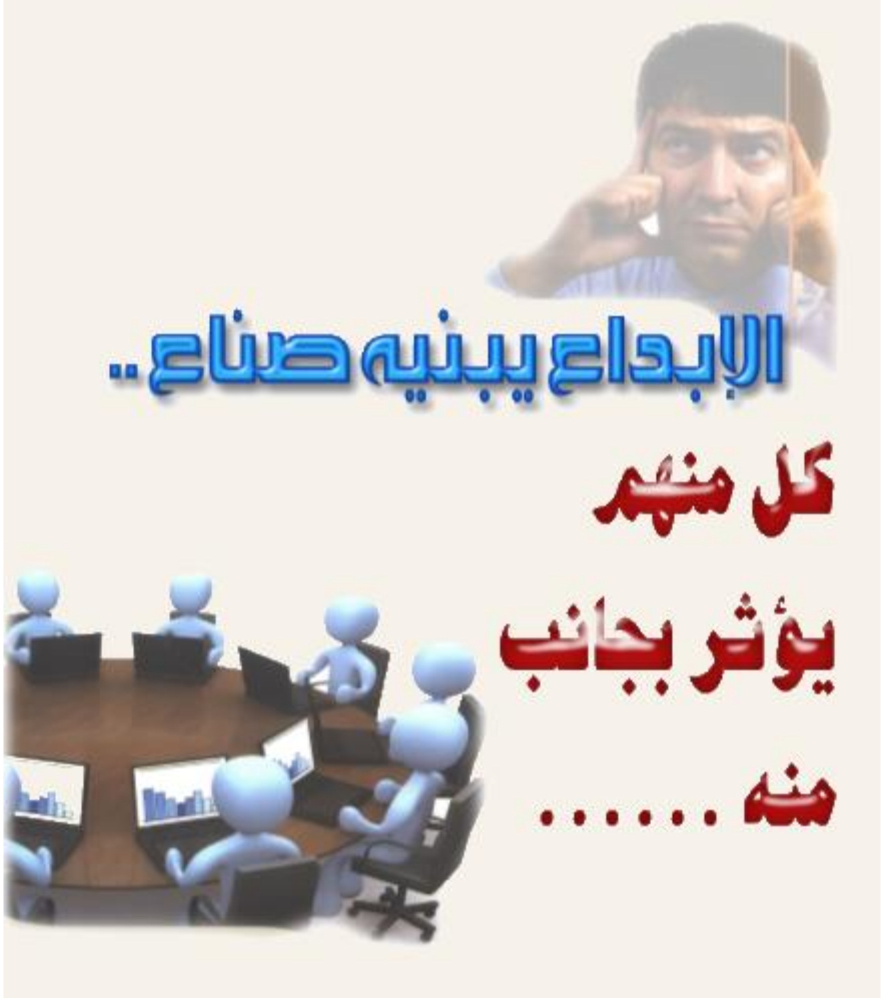
Particular care must be taken when applying an AI tool to a population, demographic, or ethnic group for which it has not been proven effective.

To minimize bias, the same standard of evidence used for other clinical interventions must be applied when regulating AI, and its limitations must be transparently stated.

PRINCIPLE 4: TRANSPARENCY AND EXPLAINABILITY

AI can produce results that are difficult to interpret or replicate. When used in medicine, the doctor must be capable of interpreting the basis on which a result was reached, weighing up the potential for bias, and exercising clinical judgment regarding findings.

When designing or implementing AI, consideration must be given to how a result that can impact patient care can be understood and explained by a discerning medical practitioner.



PRINCIPLE 5: APPLICATION OF HUMAN VALUES

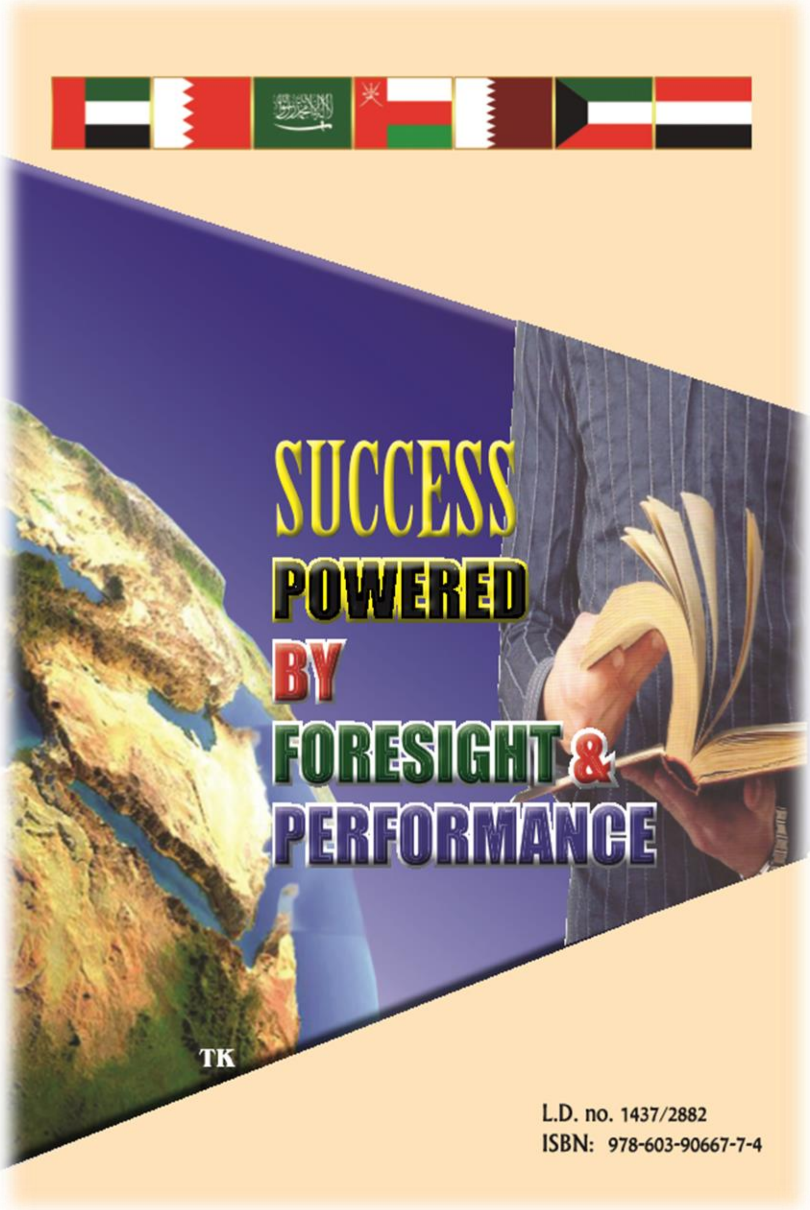
The development of ML and AI for medicine should ultimately benefit the patient and society. ML and AI are programmed to operate in line with a specific worldview (*Note*: Specific worldview implies the values, learnings, and experience of those who contributed to its development.); however, the use of ML and AI should function without unfair discrimination and not exacerbate existing disparities in health outcomes. Any shortcomings or risks of ML or AI should be considered and weighed against the benefits of enhanced decision-making for specific patient groups.

