

COMMENT

DECODING THE DIGITAL DOCTOR: UNVEILING THE MATERIALITY OF AI/ML IN HEALTHCARE AND THE CALL FOR INFORMED CONSENT DISCLOSURE

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ABSTRACT

Technological innovations in the practice of medicine have benefited patients and physicians alike. This is true regarding the recent introduction of artificial intelligence and machine learning (AI/ML) in clinical practice. Patients have received precise medical care and physicians have enjoyed streamlined workflows. However, with innovation comes risks, and medical AI/ML has already mustered a rap sheet of serious mistakes in its relatively short clinical utility.

Algorithmic inaccuracy in medical AI/ML has caused misdiagnoses of life-threatening illnesses in patients, distorted predictions due to racial bias, and disrupted the physician-patient care relationship. Key to understanding the risks associated with medical AI/ML is thorough and interactive discussions between a physician and patient. Transparency has long been the model for effective physician-patient communication and is why the law imposes a duty on physicians to inform patients of a treatment's benefits and risks before obtaining their consent. This doctrine of informed consent is the cornerstone of the physician-patient care relationship.

Informed consent discussions between a physician and patient protects both parties—patients can exercise unclouded medical decision making and physicians are better shielded against a patient's lack of informed consent action. What a physician is required to disclose to patients varies in scope depending on the state and the nature of the procedure, but the determination often depends on the materiality of the information. When a fact is material to a patient's medical judgment, its disclosure is generally required. This Comment proposes that a physician's use of AI/ML to diagnose or treat a patient is material and should be disclosed for best practice in the absence of uniform regulation.

To support the assertion that physicians should disclose their use of medical AI/ML to patients, this Comment first investigates the risks and materiality of medical AI/ML. These risks alone likely justify disclosure to patients, but this Comment reviews current informed consent jurisprudence to show the broader coverage of required disclosures that can include physician-specific characteristics and financial conflicts of interest. Medical AI/ML is not the first technology to warrant disclosure to patients. This Comment analyzes how the risks of anesthesia and X-ray technology led to disclosure requirements for patient safety. Creating physician guidelines for the use and disclosure of medical AI/ML will ensure that these programs will benefit patients, physicians, and the healthcare community.

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I. INTRODUCTION

Hindsight is 20/20. But what if you could know all the material information about an event up front? Consider the following scenario:

You are a passenger boarding an airplane, and your destination is that beautiful vacation spot you always dreamed of seeing. After taking your seat in the first class section the pilot greets the passengers over the intercom and ensures the flight will be fast and worry-free. The plane takes off and you can feel the relaxation of vacation setting in, but then you overhear something startling. The flight attendants near you are discussing a new automated flight control system being employed on the plane. In simulations this system has performed well, but its long-term reliability is uncertain. You learn that this system completely operates the plane and makes pilot navigation obsolete. In fact, you aren't even sure there is a pilot on board the plane! You look out of your window and realize that buildings and natural features are becoming unrecognizable as the plane increases in altitude. Wouldn't you have wanted to know about the use of this new flight control system before you boarded the plane?

This scenario is analogous to the problem facing patients contemplating a medical treatment or procedure. Hospitals and physicians are increasingly using artificial intelligence and machine learning (AI/ML) to perform administrative activities and to diagnose and treat medical patients.¹ However, with the expanding integration of AI/ML in medicine, there are concerns that algorithm inaccuracy could lead to patient injury and a general distrust for medical technology.² A problem arises when the patient is unaware that their physician has used AI/ML in the patient's diagnosis or treatment.

AI/ML has the potential to improve patient care and quality of life, but as with any new technology, the unintended consequences have not yet been fully realized.³ While state and federal governments and medical organizations scramble to develop regulatory frameworks for the governance of AI/ML in health care,⁴ a physician's disclosure of their use of AI/ML to patients is best practice and should be required before obtaining a patient's consent to medical treatment.⁵

Although risks and adverse effects are inherent in many medical procedures, interactive discussions between a physician and patient facilitates the exchange of information, increasing the transparency of a patient's medical care.⁶ The cornerstone of effective physician-patient communication is the doctrine of informed consent. Informed consent requires a physician to communicate all relevant information to a patient regarding their diagnosis or proposed treatment options, and a physician's failure of this requirement can expose them to civil liability.⁷ This Comment argues that a physician's use of AI/ML in diagnosing,

¹ Thomas Davenport & Ravi Kalakota, *The Potential for Artificial Intelligence in Healthcare*, 6 FUTURE HEALTHCARE J. 2, 96 (2019).

² See discussion *infra* Section II.B. See also George Maliha et al., *Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation*, 99 MILBANK Q. 629 (2021).

³ Shuroug A. Alowais et al., *Revolutionizing Healthcare: The Role of Artificial Intelligence in Clinical Practice*, 23 BMC MED. EDUC. 689 (2023).

⁴ See Brian Johnson, *State Legislators Look to Regulate Use of AI in Healthcare*, LEXISNEXIS (Aug. 18, 2023), <https://www.lexisnexis.com/community/insights/legal/capitol-journal/b/state-net/posts/state-legislators-look-to-regulate-use-of-ai-in-healthcare> (summarizing AI bill information, *Artificial Intelligence 2023 Legislation*, NAT'L CONF. OF STATE LEGISLATORS (Jan. 12, 2024), <https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation>).

⁵ See discussion *infra* Section III.C–D.

⁶ See Jennifer Fong Ha, *Doctor-Patient Communication: A Review*, 10 OCHSNER J. 38 (2010) (“Effective doctor-patient communication is a central clinical function . . . which is the heart and art of medicine.”).

