

# Patient Safety and Artificial Intelligence

## Considerations for Key Groups



## Regulators and Policymakers

By fostering responsible generative artificial intelligence (genAI) adoption and use, regulators and policymakers can help patients, clinicians, and health care systems leverage the promise of genAI to enhance patient care and outcomes without compromising safety or quality. The IHI Lucian Leape Institute offers the following recommendations for regulators and policymakers:

- **Establish clear guidelines for ethical and trustworthy use of AI:** Develop comprehensive regulations for the development and deployment of genAI in health care, focusing on patient safety, data protection, and ethical use of technology. Regulators and policymakers need to collaborate with ongoing efforts in health care to develop guidelines such as the National Academy of Medicine’s Health Care Artificial Intelligence Code of Conduct,<sup>1</sup> the guidelines and guardrails by the Coalition for Health AI,<sup>2</sup> and the Association for the Advancement of Medical Instrumentation’s guidance on medical device cybersecurity (ANSI/AAMI SW96)<sup>3</sup>.
- **Support transparency and accountability:** Mandate transparency in genAI systems to ensure that users understand how AI makes decisions, with mechanisms in place for accountability in case of errors or adverse outcomes. It is critical that regulators and policymakers, in a collaborative effort with AI developers and users, establish definitions of and thresholds for transparency. Because genAI results are likely to be persuasive, this increases the possibility that self-interested parties (e.g., corporations selling a relevant product) will try to insert themselves into the process to influence the AI recommendations. It is important that such efforts are anticipated and dealt with through appropriate regulations.

### IHI Lucian Leape Institute Expert Panel Report on Patient Safety and AI

In January 2024, the IHI Lucian Leape Institute convened an expert panel to further explore the promise of generative artificial intelligence (genAI) and its potential risks for patient safety.

The panel reviewed the literature on AI and patient safety and engaged in a robust discussion that focused on three likely use cases for genAI in health care: documentation support, clinical decision support, and patient-facing chatbots.

The panel also reviewed considerations for key groups and provided specific recommendations and mitigation strategies for these audiences.

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- **Promote AI literacy:** Advocate for and fund initiatives that enhance AI literacy among clinicians, health care staff, and patients, ensuring that they are informed about the benefits and limitations of genAI tools. These efforts can include facilitating training for health care professionals on genAI fundamentals, ethical considerations, and practical applications; public awareness campaigns; and incentives for learning such as accredited certification programs or open access continuing education credits on genAI in health care.
- **Incentivize AI development and research that prioritizes safety:** Encourage the creation of genAI tools that prioritize patient safety through incentives for AI developers and health care systems that meet high testing thresholds and safety and quality standards. Research should also be incentivized to ensure the creation of a robust, impartial evidence base.
- **Facilitate localized decision-making:** Recognize the importance of context and nuance in health care by allowing for local governance in the implementation of genAI, while providing a federal framework for overarching AI safety and ethical standards. This can help ease user anxiety and temper overexcitement while providing a standard framework that allows for safe design, implementation, and use of genAI tools across hospitals and health care systems. This effort can be further bolstered through required safety data reporting from health care systems and developers, overseen by appropriate regulatory and enforcement bodies.

## References

<sup>1</sup> Health Care Artificial Intelligence Code of Conduct. National Academy of Medicine. <https://nam.edu/programs/value-science-driven-health-care/health-care-artificial-intelligence-code-of-conduct/>

<sup>2</sup> *Blueprint for Trustworthy AI Implementation Guidance and Assurance for Healthcare (Version 1.0)*. Coalition for Health AI; April 2023. [https://coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai\\_V1.0.pdf](https://coalitionforhealthai.org/papers/blueprint-for-trustworthy-ai_V1.0.pdf)

<sup>3</sup> *ANSI/AAMI SW96:2023; Standard for Medical Device Security—Security Risk Management for Device Manufacturers*. Association for the Advancement of Medical Instrumentation; 2022. <https://array.aami.org/doi/10.2345/9781570208621.ch1>