The doctor must apply humanitarian values (from their training and the ethical framework in which they operate) to any circumstances in which ML or AI is used in medicine, but they also must consider the personal values and preferences of their patient in this situation.

PRINCIPLE 6: DECISION-MAKING ON DIAGNOSIS AND TREATMENT

Fundamental to quality health care is the relationship between the doctor and the patient. The doctor is the trusted advisor on complex medical conditions, test results, procedures, and treatments who then communicate findings to the patient clearly and sensitively, answer questions, and provide advice on the next steps.

While ML and AI can enhance decision-making capability, final care decisions are made after a discussion between the doctor and patient, taking into account the patient’s presentation, history, options, and preferences.



PRINCIPLE 7: TEAMWORK

ML and AI will necessitate new skill sets and teams forming in research and medicine. It is imperative that all team members get to know each other’s strengths, capabilities, and integral roles in the team.

To deliver the best care for patients, each team member must understand the role and contribution of their colleagues and leverage them through collaboration.

PRINCIPLE 8: RESPONSIBILITY FOR DECISIONS MADE

- Responsibility for decisions made about patient care rests principally with the medical practitioner in conjunction with the patient. Medical practitioners need to be aware of the limitations of ML and AI and must always exercise solid clinical judgment. However, given the multiple potential applications of ML and AI in the patient journey, there may be instances where responsibility is shared between:
  - The medical practitioner caring for the patient;
  - The hospital or practice management who decided to use the systems or tools; and
  - The manufacturer that developed the ML or AI.

The potential for shared responsibility when using ML or AI must be identified, recognized by the relevant party, and recorded upfront when researching or implementing ML or AI.

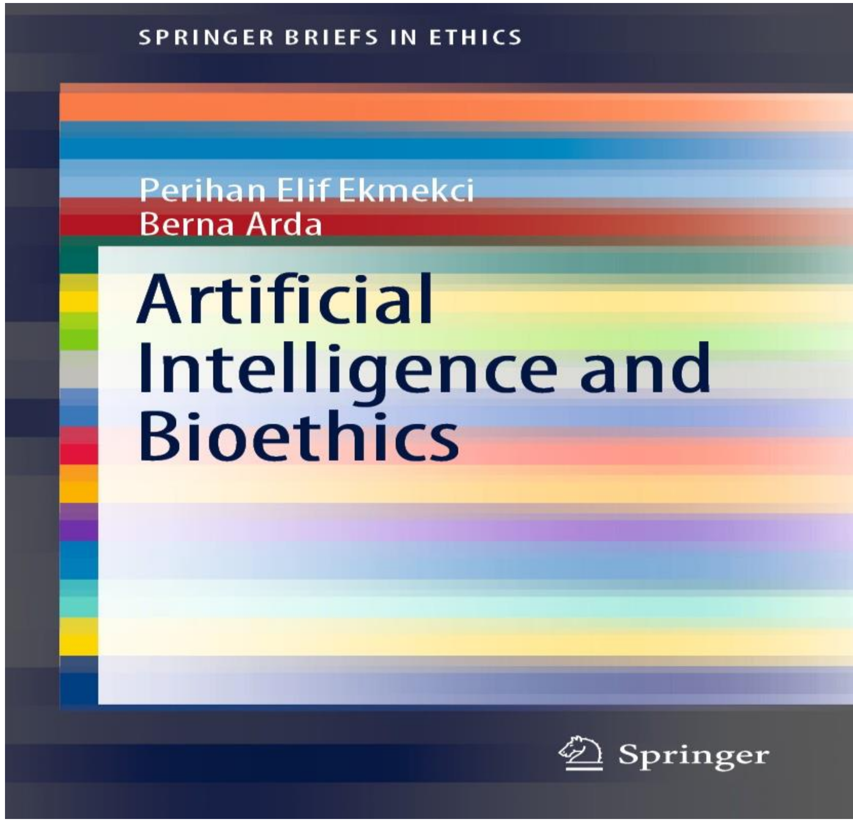
PRINCIPLE 9: GOVERNANCE

ML and AI are fast-moving areas with potential to add great value, but also to do harm. The implementation of ML and AI requires consideration of a broad range of factors, including how the ML or AI will be adopted across a hospital or practice to which patient groups, and how it might align with patients' goals of care and values.

A hospital or practice using or developing ML or AI for patient care applications must have accountable governance to oversee the implementation and monitoring of performance and use, to ensure practice is compliant with ethical principles, standards, and legal requirements.

PRINCIPLE 10: Bioethics laws and policies:

Bioethics laws and policies play a role in regulating the use of AI, and several bioethics laws have been revised in recent years to include recognition of the growing use of AI in science, health care and medicine. The French Government’s most recent revision of its national bioethics law (98), which was endorsed in 2019, establishes standards to address the rapid growth of digital technologies in the health-care system. It includes standards for human supervision, or human warranty, that require evaluation by patients and clinicians at critical points in the development and deployment of AI. It also supports free, informed consent for the use of data and the creation of a secure national platform for the collection and processing of health data.



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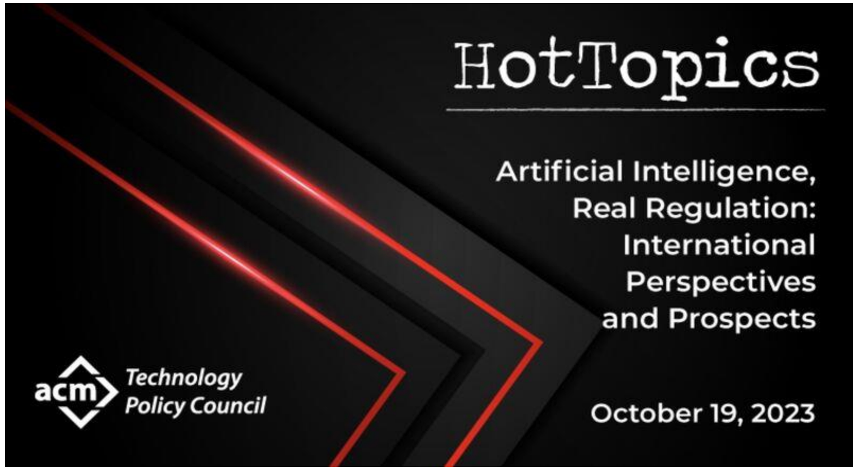


