Artificial Intelligence

There is great excitement around the numerous current opportunities to incorporate artificial intelligence (AI) into your healthcare organization's operations. Examples of these opportunities include patient-monitoring devices, voice recognition for EMR dictation, computer-aided diagnosis (CAD) of imaging and pathology, and computerized treatment recommendations. According to a survey from Definitive Healthcare, "One-third of hospitals and imaging centers report using artificial intelligence, machine learning, or deep learning to aid tasks associated with patient-care imaging or business operations." The AI healthcare market is growing rapidly—so rapidly that federal and state regulatory agencies have not developed many regulations, and these bodies are exploring potential legal implications. This lack of regulation does not mean that utilization of this technology is without risk, however. Tedros Adhanom Ghebreyesus, Director-General of the World Health Organization (WHO), warned that "Like all new technology, artificial intelligence…can also be misused and cause harm."

Although AI liability is not yet well developed, it is important that organizations develop well defined processes for:

- Identifying and cataloging all AI tools that may already be in use in your organization
- Analyzing and assessing those tools already in use for opportunities to minimize risk
- Creating an organized intake process to assess proposed AI tools
- Developing a governance process to administer the approval or denial of AI tools

When developing a governance process, determine the relevant stakeholders in your organization. Every organization is unique and varies in size and composure. Key stakeholders may include:

- Medical leaders (Chief Medical Officer, Physician Champion, etc.)
- Clinicians (Department leadership, end user, pharmacy, research, etc.)
- Health information management
- Information Technology
- Human Resources
- Compliance
- Risk management
- Quality assurance

To ensure consistency, it can be helpful to develop and implement tools to assess AI devices and software. Items on these checklists may include, but are not limited to:

- Who owns the project? (Include clinical and IT owners)
- Who will track complaints/issues/problems/costs/successes of the project?
- Is the software FDA-cleared?
- What is the category of problem that the software is designed to solve? (For example, is it a research question or a quality/clinical/patient/or population health problem?)

- Is this for all patients, or will a select population of patients be exposed to the intervention?
- Has a medical-device tool assessment been completed?
- How are clinicians/staff trained in using this technology?
- How is that training documented?
- Will the AI be utilized by all physicians and other healthcare professionals, or only certain clinicians?
- What new finding/recommendation is generated?
- Are there any conflicts of interest?
- How is the clinician notified that AI was utilized? (For example, is there notation on final reports that AI was utilized?)
- How is the patient notified that AI was utilized?
- What is the consent process (including consent for data repurposing, if indicated)?
- How is the data handled?
- How will you manage software upgrades?
- When and how will ongoing evaluation be done?

Health systems may face legal challenges as well, such as allegations of a negligent credentialing claim. There may be liability claims for failure to properly assess a new AI system, failing to provide training, or failing to complete and process updates and maintenance on equipment for an AI algorithm. Another vulnerability could be related to how the technology may perpetuate inequity in healthcare delivery. In their 2019 paper in the *Journal of Global Health,* "Artificial Intelligence and Algorithmic Bias: Implications for Health Systems," Panch, Mattie, and Atun define algorithmic bias as "the application of an algorithm that compounds existing inequities in socioeconomic status, race, ethnic background, religion, gender, disability, or sexual orientation and amplifies inequities in health systems." Therefore, it is recommended that you initiate conversations about bias early. Sample questions to ask your potential AI vendors include:

- What ongoing efforts are you making to eliminate bias in your technology?
- Do you have multiple sources of data?
- What metrics do you use to evaluate your work?

Some other considerations include ensuring that AI does not increase "pop-up alert" fatigue. This could potentially cause the clinician to unintentionally accept orders or acknowledge alerts. AI technology introduces a new means for misdiagnosis if the clinician agrees with an AI decision-making "suggestion" that turns out to be wrong, or if the clinician disagrees with the AI suggestion and it turns out to be correct. Also consider potential outcomes if a clinician becomes overly dependent on AI—they may have difficulties if the AI software becomes unavailable. This could lead to liability issues if the clinician is not prepared to complete the surgery, task, or procedure without relying on AI. It is unknown if future litigation could arise because a clinician refused to utilize available AI in care delivery. Discuss these topics with your governance team, and develop guidance proactively.

