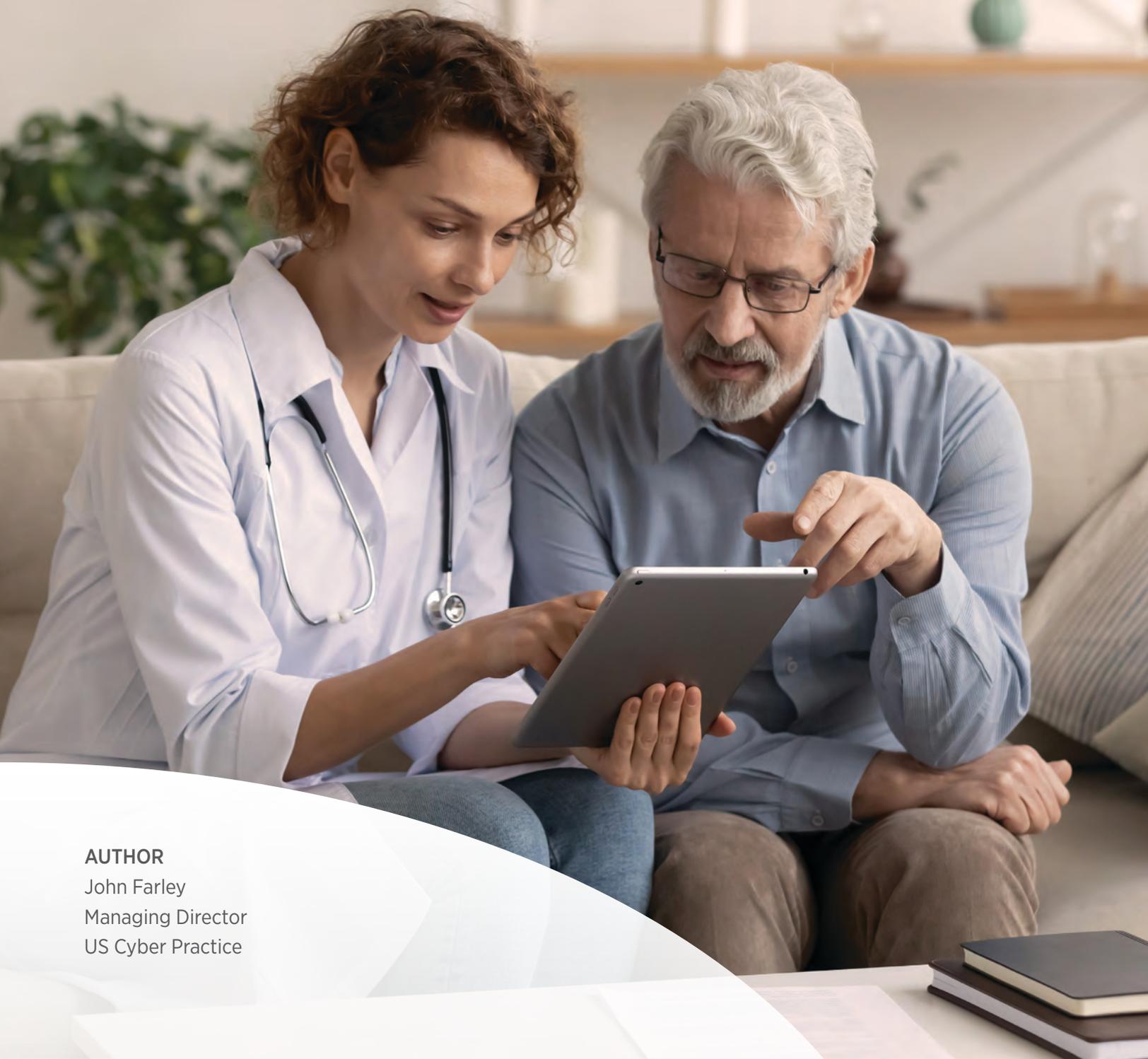# WHEN AI MEETS MEDICINE

Risk Management in the
Age of Smart Healthcare

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Artificial Intelligence (AI) is revolutionizing healthcare, offering unprecedented opportunities to enhance patient outcomes, streamline operations and transform the way care is delivered. From predictive analytics that anticipate disease outbreaks to machine learning algorithms that assist in early diagnosis and personalized treatment plans, AI holds the promise of a smarter, more efficient healthcare system. However, alongside these advancements come significant risks and challenges. The reliance on AI introduces concerns about data privacy, algorithmic bias and the potential for errors in critical decision-making processes. Moreover, the ethical implications of delegating life-altering decisions to machines raise questions about accountability and trust. As healthcare increasingly integrates AI technologies, it is imperative to strike a delicate balance between harnessing its transformative potential and mitigating the perils that could compromise patient safety and equity. This paper explores the dual nature of AI in healthcare, examining both its promise and the risks it poses to the future of medicine.