⁷ See discussion *infra* Section III.A.

recommending a procedure, or treating a patient is relevant for the patient to form the basis of intelligent consent and should therefore be a required disclosure. A physician’s proper disclosure of their use of AI/ML in a patient’s medical care protects both the physician and patient, and this also helps ensure that AI/ML technology safely benefits society.⁸

In order to illustrate the necessity for requiring a physician’s disclosure of their use of AI/ML, Section II of this Comment provides a non-exhaustive summary of the risks associated with AI/ML in healthcare and explains its current lack of governance. Section III then explores the physician’s duty to disclose under the doctrine of informed consent. Additionally, Section III maintains why a physician’s use of AI/ML is material to a patient’s medical decision making and discusses the balance of liability for physicians. Section IV concludes this Comment by answering the question, what should a physician tell a patient when they plan to, or have used, AI/ML in the patient’s medical care?

II. AI/ML IN HEALTHCARE: INNOVATION WITH RISKS

AI/ML needs little introduction. It has become assimilated into almost every corner of human influence—including healthcare. AI/ML’s capabilities and applications are expanding, and its definition is not settled, either. The FDA provides a practical definition of medical artificial intelligence as “a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments.”⁹ Machine learning is a type of AI that essentially teaches itself by using algorithms to improve its own performance as it is exposed to more data over time.¹⁰

Medical AI/ML has the potential to “revolutionize different aspects of health care” by assisting hospitals and physicians in the diagnosis and treatment of patients.¹¹ However, no technological innovation is without risks. This Section begins with a survey of the various medical AI/ML applications and follows with a discussion of the associated risks to physicians and, most importantly, patients.

A. *The Roles of AI/ML in Healthcare*

Some goals for employing medical AI/ML is to make healthcare more personalized, predictive, preventative, and interactive for patients.¹² Physicians are achieving these goals by using AI/ML to assist in the diagnosing and imaging of patients and by providing precise medicine and clinical decision support. Let’s consider both of these applications.¹³

1. Diagnostic and Imaging Applications

AI/ML can synthesize large amounts of patient data and identify key disease detection patterns, which are highly applicable for diagnosing, predicting, or classifying diseases.¹⁴ In fact, results have shown

⁸ See discussion *infra* Section III.C.

⁹ *Artificial Intelligence and Machine Learning in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN. (last updated Mar. 15, 2024), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>.

¹⁰ *NIH Workshop: Harnessing Artificial Intelligence and Machine Learning to Advance Biomedical Research*, NAT’L INST. OF HEALTH (July 23, 2018), https://datascience.nih.gov/sites/default/files/AI_workshop_report_summary_01-16-19_508.pdf.

¹¹ Alowais et al., *supra* note 3, at 691.

¹² Bangul Khan et al., *Drawbacks of Artificial Intelligence and Their Potential Solutions in the Healthcare Sector*, BIOMED. MATERIALS & DEVICES, Feb. 2023, at 1, 2.

¹³ AI/ML applications in the healthcare sector are numerous and range on the spectrum from drug discovery and development to administrative automation like appointment scheduling and billing. It is necessary for this discussion to consider only the clinical applications of AI/ML directly associated with a patient’s diagnosis or treatment recommendation.

¹⁴ Alowais et al., *supra* note 3.

that AI/ML systems have achieved “specialist-level performance in many diagnostic tasks [and] can better predict patient prognosis than clinicians” in many areas.¹⁵

AI/ML is also being applied to medical imaging and radiomics, or the detection of clinically relevant information found in imaging data that may be unperceived by the human eye.¹⁶ For example, AI/ML can recognize potentially cancerous lesions in a patient’s radiology images.¹⁷ One study showed that utilizing an AI/ML system to analyze mammograms had a reduction in false positives and false negatives by 5.7 percent and 9.4 percent, respectively.¹⁸ Another study found that AI/ML was better at detecting early breast cancer than radiologists.¹⁹ AI/ML has also been used to detect skin cancer, diagnose melanoma cases, detect diabetic retinopathy and EKG abnormality for cardiovascular diseases, and discover pneumonia from chest radiographic images.²⁰ These abilities of AI/ML can help physicians provide precise medical care to patients.

2. Clinical Decision Support

Personalized treatment is an approach that tailors medical care to individual patients based on their unique characteristics. Healthcare providers have improved processes for personalizing treatment and optimizing patient medical care by incorporating AI/ML algorithms into clinical decision support systems.²¹ Clinical decision support refers to computer-based tools, systems, and processes that assist physicians, usually at the point of care, in informing decisions about a patient’s care.²²

AI/ML’s application in this regard can add value to a patient’s care by being able to provide real-time predictions and recommendations.²³ One particular study showed encouraging outcomes with AI/ML achieving a prediction accuracy of over 80 percent across multiple drugs.²⁴ AI/ML can also optimize medication dosages for patients and predict potential adverse drug reactions.²⁵ One algorithm outperformed expert physicians for warfarin dose optimization, which is commonly used to treat and prevent blood clots.²⁶ AI/ML’s ability to analyze large data sets enables physicians to identify potential drug interactions and improve patient outcomes.²⁷ The applications of AI/ML in assisting physicians with treatment decisions and personalized recommendations for patients also reduces medical costs and streamlines healthcare administration.²⁸ These advances have not come without error, however.

¹⁵ Kun-Hsing Yu et al., *Artificial Intelligence in Healthcare*, 2 NATURE BIOMED. ENG’G 719, 722 (2018).