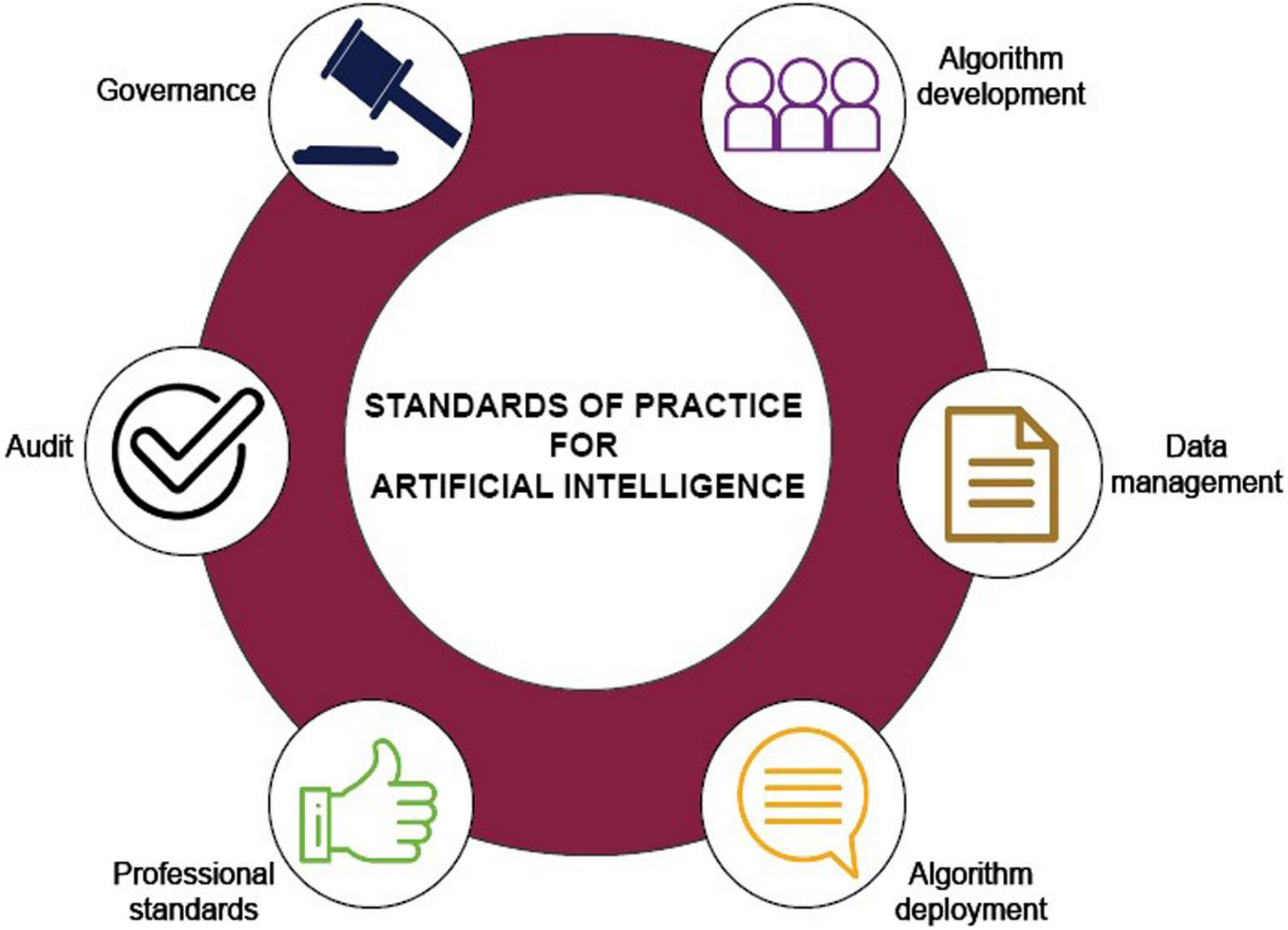
HotTopics

Artificial Intelligence, Real Regulation: International Perspectives and Prospects

acm Technology Policy Council

October 19, 2023

Ethics and standards in the use of artificial intelligence in medicine on behalf of the Royal Australian and New Zealand College of Radiologists



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When an AI model is implemented, those responsible should be able to answer these questions, and other similar questions, about the ethics of data:

1. **How will we document and notify patients about how their data are used?**
2. **How should we document data used to train an algorithm, including descriptors for features traditionally associated with bias and discrimination?**
3. **How and by whom are labels generated? What bias might arise from the processes used?**
4. **What kinds of bias may exist in the data used to train and test algorithms?**
5. **What have we done to evaluate how data are biased, and how it may affect our model?**
6. **What are the possible risks that might arise from biases in the data?**
7. **What steps have we taken to mitigate these biases, and how should users take remaining biases into account?**
8. **Is our method of ground truth labeling appropriate to the clinical use case we are trying to resolve? What are its limitations?**

When an AI model is implemented, those responsible for any part of its life cycle should be able to answer these and other similar questions about the ethics of algorithms:

A. Are we able to explain how our AI makes decisions or at least reliably predicts the results of our AI analysis in known data sets?
B. How do we protect against malicious attacks on AI tools and data?
C. How do we create sustainable version control for AI data, algorithms, models, and vended products?
D. How will we minimize the risk of patient harm from malicious attacks and privacy breaches?
E. How will we evaluate trained models before clinical application, for clinical effectiveness, ethical behavior, and security?
F. How will we monitor AI models in clinical workflow to ensure they perform as predicted and that performance does not degrade over time?

As Health Care Providers incorporates autonomous and intelligent AI products into widespread, demanding clinical practice, those responsible should be able to answer these and other similar questions about the ethics of this new practice paradigm:

I. **What are the patient and provider risks associated with this AI implementation, and what level of human oversight is necessary to mitigate these risks?**
II. **What education and skills are needed to decide whether to apply AI to our patients and to safely and effectively use it when appropriate?**
III. **How do we ensure that testing data accurately reflects the targeted clinical cohort?**
IV. **What processes should we implement to monitor the impact (outcomes, privacy, and unintended discrimination) of AI on our patients and providers (automation bias)?**
V. **How do we continuously and actively monitor AI-driven autonomous and intelligent tools to verify they are working as expected in clinical care?**
VI. **What guardrails should we use to determine when, and more importantly when not, to implement autonomous or intelligent mechanical agents?**

Protection of Privacy

The protection of individual privacy is of paramount importance in the secondary use of clinical data.

The principle of beneficence mandates that caregivers act in patients’ best interest and prevent them from harming them.

Because unwanted disclosure of sensitive clinical data can cause harm, such data must be carefully protected. This includes the application of the principle of the “minimum necessary” standard, meaning that an entity that shares medical information “must make reasonable efforts to limit protected health information to the minimum necessary to accomplish the intended purpose of the use, disclosure, or request”.

The level of reliability of deidentification efforts should correspond to the trustworthiness and integrity of the entities with whom the data are shared.

The additional ethical responsibility of those receiving the data to protect patient privacy and to inform the originating institution of any inclusion of identifying information serves as an additional check for securing patient privacy.

Consent for Secondary Use of Data

A common ethical question is whether patients have the right to control secondary uses of their clinical data.

In Faden and colleagues' framework, patients must contribute to the improvement of care in the future.

Although the principle of respect for persons indicates that individuals have the right to make their own choices about actions that affect them, this principle does not grant individuals the right to prevent others from learning from aggregated deidentified observations about them when it poses no significant risk to them as individuals.

Furthermore, the requirement of consent may impede or even preclude the aggregation of clinical data to benefit populations, adding substantial costs and essentially granting veto power to each individual patient.