The risks we are addressing are not merely hypothetical; they are grounded in a wide variety of real-world incidents and clinical studies that have already taken place.

## CASE STUDIES

### 1. AI Misdiagnosis in Breast Cancer Screening[1]

- **Sector:** Healthcare — Diagnostics.
- **Incident:** In one study, an AI system designed to assist in breast cancer screening was found to misdiagnose patients, either failing to detect cancer or flagging false positives.
- **Impact:** Misdiagnoses could lead to delayed treatments for some patients and unnecessary stress and invasive procedures for others. This study highlights the risks of deploying AI systems without ensuring they are trained on diverse and representative datasets.
- **Key Lesson:** AI systems in healthcare must undergo rigorous validation and testing across diverse populations to ensure equitable and accurate outcomes.

### 2. AI Bias in Liver Transplant Allocation[2]

- **Sector:** Healthcare — Organ transplantation.
- **Incident:** An AI algorithm used to prioritize liver transplant recipients was found to disadvantage certain groups of patients. The algorithm relied on a formula that underestimated the severity of liver disease in patients of a specific ethnic background, delaying their access to life-saving transplants.
- **Impact:** This bias led to systemic inequities in healthcare delivery, with one group of patients receiving transplants at a lower rate than other groups.
- **Key Lesson:** Healthcare AI must be audited for racial and demographic biases to prevent perpetuating systemic inequities.

### 3. AI-Powered Chatbot Gives Harmful Advice[3]

- **Sector:** Healthcare — Mental health.
- **Incident:** Researchers found an AI-powered mental health chatbot provided harmful advice to users experiencing mental health crises. In one instance, the chatbot failed to recognize the severity of a user's situation and offered generic, unhelpful responses.
- **Impact:** The chatbot's failure to provide appropriate support could exacerbate mental health issues and lead to potential harm for users in crisis. This incident raised concerns about the reliability of AI in sensitive healthcare applications.
- **Key Lesson:** AI systems in mental health must be carefully designed and monitored to ensure they provide safe and effective support, especially in high-stakes situations.

### 4. AI-Driven Drug Discovery Errors[4]

- **Sector:** Healthcare — Pharmaceutical research.
- **Incident:** An AI system used for drug discovery generated a list of potential drug candidates, but some of the suggested compounds were found to be ineffective for certain individuals.
- **Impact:** This incident delayed the drug development process and raised concerns about the reliability of AI in critical research applications.
- **Key Lesson:** AI in pharmaceutical research must be paired with rigorous human review to ensure safety and efficacy in drug development.

### 5. AI Fails in Sepsis Detection[5]

• **Sector:** Healthcare — Hospital management.

• **Incident:** An AI system designed to detect sepsis in hospitalized patients failed to identify cases in a timely manner in a case study. The system's predictions were often inaccurate and, in real-world scenarios, could have led to delayed interventions and, in some cases, preventable deaths.

• **Impact:** The failure of the AI system to detect sepsis in time could have resulted in loss of life and eroded trust in AI-based healthcare tools. Hospitals would have faced legal and reputational consequences as a result.

• **Key Lesson:** AI systems in critical care must be thoroughly validated and continuously monitored to ensure they meet the high standards required for patient safety.

### 6. AI Bias in Health Insurance Approvals[6]

• **Sector:** Healthcare — Insurance.

• **Incident:** Several major health insurance companies were using AI systems to automate claims processes and prior authorizations.

• **Impact:** This resulted in a notable increase in claim denials, leading to public outcries and financial and emotional distress for affected patients. Several state regulatory authorities then banned insurance companies from using AI as the sole decision-maker in the claims approval process.

• **Key Lesson:** This increased regulatory risk and reputational harm for the health insurance companies. The incident highlighted the ethical risks of using AI in healthcare insurance, which must be designed with fairness, transparency and some form of human oversight to avoid perpetuating unfair health insurance claims adjudication.