¹⁶ See Alanna Vial et al., *The Role of Deep Learning and Radiomic Feature Extraction in Cancer-Specific Predictive Modelling: A Review*, 7 TRANSLATIONAL CANCER RSCH. 803, 807 (2018); Chan Heang-Ping et al., *Deep Learning in Medical Image Analysis*, 1213 ADVANCES IN EXPERIMENTAL MED. & BIOLOGY 3 (2020).

¹⁷ Davenport & Kalakota, *supra* note 1.

¹⁸ Scott Mayer McKinney et al., *International Evaluation of an AI System for Breast Cancer Screening*, 577 NATURE 89 (2020).

¹⁹ Hyo-Eun Kim, *Changes in Cancer Detection and False-Positive Recall in Mammography Using Artificial Intelligence: A Retrospective, Multireader Study*, 2 LANCET DIGIT. HEALTH E138 (2020).

²⁰ Alowais et al., *supra* note 3.

²¹ See Chris Giordano et al., *Assessing Artificial Intelligence for Clinical Decision-Making*, 3 FRONTIERS IN DIGIT. Health 1 (2021).

²² *Clinical Decision Support*, AGENCY FOR HEALTHCARE RSCH. & QUALITY (last updated Sep. 2023),

<https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html#:~:text=Clinical%20decision%20support%20provides%20timely,to%20higher%2Dquality%20health%20care.>

²³ Alowais et al., *supra* note 3, at 694.

²⁴ Cai Huang et al., *Machine Learning Predicts Individual Cancer Patient Responses to Therapeutic Drugs with High Accuracy*, 8 SCI. REP. 1, 2 (2018).

²⁵ Alowais et al., *supra* note 3, at 694.

²⁶ Agata Blasiak et al., *PRECISE CURATE.AI: A Prospective Feasibility Trial to Dynamically Modulate Personalized Chemotherapy Dose With Artificial Intelligence*, 40 J. CLINICAL ONCOLOGY 1574, 1574 (2022).

²⁷ See Ke Han et al., *A Review of Approaches for Predicting Drug-Drug Interactions Based on Machine Learning*, 12 FRONTIERS IN PHARMACOLOGY 1 (2022).

²⁸ Alowais et al., *supra* note 3, at 692.

B. *The Associated Risks of Medical AI/ML*

With innovation comes risks. This is especially troubling in healthcare where patient safety is paramount.²⁹ Although the long-term problems associated with the applications of AI/ML in healthcare have yet to be seen, these systems have already documented mistakes, presenting a new set of challenges and liabilities for physicians and healthcare providers.³⁰

The first problem with AI/ML diagnostic and image reading is algorithm inaccuracy and the inaccessibility of relevant data.³¹ AI/ML systems require large datasets in order to generate more refined algorithms and outputs.³² An initial challenge when training an AI/ML system is that patient records, because they often regarded as confidential, are not always available for algorithmic processing.³³ AI/ML systems instead “learn” by using training data, which may not be reflective of real-world patient characteristics.³⁴ Consequently, AI/ML systems “may unknowingly apply programmed methodology for assessment inappropriately,” which can result in inaccurate predictions.³⁵ Once real patient information is available for AI/ML algorithms and is added to the training dataset, the existing discrepancies may not perfect the system’s prediction accuracy.³⁶ Underscoring the problems associated with the collection of patient data are the concerns of privacy and data protection.³⁷

Potentially distorted predictions may also be the consequence of biases in the AI/ML’s data collection process.³⁸ This poses a second problem: “under-representation of minorities as a consequence of racial biases in dataset development might lead to subpar prediction results.”³⁹ One alarming study found that a clinical AI/ML algorithm used by many hospitals to decide which patients need care showed racial bias in that black patients had to be deemed much sicker than white patients to be recommended for the same care.⁴⁰ This happened because the algorithm had been trained on healthcare spending data, which reflects the historical trend that black patients had less to spend on their healthcare than white patients.⁴¹ Unless algorithmic bias is mitigated, an underlying problem in one AI/ML system might result in injuries to thousands of patients, rather than the limited number of patients under a single physician’s care.⁴²

AI/ML systems, just by their technological nature, can cause operators to experience another form of bias: automation bias. This occurs “where people are more inclined to trust erroneous instructions issued

²⁹ See Mary Dixon-Woods et al., *Problems and Promises of Innovation: Why Healthcare Needs to Rethink Its Love/Hate Relationship With the New*, 20 *BMJ QUALITY & SAFETY* i47 (2011).

³⁰ See generally Jan Brauner & Alan Chan, *AI Poses Doomsday Risks—But That Doesn’t Mean We Shouldn’t Talk About Present Harms Too*, *TIME* (Aug. 10, 2023), <https://time.com/6303127/ai-future-danger-present-harms/>.

³¹ Khan et al., *supra* note 12.

³² *Id.*

³³ *Id.*

³⁴ Kendall K. Hall & Eleanor Fitall, *Artificial Intelligence and Diagnostic Errors*, *PATIENT SAFETY NETWORK* (Jan. 31, 2020), <https://psnet.ahrq.gov/perspective/artificial-intelligence-and-diagnostic-errors>.

³⁵ *Id.* This is known as overfitting, and it happens when an AI/ML algorithm learns unimportant associations between patient features and outcomes. *Id.*

³⁶ Khan et al., *supra* note 12.

³⁷ Dariush D. Farhud & Shaghayegh Zokaei, *Ethical Issues of Artificial Intelligence in Medicine and Healthcare*, 50 *IRANIAN J. PUB. HEALTH* i, i (2021).

³⁸ Khan et al., *supra* note 12.

³⁹ *Id.* See also Katherine J. Igoe, *Algorithmic Bias in Health Care Exacerbates Social Inequities—How to Prevent It*, *HARV. SCH. OF PUB. HEALTH* (Mar. 12, 2021), <https://www.hsph.harvard.edu/ecpe/how-to-prevent-algorithmic-bias-in-health-care/>.