Patient-disclosure rules and regulations are not clearly defined, and there is no widespread agreement on the patient-consent process. Knowing your state's legal obligations for informed consent is crucial when developing this guidance, especially since some states specify informed consent for surgical or invasive procedures only. Defining the expectations based on how you are using AI is another important function of your governance process. Potential ways of handling disclosure and consent (after exploring state law) include:

- In cases where AI is used as a tool that accompanies the decision-making process (screening tools for sepsis, discharge readiness tools, etc.), or when using de-identified data retrospectively, include permission in the general consent-to-treat form.
- In cases where AI is being used in surgical/invasive procedures, patients should be provided with information that explains the way AI programs works. Daniel Schiff, MS, and Jason Borenstein, PhD, writing in the *AMA Journal of Ethics*'s "How Should Clinicians Communicate With Patients About the Roles of Artificially Intelligent Team Members?" commentary, advise that "explaining to patients the specific roles of health care professionals and of AI and robotic systems as well as the potential risks and benefits of these new systems, physicians can help improve the informed consent process and begin to address major sources of uncertainty about AI."
- For diagnostic reports that are aided or augmented with AI, consider adding language such as, "This study was aided by the use of artificial intelligence."

The use of AI as part of the informed-consent process should include the following elements:

- An explanation and rationale for the recommended treatment or procedure, including any technologies used, any associated capabilities and limitations, and the expected outcome
- Names of involved physicians, physician assistants and/or nurse practitioners, and their experience and credentials
- Disclosure of the known risks associated with the use of artificial intelligence—such as technology disruptions, transmission errors, failures, and vulnerabilities to the security of PHI—and measures implemented to address each risk
- Explanation of the anticipated benefits of artificial intelligence

As AI continues to be utilized in the healthcare space, privacy and security will remain significant issues. Large amounts of data may be accessed between systems, which may increase the risk for a breach or cyber-attacks. Suggestions to mitigate this risk could include:

- Ensuring that your current privacy regulations are updated to take AI systems and use of data into account
- Identifying any confidentiality and data-privacy risks
- Making sure you have a clear understanding of your Business Associate Agreements or other agreements to share data
- If you are committed to sharing de-identified data, ensuring that you can meet the HIPAA Privacy Rule's de-identification standard outlined in sections 164.514(b) and (c)—covered entities must use one of two validated methods: expert determination or safe harbor. (Data sharing between different organizations could violate the Health Insurance Portability and Accountability Act if this process is not followed.)

AI is a rapidly developing technology, and clinicians and organizations need to prepare for changes in laws affecting its use. Risk managers should remain alert to emerging technologies and regulations that can affect patient care and safety.

Governance board—Implementing a governance board to evaluate the technology's risks and benefits to patient care is an important action item prior to purchasing an AI product.

Policy development—If you decide to move forward with AI usage, identify and clearly develop a policy on transparency and patient-consent processes before the first day of using the product in clinical operations.

IT maintenance and security–Partner with IT to ensure that cybersecurity requirements have been met, and develop a process that assigns maintenance and software update management. It is recommended that you develop a system to monitor updates to ensure the system is working as designed.

User training and documentation–Develop user training. Determine whether the technology requires credentialing, and make sure this takes place and is documented prior to any staff using the technology.

Ongoing evaluation–Conduct routine evaluations of the performance of machine-learning algorithms and staff compliance, then review the documentation of all education processes to identify any risks of unexpected outcomes and ensure that AI is helping the organization accomplish its goals.

For additional in-depth information on this topic, we recommend the WHO's guidance resource, Ethics and Governance of Artificial Intelligence for Health (who.int), and the National Library of Medicine's Sources of Risk of AI Systems–PMC (nih.gov).

This information should be modified based on individual circumstances, professional judgment, and local resources. This document is provided for educational purposes and is not intended to establish guidelines or standards of care. Any recommendations contained within the document is not intended to be followed in all cases and does not provide any medical or legal advice.

Resources

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