These case studies demonstrate the critical need for ethical AI development, rigorous testing and continuous monitoring in healthcare applications.

To prevent or mitigate harm from AI-driven losses in the healthcare sector, organizations should consider the following risk management strategies:

### 1. Ethical AI Development

• **Ensure Diversity in Training Data:** Use diverse and representative datasets to train AI systems, ensuring they perform accurately across all demographics, including race, gender, age and socioeconomic status.

• **Bias Audits:** Regularly audit AI algorithms for biases and inequities, especially in sensitive areas like diagnostics, treatment recommendations and insurance approvals.

• **Transparency:** Make AI decision-making processes explainable and transparent to healthcare professionals and patients.

### 2. Rigorous Testing and Validation

• **Clinical Trials for AI Systems:** Treat AI systems like medical devices and subject them to rigorous clinical trials to validate their accuracy, reliability and safety.

• **Stress Testing:** Test AI systems under various scenarios to ensure they perform well in real-world conditions.

• **Continuous Monitoring:** Implement systems to monitor AI performance post-deployment and identify errors or deviations in real-time.

### 3. Human Oversight

• **Deploy a "Human-in-the-loop":** Use AI to augment human decision-making rather than replace it entirely. Ensure healthcare professionals have the final say in critical decisions.

• **Training for Healthcare Professionals:** Train healthcare staff to understand AI systems, their limitations and how to interpret AI-generated insights.

• **Escalation Protocols:** Establish clear protocols for escalating cases where AI outputs are uncertain or potentially harmful.

## 4. Regulatory Compliance

- **Adhere to Healthcare Standards:** Ensure AI systems comply with healthcare regulations such as HIPAA (Health Insurance Portability and Accountability Act) for data privacy and security.

- **FDA Approval for AI Tools:** Obtain necessary approvals from regulatory bodies like the FDA for AI systems used in diagnostics, treatment or medical devices. Details can be found at the FDA's AI/ML-Based Software as a Medical Device (SaMD) Action Plan.[7]

- **Ethical Guidelines:** Follow ethical guidelines for AI in healthcare, such as those outlined by the World Health Organization (WHO) or other governing bodies.[8]

## 5. Robust Data Privacy and Security

- **Secure Patient Data:** Implement strong encryption and cybersecurity measures to protect sensitive patient data from breaches or misuse.

- **Minimize Data Collection:** Collect only the data necessary for AI functionality to reduce risks associated with data storage and processing.

- **Anonymization:** Use anonymized data wherever possible to protect patient identities.

## 6. Stakeholder Collaboration

- **Engage Patients:** Involve patients in the development and deployment of AI systems to ensure their needs and concerns are addressed.

- **Multidisciplinary Teams:** Collaborate with experts in medicine, AI, ethics and law to design and deploy AI systems responsibly.

- **Feedback Loops:** Create mechanisms for healthcare professionals and patients to provide feedback on AI systems, enabling continuous improvement.

## 7. Proactive Risk Management

- **Risk Assessments:** Conduct regular risk assessments to identify potential harms associated with AI systems and develop mitigation strategies.

- **Fail-Safe Mechanisms:** Build fail-safe mechanisms into AI systems to prevent catastrophic failures, such as reverting to human decision-making in critical situations.

- **Incident Response Plans:** Develop and maintain incident response plans to address AI-related errors or failures promptly.

## 8. Ethical Use of AI in Insurance

- **Fair Algorithms:** Design insurance approval algorithms to ensure fairness.

- **Transparency in Decisions:** Provide clear explanations for insurance claim approvals or denials made by AI systems.

- **Regular Reviews:** Periodically review AI systems used in insurance to ensure compliance with ethical and legal standards.

## 9. Continuous Education and Awareness

- **AI Literacy:** Educate healthcare professionals and patients about AI capabilities, limitations and risks.

- **Ethics Training:** Provide training on ethical considerations in AI use for healthcare staff and developers.

- **Public Awareness Campaigns:** Inform the public about how AI is used in healthcare and the safeguards in place to protect them.

## 10. Adopt AI Governance Frameworks

- **Establish AI Governance Committees:** Create committees to oversee AI development, deployment and monitoring in healthcare organizations.

- **Periodic Reviews:** Conduct regular reviews of AI systems to ensure they align with organizational goals and ethical standards.