Even relatively small individual costs in this setting can add up to large aggregated costs that stifle innovation and preclude the generation of knowledge and tools that could be of substantial societal benefit.

According to the ethical framework of the learning health care system, researchers in this field propose that additional patient consent is not required to use clinical data for research or algorithm development, under the following conditions:

- **1. Individual privacy is carefully safeguarded.**
- **2. Data are aggregated when used for research and development.**
- **3. Institutional oversight mechanisms are in place to ensure that clinical data are used appropriately and only for purposes that will be beneficial to future patients.**
- **4. Patients are made aware of how their data may be used when they consent for care, through a public website, or other means convenient to patients.**

David B. Larson et al, have specifically addressed seven questions regarding the use of clinical data that we have frequently encountered, as shown in Table 2:

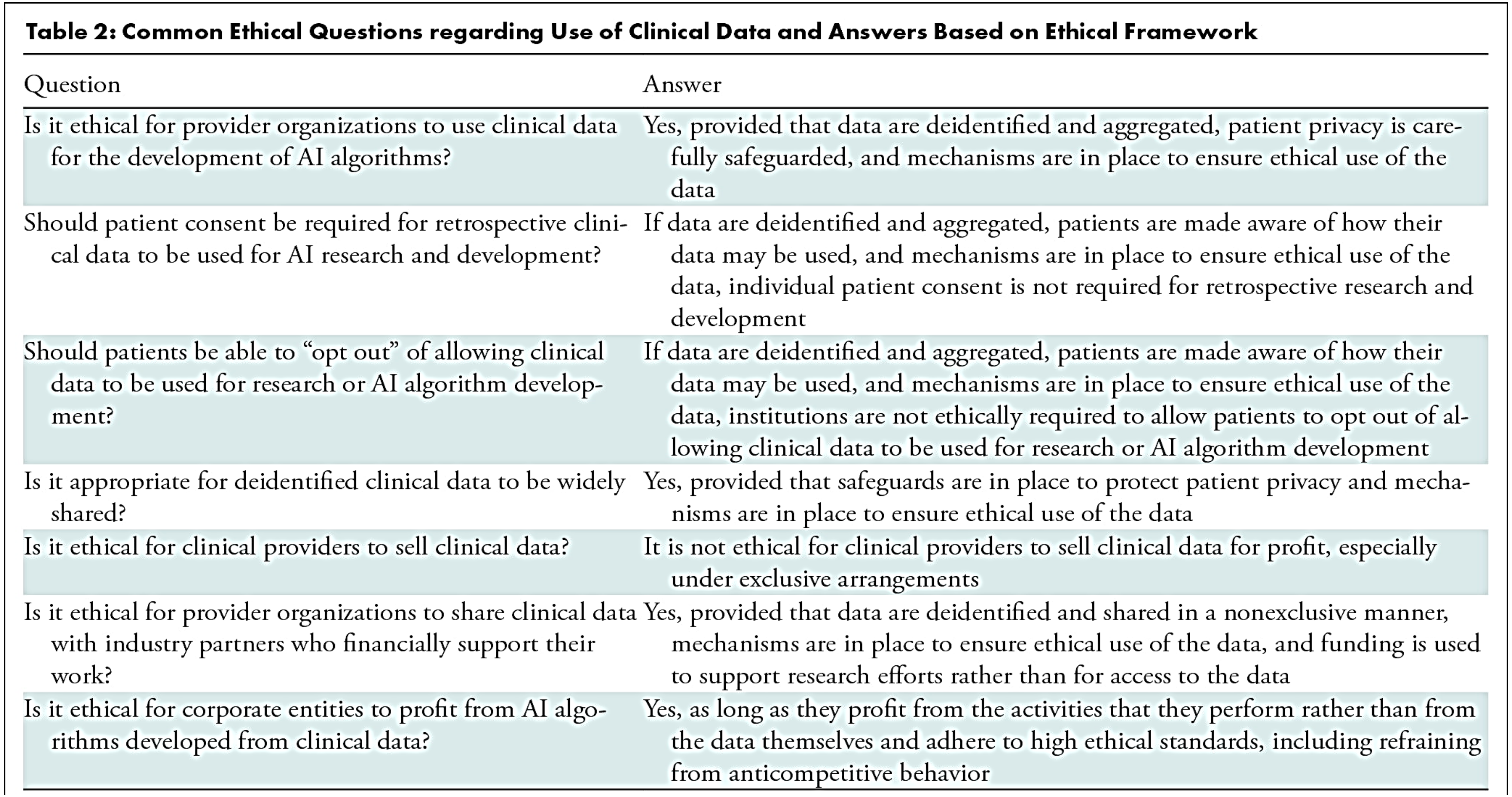

Table 2: Common Ethical Questions regarding Use of Clinical Data and Answers Based on Ethical Framework

Question	Answer
Is it ethical for provider organizations to use clinical data for the development of AI algorithms?	Yes, provided that data are deidentified and aggregated, patient privacy is carefully safeguarded, and mechanisms are in place to ensure ethical use of the data
Should patient consent be required for retrospective clinical data to be used for AI research and development?	If data are deidentified and aggregated, patients are made aware of how their data may be used, and mechanisms are in place to ensure ethical use of the data, individual patient consent is not required for retrospective research and development
Should patients be able to “opt out” of allowing clinical data to be used for research or AI algorithm development?	If data are deidentified and aggregated, patients are made aware of how their data may be used, and mechanisms are in place to ensure ethical use of the data, institutions are not ethically required to allow patients to opt out of allowing clinical data to be used for research or AI algorithm development
Is it appropriate for deidentified clinical data to be widely shared?	Yes, provided that safeguards are in place to protect patient privacy and mechanisms are in place to ensure ethical use of the data
Is it ethical for clinical providers to sell clinical data?	It is not ethical for clinical providers to sell clinical data for profit, especially under exclusive arrangements
Is it ethical for provider organizations to share clinical data with industry partners who financially support their work?	Yes, provided that data are deidentified and shared in a nonexclusive manner, mechanisms are in place to ensure ethical use of the data, and funding is used to support research efforts rather than for access to the data
Is it ethical for corporate entities to profit from AI algorithms developed from clinical data?	Yes, as long as they profit from the activities that they perform rather than from the data themselves and adhere to high ethical standards, including refraining from anticompetitive behavior

Ethics of Artificial Intelligence in Radiology: Summary of the Joint European and North American Multisociety Statement

Key ethical issues as radiology incorporates artificial intelligence (AI) products into clinical practice:

- Patient and provider risks associated with AI implementation must be assessed.
- Determine which education and skills are needed to safely apply AI to our patients.
- Ensure that testing data accurately reflects the targeted clinical cohort.
- Establish processes to monitor the impact (outcomes, privacy, and unintended discrimination) of AI on our patients and providers (automation bias).
- Monitor AI-driven autonomous and intelligent tools to verify they are working as expected in clinical care.
- Establish guardrails to determine when, and when not, to implement autonomous or intelligent mechanical agents.

This article is a joint publication in *Radiology*, *JACR*, *Canadian Association of Radiologists Journal*, and *Insights into Imaging*.