⁴⁰ Ziad Obermeyer et al., *Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations*, 366 *SCI.* 447, 450 (2019).

⁴¹ *Id.*; Crystal Grant, *Algorithms Are Making Decisions About Health Care, Which May Only Worsen Medical Racism*, *ACLU* (Oct. 3, 2022), <https://www.aclu.org/news/privacy-technology/algorithms-in-health-care-may-worsen-medical-racism>.

⁴² W. Nicholson Price II, *Risks and Remedies for Artificial Intelligence in Health Care*, *BROOKINGS* (Nov. 14, 2019), <https://www.brookings.edu/articles/risks-and-remedies-for-artificial-intelligence-in-health-care/>.

by a machine,” even when a person’s own senses contradict such instructions.⁴³ AI/ML systems make predictions but not explanations, leaving physicians potentially unable to explain the algorithm’s decisions.⁴⁴ Furthermore, overconfidence in medical AI/ML algorithms can also cloud a physician’s judgment, and incorrect recommendations accepted by the physician can cause the algorithm to “relearn and perpetuate the same mistakes.”⁴⁵ Some patients have similarly expressed confidence that AI/ML systems could achieve greater accuracy in their diagnosis and treatment compared to a physician.⁴⁶ This confidence in medical AI/ML can cause patients to have a hollow trust for their physician, which “disrupt[s] the traditional doctor-patient relationship.”⁴⁷

While the operating risks of AI/ML algorithms have the potential to endanger a patient’s medical needs, the most immediate effect of a physician’s use of AI/ML is the diminution of the physician-patient relationship. A frequent criticism of medical AI/ML is that technology cannot provide emotional support or empathy for the patient’s condition.⁴⁸ In other words, AI/ML does not have bedside manners. This may be especially problematic for children patients or patients with severe psychiatric disorders. Ultimately, the lack of empathy and human emotion is “one of the most significant negative aspects of artificial intelligence in medical science.”⁴⁹

The associated risks of AI/ML has increased calls for its regulation. Yet, medical AI/ML remains largely unregulated, and gaps in the regulatory frameworks leaves questions about physician liability unanswered.⁵⁰

C. “*The Sheriff is MIA*”⁵¹—*The Lack of Regulations For Medical AI/ML*

The use of AI/ML systems to assist physicians and hospitals in providing medical care to patients poses real challenges. These systems undoubtedly have the potential for good by helping provide precise care to patients and alleviating physician burnout by streamlining workflows.⁵² But the shadow of liability always looms over a person who owes a duty of care to another.⁵³ It was recently revealed that an AI/ML tool employed by more than 170 hospitals and health systems failed to predict sepsis in 67 percent of patients

⁴³ Paul Hsieh, *How ‘Automation Bias’ Plus Artificial Intelligence Can Lead to Medical Misdiagnoses*, FORBES (May 30, 2023), <https://www.forbes.com/sites/paulhsieh/2023/05/30/how-automation-bias-plus-artificial-intelligence-can-lead-to-medical-misdiagnoses/?sh=71f6be13292a>.

⁴⁴ See Benjamin Bartlett, *The Possibility of AI-Induced Medical Manslaughter: Unexplainable Decisions, Epistemic Vices, and a New Dimension of Moral Luck*, 23 MED. L. INT’L 241 (2023).

⁴⁵ Daiju Ueda, *Fairness of Artificial Intelligence in Healthcare: Review and Recommendations*, 42 JAPANESE J. RADIOLOGY 3, 6 (2023).

⁴⁶ Christopher Robertson et al., *Diverse Patients’ Attitudes Towards Artificial Intelligence (AI) in Diagnosis*, 2 PLOS DIGIT. HEALTH 1, 4 (2023).

⁴⁷ *Navigating the Security Risks of AI in Healthcare*, HITRUST (Nov. 21, 2023), <https://hitrustalliance.net/blog/navigating-the-security-risks-of-ai-in-healthcare>.

⁴⁸ Anto Ćartolovni et al., *Critical Analysis of the AI Impact on the Patient-Physician Relationship: A Multi-Stakeholder Qualitative Study*, 9 DIGIT. HEALTH 1, 8 (2023).

⁴⁹ Farhud & Zokaei, *supra* note 37, at iii.

⁵⁰ See Ruth Reader, *Artificial Intelligence is Making Critical Health Care Decisions. The Sheriff is MIA.*, POLITICO (Feb. 18, 2024), <https://www.politico.com/news/2024/02/18/artificial-intelligence-health-care-fda-00141768#:~:text=Advancements%20in%20AI%20have%20created,perform%20other%20critical%20administrative%20tasks>.

⁵¹ *Id.* This title refers to the lack of regulations for medical AI/ML systems.

⁵² Patrick Boyle, *Can Artificial Intelligence Improve Doctor-Patient Visits and Reduce Burnout?*, AAMC (Jan. 30, 2024), <https://www.aamc.org/news/can-artificial-intelligence-improve-doctor-patient-visits-and-reduce-burnout>.

⁵³ See discussion *infra* Section III.A. This Comment argues that physicians should be required to disclose their use of AI/ML systems in diagnosing or treating patients and does not consider the theories of liability for algorithmic errors. For further reading regarding liability for incorrect AI/ML diagnostic algorithms, see Clara Cestonaro et al., *Defining Medical Liability When Artificial Intelligence is Applied on Diagnostic Algorithms: A Systematic Review*, FRONTIERS IN MED., Nov. 2023, at 1.

who developed the life-threatening illness, while generating false sepsis diagnoses on thousands of patients who did not.⁵⁴ The need for regulation and accountability is great.