- **Accountability Mechanisms:** Assign accountability for AI-related decisions and outcomes to specific teams or individuals.
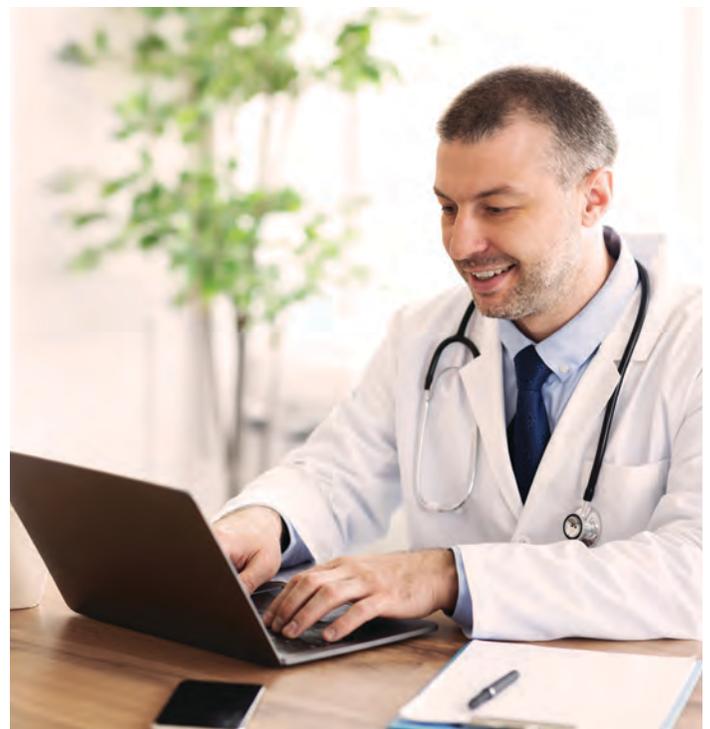
## AI RISK TRANSFER: INSURANCE IMPLICATIONS

The insurance industry plays a critical role in addressing the risks associated with AI-driven healthcare, but its ability to cover such losses depends on the specific circumstances and the type of insurance policy in question.

Medical malpractice insurance, for instance, is designed to cover healthcare providers for claims arising from errors, omissions or negligence in patient care. However, when AI systems are involved, determining liability becomes more complex. If an AI-driven diagnostic tool or treatment recommendation leads to patient harm, questions arise about whether the fault lies with the healthcare provider, the AI developer or other parties. Beyond medical malpractice, other lines of insurance may come into play. For example, product liability insurance could be relevant if the harm is attributed to a defect in the AI system itself, such as flawed algorithms or inadequate testing by the manufacturer. Cyber insurance might also be applicable in cases where data breaches or system failures compromise patient privacy or safety or lead to other financial losses. Additionally, technology Errors & Omissions insurance could provide coverage for AI developers if their technology fails to perform as intended. Traditional insurance policies may not explicitly address these scenarios or may be subject to AI-specific exclusionary language, potentially leaving gaps in coverage.

The rapid evolution of AI in healthcare may present insurance coverage challenges. Organizations utilizing AI should work with their insurance broker to update or tailor coverage to address the unique risks posed by AI, such as algorithmic bias, lack of transparency in decision-making, regulatory risk and the potential for errors that lead to systemic losses. Insurers must also consider how to underwrite these risks effectively, given the limited historical data on AI-related claims. As AI continues to transform healthcare, the insurance industry will need to adapt to ensure comprehensive coverage for all parties involved while fostering innovation and patient safety.

By implementing best practices in AI risk management and deploying risk transfer strategies, healthcare organizations can harness the potential of AI and mitigate risks while ensuring patient safety, equity and trust. AI in healthcare must be approached with caution, responsibility and a commitment to ethical principles to prevent harm and maximize benefits.

### Sources

[1] "AI could help improve early detection of breast cancers between screenings, UCLA-led study shows," *UCLA*.

[2] https://dash.harvard.edu/server/api/core/bitstreams/a9522a78-b331-464e-bafe-3c05992a59db/content.

[3] "New study: AI chatbots systematically violate mental health ethics standards," *Brown University*.

[4] "AI in Drug Discovery: The Illusion of Speed and the Reality of Clinical Failure," *Infiuss Health*.

[5] https://arxiv.org/pdf/2309.12368.

[6] "AI vs. AI: Patients deploy bots to battle health insurers that deny care," *Stateline*.

[7] https://www.fda.gov/media/145022/download?attachment.

[8] https://www.who.int/publications/i/item/9789240084759.