Geis JR et al. Published Online: October 1, 2019
https://doi.org/10.1148/radiol.2019191586

Radiology

Rapid developments in artificial intelligence (AI) promise improved diagnosis and care for patients but raise ethical issues. However, there are potential ethical concerns, with a focus on applications of AI in clinical care that are deployed or will be deployed soon.

Nicholas G. Evans et al, identified pressing issues:

(1) Transparency, paradigmatically through the explanation or interpretation of AI models; Transparency may be important when an AI model does not perform as expected or gives a false answer. Given a novel image to analyze, for example, AI may misdiagnose a patient based on an incomplete or inadequate training set. Others said that excessive trust in AI may be worse for patient outcomes than if AI were approached more skeptically.

(2) Responsibility issues for harms arising from the use or misuse of AI. Companies are responsible for ensuring that AI algorithms function appropriately and safely when used as indicated but may not be for off-label uses. Responsibility issues may become more acute in future adaptive AI that update their weightings of factors associated with a diagnosis in response to new data. Here, responsibility for appropriate use might include managing which data are retained by the system.

WHO has worked with a leading group of twenty experts to identify core principles to promote the ethical use of AI for health - these are the first consensus principles in this field. The six core principles identified by the WHO Expert Group are the following:

(1) Protect autonomy;

(2) Promote human well-being, human safety, and the public interest;

(3) Ensure transparency, explainability, and intelligibility;

(4) Foster responsibility and accountability;

(5) Ensure inclusiveness and equity;

(6) Promote AI that is responsive and sustainable.

To implement these principles and human rights obligations into practice, all stakeholders, whether designers and programmers, providers, and patients, as well as Ministries of Health and Ministries of Information Technology, must work together to integrate ethical norms at every stage of a technology's design, development, and deployment.

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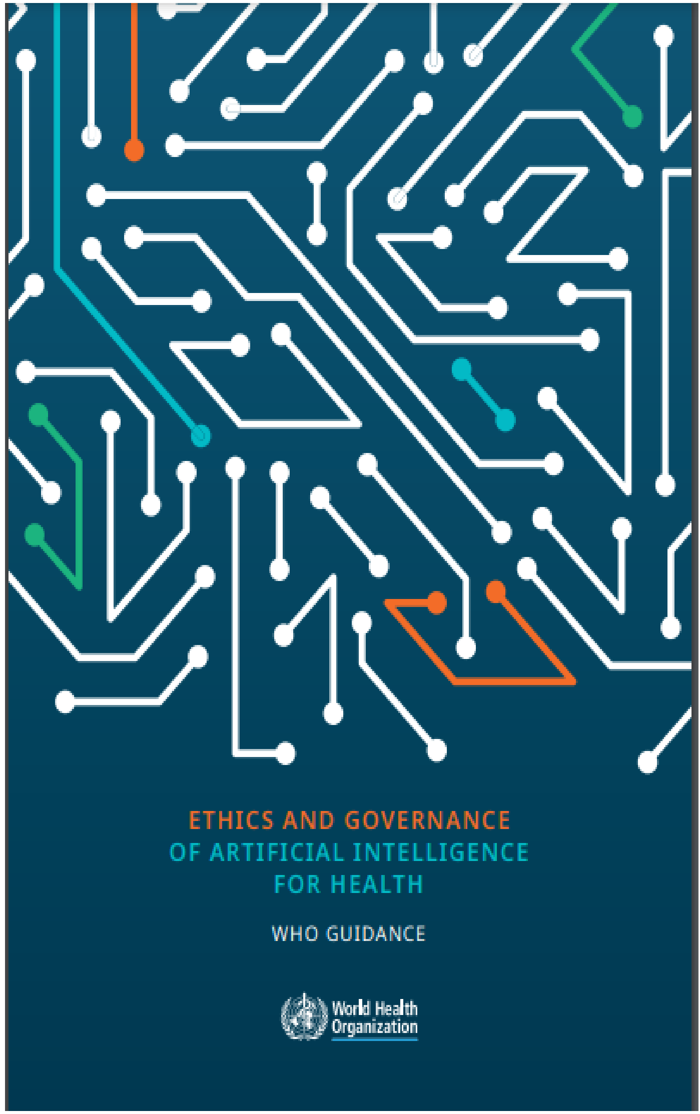


ETHICS AND GOVERNANCE
OF ARTIFICIAL INTELLIGENCE
FOR HEALTH

WHO GUIDANCE

World Health Organization

Building an evidence standards framework for artificial intelligence-enabled digital health technologies

HTA programs are tasked with a broad remit, with responsibility for assessing “medical devices, medicines, procedures, and systems developed to solve a health problem and improve quality of lives”.

To effectively manage this breadth, these programs are supported by expert-derived frameworks, which ensure uniformity between discrete assessments and identify specific evidence requirements.

The emergence of artificial intelligence (AI) as a medical device, a new group of complex health technologies known as AIaMD, has posed unique challenges to HTA evaluators owing to the lack of a similarly aligned classification system for these technologies.

As a result, undue reliance has been placed on non-specific digital health technology (DHT) evaluation frameworks, which were initially driven by the need to triage and assess mobile health applications.

Although classification systems for AI technologies do exist within the literature, many of which are based on underlying computational methodology, these systems were not constructed for HTA use.

AI health technologies are a global opportunity. HTA evaluators and regulators worldwide are tackling the same challenges.

As part of the development of the NICE DHT evidence standards framework NICE ESF, the aim is to produce a classification system for AI health technologies that is based on common HTA principles and can be used for HTA evaluations worldwide.

Harriet Unsworth et al, invite international stakeholders—including clinicians, AI academics, industry representatives, policymakers, regulators, funders, bioethicists, legal experts, and patient representatives—to contribute to this open and transparent development process, as we work together to provide a consensus-driven framework for the effective and efficient evaluation of AI health technologies for the benefit of patients and health systems.

Protecting human autonomy:

- **The use of AI can lead to situations in which decision-making power could be transferred to machines.**

- **The principle of autonomy requires that the use of AI or other computational systems does not undermine human autonomy.**

- **Humans should remain in control of health-care systems and medical decisions.**

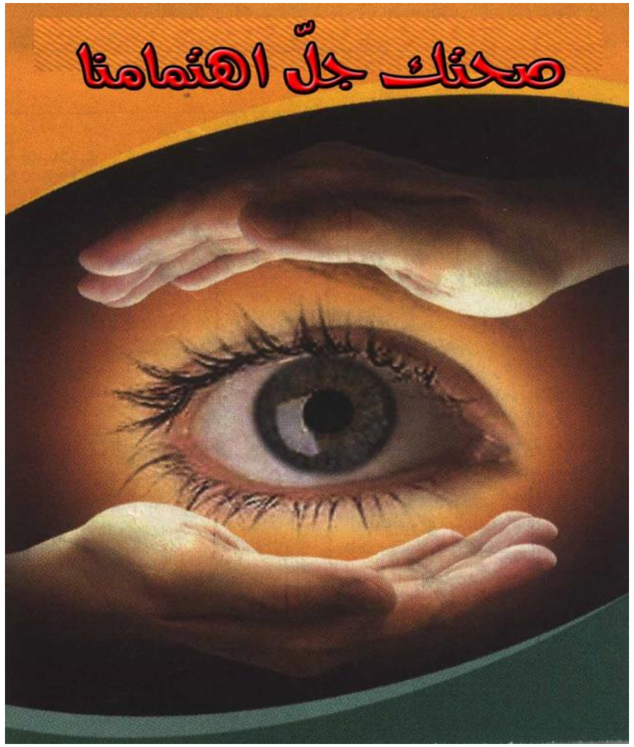
- **Respect for human autonomy also entails related duties to ensure that providers have the information necessary to make safe, effective use of AI systems and that people understand the role that such systems play in their care.**