Uniformity in the regulation of medical AI/ML is lacking as the FDA has conceded that its “traditional paradigm of medical device regulation was not designed for adaptive artificial intelligence and machine learning technologies.”⁵⁵ This has left states on their own to develop regulatory frameworks. In 2023, twenty-five states and the District of Columbia and Puerto Rico considered or enacted legislation for regulating AI/ML in various uses.⁵⁶ Pending legislation in some of these states if enacted will require persons and entities, both in the public and private sectors, to disclose their use of AI/ML in advertisement and election communications.⁵⁷ However, of the twelve states that proposed legislation for regulating AI/ML in health uses, only Pennsylvania has introduced a bill to require health insurers to disclose the use of AI/ML algorithms in utilization review process.⁵⁸ No legislation has been introduced requiring physicians to disclose their use of AI/ML to patients.⁵⁹

As states scramble to establish guardrails for the governance of AI/ML systems, it is clear that accountability for physicians remains unclear.⁶⁰ While the American Medical Association (AMA) has provided a framework for recommended disclosures when physicians use AI/ML in a “manner which directly impacts patient care,” these are only recommendations.⁶¹ The AMA has deferred to “clinical experts” to determine whether AI/ML tools are appropriate for medical practice and to also “validate the clinical knowledge, clinical pathways, and standards of care used” in the application of such systems.⁶² In other words, states remain responsible for determining the scope of disclosures, if any, when physicians use AI/ML in a patient’s care. In the absence of uniform regulations governing medical AI/ML applications, state informed consent laws can provide an opportunity to protect patients and balance liability for physicians.

III. INFORMED CONSENT: THE CORNERSTONE OF THE CARE RELATIONSHIP

Likely we’ve all experienced some aspect of healthcare, whether as a patient receiving treatment or as a supporter of someone else. It is widely known that before a physician can administer any medical care they must first obtain the consent of the patient, which occurs after the patient has been informed about the treatment or procedure. This process of sharing information is the essence of informed consent and is the foundation of the physician-patient care relationship.

⁵⁴ Liz Richadson, *Artificial Intelligence Can Improve Health Care—But Not Without Human Oversight*, PEW (Dec. 16, 2021), <https://www.pewtrusts.org/en/research-and-analysis/articles/2021/12/16/artificial-intelligence-can-improve-health-care-but-not-without-human-oversight>.

⁵⁵ *Artificial Intelligence and Machine Learning in Software as a Medical Device*, U.S. FOOD & DRUG ADMIN. (last updated Mar. 15, 2024), <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device>.

⁵⁶ *Artificial Intelligence 2023 Legislation*, NCSL (last updated Jan. 12, 2024), <https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation>.

⁵⁷ *Id.*; see Political Artificial Intelligence Disclaimer (PAID) Act, 2023 NY A 7106; 2023 NY S 6859; Artificial Intelligence Content Disclosure, 2023 WI A 664; Artificial Intelligence: Regulation, 2023 CA S 294.

⁵⁸ *Artificial Intelligence 2023 Legislation*, NCSL (last updated Jan. 12, 2024), <https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation>; 2023 PA H 1663.

⁵⁹ *Artificial Intelligence 2023 Legislation*, NCSL (last updated Jan. 12, 2024), <https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation>.

⁶⁰ See *Principles for Augmented Intelligence Development, Deployment, and Use*, AMA (Nov. 14, 2023), <https://www.ama-assn.org/system/files/ama-ai-principles.pdf> (“There is currently no national policy or governance structure in place to guide the development and adoption of non-device AI.”).

⁶¹ *Id.*

⁶² *Id.* Furthermore, the AMA “encourages a whole of government approach to implement governance policies” for the mitigation of AI/ML risks. *Id.*

Informed consent is the process in which a physician educates a patient about the risks, benefits, and alternatives of a recommended treatment or procedure.⁶³ What a physician is required to disclose to a patient differs among states and varies in scope depending on the treatment or procedure.⁶⁴ However, a physician's use of AI/ML should be a required disclosure under the doctrine of informed consent regardless of the jurisdiction. This Section examines how the obligation to disclose medical AI/ML fits under current informed consent jurisprudence, beginning with a brief summary of U.S. informed consent law.

A. *A Physician's Duty to Inform and a Patient's Right to Consent*

A patient's right to decide on a procedure or course of treatment flows from the principle of individual autonomy.⁶⁵ To consent or not consent is a decision solely for the patient.⁶⁶ The consequences for violating a patient's right to consent are unmistakable—a physician may be liable for battery if they touch a patient without their consent.⁶⁷ What the patient voluntarily consents to is determined by the scope of disclosures made by the physician.⁶⁸

The question then becomes: What information is required to be disclosed to the patient? Complicatedly, there is no universal rule. No standardized list has been adopted for informed consent in medical practice, and required disclosures vary in scope depending on the nature of the care.⁶⁹ However, patient disclosures should generally include: a description of the proposed treatment or procedure, including its purpose and how it will be performed; an explanation of the potential risks and anticipated benefits; a discussion of any alternative treatments or procedures, including the option of not undergoing treatment; and an opportunity for the patient to ask questions and seek clarification.⁷⁰ The idea is that patients are better equipped to make intelligent decisions regarding their medical care *after* they have been fully informed of a treatment's risks and alternatives.⁷¹ The arms of the law can reach the physician-patient care relationship when a physician fails or inadequately informs a patient of their medical care.

States generally follow one of two standards in a patient's action for lack of informed consent against a physician: the physician-based standard or the patient-based standard.⁷² Under a physician-based

⁶³ Parth Shah et al., *Informed Consent*, STATPEARLS (June 5, 2023), https://www.ncbi.nlm.nih.gov/books/NBK430827/?report=reader#_NBK430827_pubdet_.

⁶⁴ Laura M. Cascella, *Artificial Intelligence and Informed Consent*, MEDPRO GRP., <https://www.medpro.com/artificial-intelligence-informedconsent> (last visited March 23, 2024).

⁶⁵ See JONATHAN PUGH, *AUTONOMY, RATIONALITY, AND CONTEMPORARY BIOETHICS 2* (2020).

⁶⁶ The Nuremberg Military Tribunal's decision in the Doctors' Trial following World War II created what is now called the Nuremberg Code, a ten point directive delimiting permissible medical experimentation on human subjects. The first directive recognizes that "[t]he voluntary consent of the human subject is absolutely essential." See *Nuremberg Code: Directives for Human Experimentation*, U.S. DEPT. OF HEALTH & HUM. SCI., <https://ori.hhs.gov/content/chapter-3-The-Protection-of-Human-Subjects-nuremberg-code-directives-human-experimentation> (last visited Mar. 22, 2024).

⁶⁷ See *Mohr v. Williams*, 95 Minn. 261 (1905) (holding that a patient's action against a surgeon for assault and battery is proper when a surgical procedure is conducted without the patient's consent).

⁶⁸ Additionally, consent given before the patient is adequately informed about the aspects of the treatment may not be considered valid or legally binding. See Tom L. Beauchamp & James F. Childress, *Informed Consent*, in *PRINCIPLES OF BIOMEDICAL ETHICS* (8th ed. 2019).

⁶⁹ Cascella, *supra* note 64. There are established guidelines and sample forms available to health care providers for obtaining informed consent, but none that have been universally adopted and legally enforced.

⁷⁰ Va. Admin. Code § 12VAC5-20-100 (2016); NAT'L COMM'N FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMED. RSCH., *THE BELMONT REPORT 10* (1978).

⁷¹ Cascella, *supra* note 64.

⁷² See *Medical Treatment and Informed Consent State Law Survey*, LexisNexis (last updated Apr. 5, 2024), https://plusai.lexis.com/document/?pdocfullpath=%2Fshared%2Fdocument%2Fanalytical-materials%2Furn:contentItem:5WHJ-TWW1-F873-BOX3-00000-00&pdmfid=1545874&pdcontentcomponentid=500749&pdproductcontenttypeid=urn:pct:16&pdisdoclinkaccess=true&pdischatbotdoc=true&pdsearchmode=chatbot_citation&cri d=406a250f-2c21-446d-9332-5a9a90f202c9. Two states, Minnesota and New Mexico, follow a hybrid approach. *Id.*

standard, physicians are required to discuss those benefits and harms that another average qualified physician would discuss in similar circumstances.⁷³ Conversely, physicians in states that have adopted the patient-based standard must disclose to patients any material risk, which includes the information that an objective “reasonable patient” would want under similar circumstances.⁷⁴ Although there is a distinction between patient- and physician-based disclosure standards, many courts “adopt something closer to a mixed model, incorporating aspects of physicians’ usual practices while at the same time recognizing the importance of the patient’s informational needs.”⁷⁵ Regardless of the standard, physicians have a legal duty to inform their patients of all relevant facts regarding a medical treatment or procedure.⁷⁶

Which facts are necessary for the patient to form the basis of intelligent consent is often measured by the materiality of the information.⁷⁷ “Materiality” refers to the significance of the information that a physician should have disclosed to the patient before obtaining their consent.⁷⁸ Current informed consent case law indicates that medical AI/ML should be a required disclosure because it is material to a patient’s decision making.⁷⁹ This Section next reviews parallel categories of cases that have broad implications for the coverage of informed consent disclosures.

B. “I Wouldn’t Have Consented Had I Known”—The Materiality of Medical AI/ML

A patient’s case against a physician for lack of informed consent follows a negligence theory of liability.⁸⁰ Patients alleging lack of informed consent must prove that they would not have agreed to the treatment or procedure had the physician made a proper disclosure of the associated risks and alternatives.⁸¹ Prevailing in a lack of informed consent action hinges on the patient’s ability to prove causation, which involves a determination of whether the undisclosed information was material.⁸²

Fortunately for plaintiffs, the substantive scope of materiality is expanding to better protect a patient’s decisional autonomy. Informed consent disclosures in clinical practice were traditionally limited to information considered material from a purely medical perspective.⁸³ Today, however, courts are becoming more receptive to weighing nonmedical information that patients might reasonably consider relevant to their medical decisions. These categories of “penumbral” cases⁸⁴ involving physician-specific characteristics and financial conflicts of interest lend credence for requiring physicians to disclose their use of AI/ML.

1. Physician-Specific Characteristics

In most states physicians are not required to disclose a risk that is not inherent in the proper performance of the procedure, which is a risk “that would result only from the procedure’s being performed

⁷³ *Id.*; Natanson v. Kline, 186 Kan. 393 (1960); Ben Moulton et al., *From Informed Consent to Informed Request: Do We Need a New Gold Standard?*, 106 J. ROYAL SOC’Y OF MED. 391, 392 (2013).

⁷⁴ *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972).

⁷⁵ Nadia N. Sawicki, *Modernizing Informed Consent: Expanding the Boundaries of Materiality*, 2016 U. ILL. L. REV. 812, 835 (2016).

⁷⁶ Parth Shah et al., *Informed Consent*, STATPEARLS (June 5, 2023), https://www.ncbi.nlm.nih.gov/books/NBK430827/?report=reader#_NBK430827_pubdet_; *Fairfax Hosp. v. Curtis*, 254 Va. 437, 442 (1997) (“[A] health care provider owes a duty of reasonable care to the patient.”).