- **It also requires protection of privacy and confidentiality and obtaining valid informed consent through appropriate legal frameworks for data protection.**

Promoting human well-being and safety and the public interest. AI technologies should not harm people. The designers of AI technologies should satisfy regulatory requirements for safety, accuracy, and efficacy for well-defined use cases or indications. Measures of quality control in practice and quality improvement in the use of AI over time should be available. Preventing harm requires that AI not result in mental or physical harm that could be avoided by the use of an alternative practice or approach.

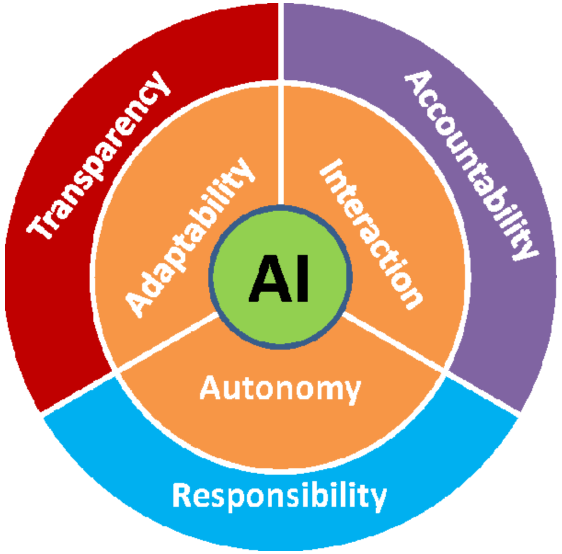
Ensuring transparency, explainability, and intelligibility.

AI technologies should be intelligible or understandable to developers, medical professionals, patients, users, and regulators. Two broad approaches to intelligibility are to improve the transparency of AI technology and to make AI technology explainable. Transparency requires that sufficient information be published or documented before the design or deployment of AI technology and that such information facilitates meaningful public consultation and debate on how the technology is designed and how it should or should not be used. AI technologies should be explainable according to the capacity of those to whom they are explained.



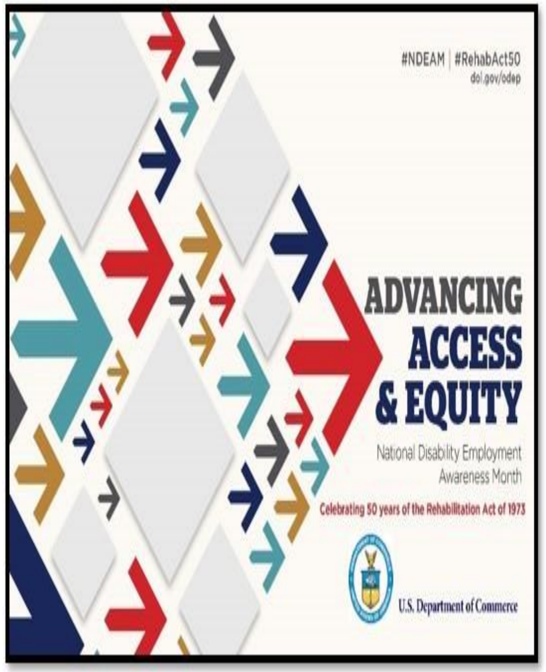
Fostering responsibility and accountability.

Humans require clear, transparent specifications of the tasks that systems can perform and the conditions under which they can achieve the desired performance. Although AI technologies perform specific tasks, it is the responsibility of stakeholders to ensure that they can perform those tasks and that AI is used under appropriate conditions and by appropriately trained people. Responsibility can be assured by the application of “human warranty”, which implies evaluation by patients and clinicians in the development and deployment of AI technologies. Human warranty requires the application of regulatory principles upstream and downstream of the algorithm by establishing points of human supervision. If something goes wrong with an AI technology, there should be accountability. Appropriate mechanisms should be available for questioning and redress for individuals and groups that are adversely affected by decisions based on algorithms.



Ensuring inclusiveness and equity.

Inclusiveness requires that AI for health be designed to encourage the widest possible appropriate, equitable use and access, irrespective of age, sex, gender, income, race, ethnicity, sexual orientation, ability or other characteristics protected under human rights codes. AI technology, like any other technology, should be shared as widely as possible. AI technologies should be available for use not only in contexts and for needs in high-income settings but also in the contexts and for the capacity and diversity of LMIC. AI technologies should not encode biases to the disadvantage of identifiable groups, especially groups that are already marginalized. Bias is a threat to inclusiveness and equity, as it can result in a departure, often arbitrary, from equal treatment. AI technologies should minimize inevitable disparities in power that arise between providers and patients, between policy-makers and people, and between companies and governments that create and deploy AI technologies and those that use or rely on them. AI tools and systems should be monitored and evaluated to identify disproportionate effects on specific groups of people. No technology, AI or otherwise, should sustain or worsen existing forms of bias and discrimination.



Promoting AI that is responsive and sustainable.

Responsiveness requires that designers, developers, and users continuously, systematically, and transparently assess AI applications during actual use. They should determine whether AI responds adequately and appropriately and according to communicated, legitimate expectations and requirements. Responsiveness also requires that AI technologies be consistent with the wider promotion of the sustainability of health systems, environments, and workplaces. AI systems should be designed to minimize their environmental consequences and increase energy efficiency. That is, the use of AI should be consistent with global efforts to reduce the impact of human beings on the Earth's environment, ecosystems, and climate. Sustainability also requires governments and companies to address anticipated disruptions in the workplace, including training for healthcare workers to adapt to the use of AI systems, and potential job losses due to the use of automated systems.

The duties of the health team and their relationship to the patient

Maintaining health professional confidentiality and privacy

Using a computer to enter and save patient data:

- **Every member of the health team and other workers in the health field must make every effort to maintain the confidentiality of all medical reports, including reports that are stored in the memory of computers. Information may not be entered into the computer record except by persons authorized to do so alone, and it must be taken into account to specify The date and time of any addition of new information, and the name of the person who made the amendment or addition must be recorded**

- **The patient or his representative must be informed of the existence of a computer data storage system in the health facility, provided that this is before the treating physician sends the information to the computer department responsible for storing it. All individuals and entities who can access the information must be identified in advance, and a declaration of all this information must be prepared. The patient must obtain his consent, and depending on the sensitivity of the patient’s data, security precautions must be taken to prevent the information from being leaked or other individuals accessing it.**

- **The patient or his representative must be informed before distributing any reports that include his data. The patient’s consent must be obtained, and any of the treating team must be notified before sending any data or information about the patient to individuals or organizations outside the scope of healthcare institutions so that Such personal data is authorized to be disclosed to any party without the patient’s consent.**

- **Computer devices must be equipped with systems for saving and retrieving information, to avoid its loss in the event of a malfunction in the programs or a malfunction in the computer server. If a file is deleted, a printed copy of it must be given to the specialist from the treating team first.**

- **Declaring any confidential medical data is limited to individuals and bodies that will handle it with strict confidentiality, according to the applicable laws and regulations. The sending of confidential medical information is limited to fulfilling the purpose specified when requesting it, and it is limited to the time frame for this purpose. All those bodies and individuals must be notified of the disclosure of that data to them This does not mean allowing it to be passed on to other parties or used for purposes other than those specified when requesting it or used to the disadvantage of the patient.**
- **Information stored on the computer may be erased or disposed of, once it is confirmed that the treating physician has a copy of it (printed, stored on a computer, or on a disc). When files are erased, the computer department must notify the specialist in the treating team in writing of the completion of the erasure process, and the patient has the right to request Erase some of his information within the framework of applicable laws.**

- **All strict measures must be taken to prevent access to the database, including establishing the necessary control systems to detect attempts to access the database by any individual or entity who do not have the right to do so.**

The ethics of documentation and certification

Documenting information and attesting to its authenticity is one of the main tasks of a health team member, and he must pay close attention to these aspects because of their extreme importance.

He/she must document every procedure he takes with the disease in accurate records and be careful in writing medical reports in a way that serves the interest, so only what is appropriate is written in the reports.

A reality that is far from exaggeration or belittling, and he/she is not led by kinship, affection, desire, or fear to give a medical report that is contrary to the truth. He should be honest and honest when issuing any certificates or documents.

Medical file:

The health team member or the entity he/she works for maintains clear and accurate electronic patient records, containing the medical history and appropriate clinical results, the decisions and actions taken, the data given to the patient, and any prescriptions or other treatments prescribed to the patient, as well as all examinations related to the patient.

1. **The electronic medical file must be kept in a safe place, and only those who have a professional relationship with the patient and are authorized to access it or handle it. All contents of the procedures related to professional confidentiality apply.**
2. **All contents of the medical file are the property of the entity for which the patient is treated, and the patient has the right to view his file and take a copy of it.**
3. **If the patient is referred to another doctor, the treating health practitioner must provide the health practitioner to whom the patient is referred with all the necessary information about his condition with complete accuracy and objectivity.**
4. **When writing data and information, the accepted scientific, administrative, legal, and ethical principles must be followed when writing, and the signature and date of each page of a document related to the electronic file. When any change or amendment is made, the date of the amendment shall be noted with the signature, and it is preferable for the change to be on a separate page.**

Take-Home Points

- **AI is complex and carries potential pitfalls and inherent biases. Widespread use of AI-based intelligent and autonomous machines in health care (radiology) can increase systemic risks of harm, raise the possibility of errors with high consequences, and amplify complex ethical and societal issues.**

- **Currently, there is little experience using AI for patient care in all its demanding and diverse settings. Extensive research remains to be done to understand how to use AI in clinical practice and the operational characteristics they should have. The approach to these issues will be shaped as much by the community's ethics as by technical factors.**

- **Ethical use of AI in health care should promote well-being, minimize harm, and ensure that the benefits and harms are distributed among the possible stakeholders in a just manner.**

- **AI in health care provision should be appropriately transparent and highly dependable, curtail bias in decision-making, and ensure that responsibility and accountability remain with human designers or operators.**

- **The health care organizations should start now to develop codes of ethics and practice for AI, and governance of AI for health.**

- **Physicians and healthcare staff will remain ultimately responsible for patient care and will need to acquire new skills to do their best for patients in the new AI ecosystem.**

- **The physician’s goal should be to derive as much value as possible from the ethical use of AI yet resist the lure of extra monetary gain from unethical uses of medical data and AI. This consensus statement aims to inform a common interpretation of the ethical issues related to using AI in health care and to inspire AI’s builders and users to enhance artificial intelligence in humane ways to promote just and beneficial outcomes while avoiding harm to those who expect the medical community to do right by them.**

- **Governments should have clear data protection laws and regulations for the use of health data and protecting individual rights, including the right to meaningful informed consent.**
- **Governments should establish independent data protection authorities with adequate power and resources to monitor and enforce the rules and regulations in data protection laws.**
- **Governments should require entities that seek to use health data to be transparent about the scope of the intended use of the data.**
- **Mechanisms for community oversight of data should be supported. These include data collectives and the establishment of data sovereignty by indigenous communities and other marginalized groups.**
- **Data hubs should meet the highest standards of informed consent if their data might be used by the private or public sector, should be transparent in their agreements with companies, and should ensure that the outcomes of data collaboration provide the widest possible public benefit.**

- **Governments should consider establishing dedicated teams to conduct objective peer reviews of software and system implementation by examining safety and quality or general system functionality (fitness for purpose) without requiring review or approval of a code.**

- **Governments should develop and implement ethical, legally compliant principles for the collection, storage, and use of data in the health sector that are consistent with internationally recognized data protection principles. Governments should take steps to avoid risks of bias in data that are collected and used for the development and deployment of AI in the public sector.**

- **. Government regulators should require that an AI system's performance be tested, and sound evidence obtained from prospective testing in randomized trials and not merely from comparison of the system with existing datasets in a laboratory.**

- **Companies must adhere to national and international laws and regulations on the development, commercialization, and use of AI for health systems, including legally enforceable human rights and ethical obligations, data protection laws, and measures to ensure appropriate informed consent and privacy.**

- **Companies should invest in measures to improve the design, oversight, reliability, and self-regulation of their products.**