⁷⁷ See *Allison v. Brown*, 293 Va. 617, 629 (2017) (quoting *Tashman v. Gibbs*, 263 Va. 65, 73-74 (2002)).

⁷⁸ Pugh, *supra* note 65, at 167–69.

⁷⁹ See discussion *infra* Section III.B.

⁸⁰ See *Mayr v. Osborne*, 293 Va. 74 (2017); *Atrium Unit Owners Ass’n v. King*, 266 Va. 288 (2003). As with a general negligence lawsuit, a plaintiff alleging lack of informed consent must prove duty, breach, causation, and damages.

⁸¹ *Allison v. Brown*, 293 Va. 617, 629 (2017) (quoting *Tashman v. Gibbs*, 263 Va. 65, 73-74 (2002)).

⁸² *Id.*

⁸³ See Marjorie M. Schultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L. J. 219, 284–85 (1985).

⁸⁴ I. Glenn Cohen, *Informed Consent and Medical Artificial Intelligence: What to Tell the Patient?*, 108 GEO. L. J. 1425, 1434 (2020).

incorrectly.”⁸⁵ However, the court in *Johnson v. Kokemoor* held that a physician may have a legal duty to disclose their level of experience with a given procedure.⁸⁶ This point can be expressed in causal terms: physicians may need to disclose their level of experience when their relative inexperience goes to the comparative risk of undergoing the procedure. Physician inexperience with a procedure also extends to medical equipment. In *DeGenarro v. Tandon*, the court held that a physician’s lack of experience with a particular machine used on a patient must be disclosed if it adds to the risk of the procedure.⁸⁷ Additionally, a line of cases suggest that physicians still bear the burden of errors resulting from incorrect AI/ML outputs.⁸⁸

Substituting medical AI/ML in these cases does not change the result—physician inexperience is still a material risk.⁸⁹ Physician inexperience regarding the use of medical AI/ML can be shown in two scenarios. First, a physician may be unversed in the workings of medical AI/ML, which leaves the physician unable to explain the algorithm’s decision to the patient. Second, a physician may be inexperienced with the actual procedure and choose to rely on decisions produced by AI/ML. To combat this practice the AMA has reinforced the point that physicians must never rely on AI/ML entirely, but to rather use these tools as “augmented intelligence.”⁹⁰ In either event, a physician’s inexperience with AI/ML or the reliance on such directly contributes to the comparative risk of a patient’s treatment and should therefore be disclosed for best practice.⁹¹

2. Financial Conflicts of Interest

Information about a physician’s financial conflicts of interest, while not medically material under the traditional model of informed consent, has been recognized by some courts as relevant to a patient’s decision making.⁹² The concern is that patients are deprived of the “ability to evaluate how an ‘extraneous’ interest might be affecting” the physician’s judgment as well as their own decision making.⁹³ The AMA, similarly concerned, issued an ethical opinion requiring physicians to disclose “any financial incentives that may limit appropriate diagnostic and therapeutic alternatives that are offered to patients or that may limit patients’ overall access to care.”⁹⁴ During the current era of managed care, financial incentives and pressures

⁸⁵ Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 VIRTUAL MENTOR 563, 565 (2012).

⁸⁶ *Johnson v. Kokemoor*, 199 Wis. 2d 615, 621 (1996).

⁸⁷ *DeGenarro v. Tandon*, 873 A.2d 191, 200 (Conn. App. Ct. 2005).

⁸⁸ For example, courts have allowed malpractice claims against physicians in cases where mistakes in medical literature were communicated to patients. See *Appleby v. Miller*, 554 N.E.2d 773 (Ill. Ct. App. 1990); *Bailey v. Huggins Diagnostic & Rehab. Ctr.*, 952 P.2d 768 (Colo. Ct. App. 1997); *Smith v. Linn*, 563 A.2d 123 (Pa. Super. Ct. 1989).

⁸⁹ See Richard J. Veerapen, *Informed Consent: Physician Inexperience is a Material Risk for Patients*, 35 J. LAW, MED. & ETHICS 478, 479 (2007); Douglas Sharrott, *Provider-Specific Quality of Care Data: A Proposal for Limited Mandatory Disclosure*, 58 BROOK. L. REV. 85 (1992).

⁹⁰ See *AMA Future of Health: The Emerging Landscape of Augmented Intelligence in Health Care*, AMA (Feb. 26, 2024), <https://www.ama-assn.org/practice-management/digital/ama-future-health-emerging-landscape-augmented-intelligence-health-care>. See also Daniel Payne, *Who Pays When AI Steers Your Doctor Wrong?*, POLITICO (Mar. 24, 2024), <https://www.politico.com/news/2024/03/24/who-pays-when-your-doctors-ai-goes-rogue-00148447>.

⁹¹ See generally Sawicki, *supra* note 75.

⁹² See, e.g., *Shea v. Esensten*, 208 F.3d 712, 717 (8th Cir. 2000) (holding that a jury could find that a physician’s failure to disclose a financial incentive to avoid referrals prevented a plaintiff “from making an informed choice of whether to seek what might have been a life-saving referral at his own expense”); *DAB v. Brown*, 570 N.W.2d 168 (Minn. Ct. App. 1997) (holding that a patient’s claim that the physician failed to disclose kickbacks was a malpractice claim). Finally, a discussion of a physician’s failure to disclose financial interests would be incomplete without mentioning *Moore v. Regents, University of California*, in which the California Supreme Court held that “a physician who is seeking a patient’s consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient’s informed consent, disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect his medical judgment.” *Moore*, 51 Cal. 3d at 131-32.