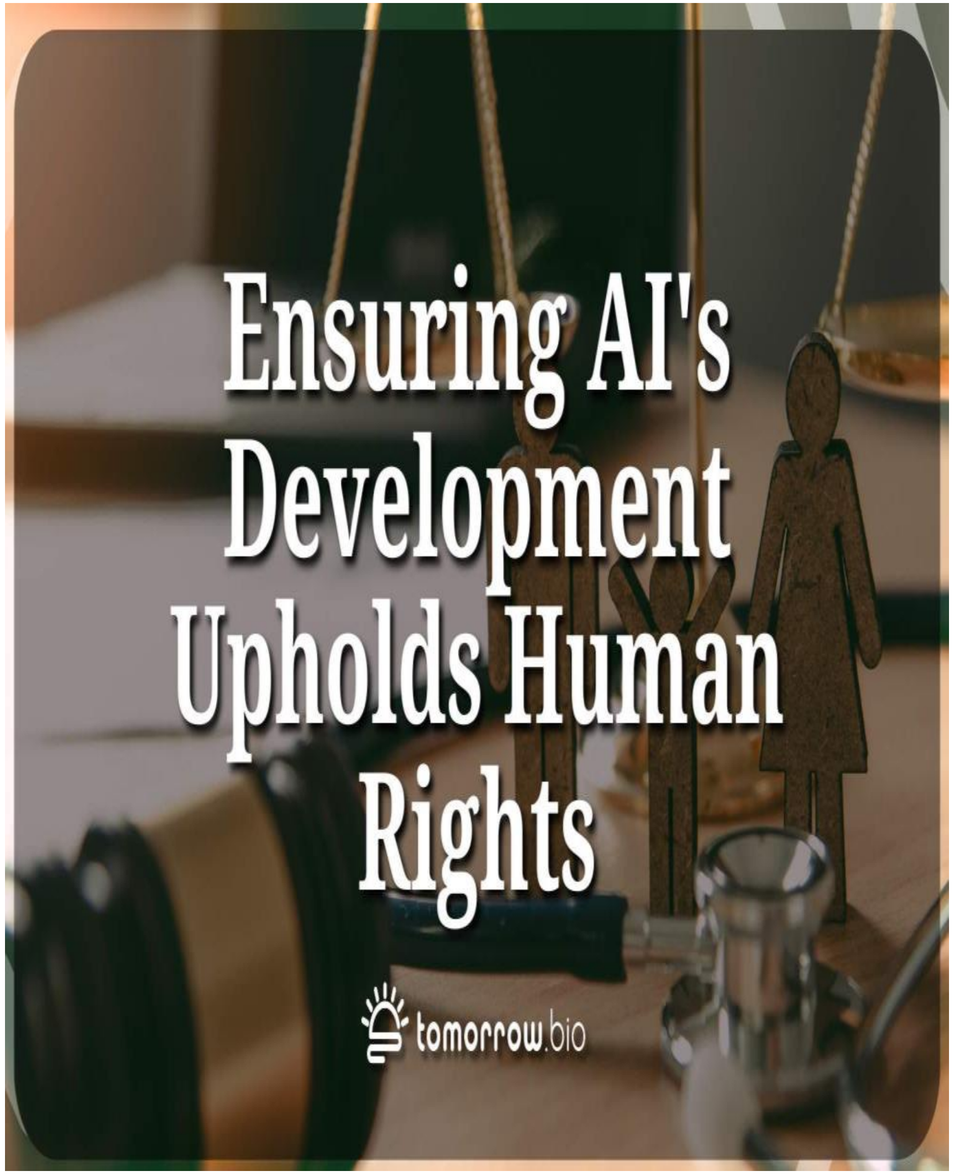
- **Companies should consider licensing or certification requirements for developers of "high-risk" AI, including AI for health.**

Physicians and health care providers considering using ChatGPT / AI or similar technology in patient care should be wary.

Despite considerable advantages, physicians have a responsibility to monitor AI development and public reception, along with advocating for its appropriate design and usage to not compromise patient care.

In the context of AI for health, autonomy means that humans should remain in full control of health-care systems and medical decisions.

It also requires that the potential of AI to detect risks to the patient or community health is incorporated into health systems in a way that advances human autonomy and dignity and does not displace humans from the center of health decision-making.



- The use of AI for health nevertheless raises transnational ethical, legal, commercial, and social concerns. Many of these concerns are not unique to AI.
- The use of software and computing in health care has challenged developers, governments, and providers for half a century, and AI poses additional, novel ethical challenges that extend beyond the purview of traditional regulators and participants in healthcare systems.
- These ethical challenges must be adequately addressed if AI is to be widely used to improve human health, preserve human autonomy, and ensure equitable access to such technologies.

Key health system challenges for Member States

- **Strengthening the capacity of ministries of health in formulating and evaluating evidence-informed policies and plans and regulating the application of AI in the health sector.**

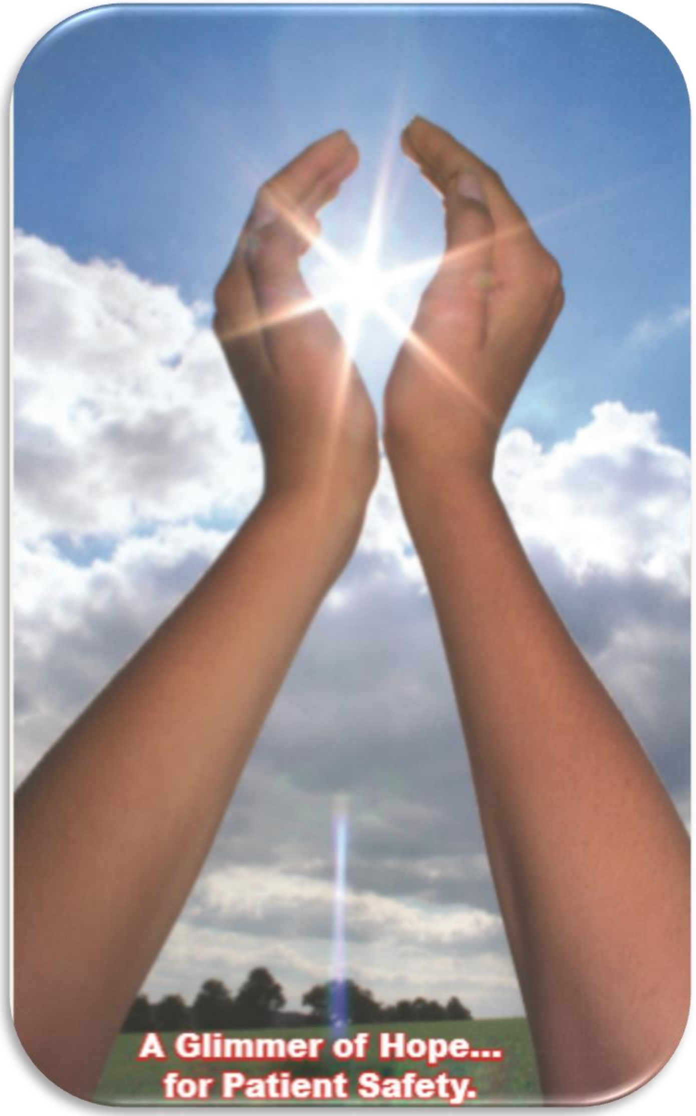
- **Strengthening the contribution of the different healthcare institutions including the private health sector towards public health goals and regulating AI to ensure quality and prevent inappropriate practices.**

- **Developing a balanced, motivated, well-distributed, and managed health workforce with the appropriate skills mix in the utilization of AI within the ethical and legal framework.**

- Adopting workable models of AI modules for the delivery of good quality and safe care to patients and the community.

- Improving access to and rational use of AI technologies in various aspects of health care provision (medicines, vaccines, biologicals, medical devices, and public health programs).

- Preparing health systems to utilize AI to respond to crises and disasters and strengthening their resilience in complex and extended emergencies.



This is to achieve the ultimate goal of providing health care, which is to keep the patient healthy and healthy, psychologically and socially, since safety and security are basic principles in patient care, and a crucial element in managing the quality of health services as one of the integral pillars of this care, and a complete right of patients from a professional and ethical perspective. To protect and prevent medical and medication errors.