⁹³ Cohen, *supra* note 84, at 1440. See generally J. O’Neill, *Materiality of Conflict of Interest in Informed Consent to Medical Treatment in the United Kingdom*, 32 ETHICS & BEHAV. 375, 375 (2021).

⁹⁴ *Opinion E-8.132: Referral of Patients: Disclosure of Limitations*, COUNCIL ON ETHICAL AND JUD. AFFAIRS, AMA (2007).

for physicians to use medical AI/ML have the potential to cloud transparent discussions between physicians and patients.

AI/ML systems are incentivized financially similar to other medical tools and prescriptions.⁹⁵ A physician or hospital's decision to deploy a specific AI/ML system "is greatly influenced by payment amounts," which is determined by the dollar amount paid for the service and the likelihood of payment by a specific patient.⁹⁶ When the likelihood of reimbursement justifies the application of a medical AI/ML system, there is a "greater risk of overutilization" and "greater potential for fraud, waste, and abuse."⁹⁷ Physician bias is also a byproduct of medical AI/ML overuse. Incentives for using these systems can distort a physician's primary interest in their patient's welfare—disrupting the foundation of the physician-patient care relationship.⁹⁸

C. *The Bottom Line—Medical AI/ML Should be Disclosed*

Humans and machines make mistakes. In a patient's medical care, mistakes could mean death or serious injury. Effective physician-patient communication is the blueprint to shedding light on the risks associated with a treatment or procedure. This is also why the law imposes a duty on physicians to fully inform patients of material facts.⁹⁹ A physician's use of AI/ML in a patient's diagnosis or treatment should be disclosed because eliminating these risks is impossible.¹⁰⁰ Medical information technology problems were linked to patient harm and death in 53 percent of studies,¹⁰¹ and future injuries attributable to medical AI/ML are "inevitable."¹⁰²

The main argument against requiring the disclosure of the use of medical AI/ML is that it unduly burdens physicians.¹⁰³ However, a physician's disclosure of their use of AI/ML protects both parties in the care relationship and balances liability.¹⁰⁴ The following analogy illustrates this point:

To use a fanciful example, suppose in deciding whether to operate or which drug to prescribe, a physician consulted a Magic 8-Ball or Astrology. Surely, a reasonable patient would want to know that *that* was the reason for a medical decision and would find that material in deciding whether to adopt the recommended course from this physician or instead seek out a second opinion. The argument is that relying on opaque medical AI/ML is unlike relying on journal articles or medical school teaching and more like the 8-Ball or AstrologyWith the Magic 8-Ball or Astrology not only can the physician not explain *why* it works, but she also has no epistemic warrant *that* it works.¹⁰⁵

⁹⁵ Michael D. Abramoff et al., *A Reimbursement Framework for Artificial Intelligence in Healthcare*, 5 NPJ DIGIT. MED. 72, 72 (2022).

⁹⁶ *Id.*

⁹⁷ Ravi B. Parikh & Lorens A. Helmchen, *Paying for Artificial Intelligence in Medicine*, 5 NPJ DIGIT MED. 63, 65 (2022).

⁹⁸ INST. OF MED. OF THE NAT'L ACADEMIES, CONFLICT OF INTEREST IN MEDICAL RESEARCH, EDUCATION, AND PRACTICE 169 (Bernard Lo & Marilyn J. Field eds., 2009).

⁹⁹ See discussion *supra* Section III.A.

¹⁰⁰ Eric Sutherland & Rishub Keelara, *AI in Health: Huge Potential: Huge Risks*, OECD (2024), <https://www.oecd.org/health/AI-in-health-huge-potential-huge-risks.pdf>. See also discussion *infra* Section III.B.1–2.

¹⁰¹ Mi Ok Kim et al., *Problems With Health Information Technology and Their Effects on Care Delivery and Patient Outcomes: A Systematic Review*, 24 J. AM. MED. INFORMATICS ASS'N 246, 246 (2017).

¹⁰² Maliha et al., *supra* note 2, at 634.

¹⁰³ *Id.*

¹⁰⁴ See generally *id.*

¹⁰⁵ Cohen, *supra* note 84, at 1443.

Informed consent discussions between a physician and patient are intended to provide opportunities for the patient to ask questions regarding their medical care so they can make “well-considered” decisions.¹⁰⁶ These transparent discussions allow patients to inquire into the physician’s decision making in curating the patient’s medical care. A patient may opt to get a second opinion or even change physicians, decisions that are squarely a patient’s right to make and are protections borne from informed consent conversations. The physician is similarly protected—disclosing all material information to a patient crumbles the footing of a patient’s action for lack of informed consent against the physician. In the wake of increasing AI/ML malpractice lawsuits, the physician can count on the saying, “Don’t say I didn’t warn you.”¹⁰⁷

D. *Historical Support*

To further show why requiring physicians to disclose their use of AI/ML to patients is best practice, perhaps it is suitable to compare how patient protections developed from other technological introductions to clinical practice. One example is the use of modern anesthesia, which began in the mid-19th century.¹⁰⁸ Thanks to this development patients have been able to overcome fears of pain in surgery. However, as anesthesia was becoming more widely used in surgical practice, concerns grew about its potential risks and side effects.¹⁰⁹ The AMA created guidelines to standardize the ethical responsibilities regarding the use of anesthesia and were adopted by the American Society of Anesthesiologists (ASA), essentially creating a standard of care for anesthesiologists.¹¹⁰ The ASA “respect[s] the right of every patient to self-determination” and requires member anesthesiologists to inform patients of the medical issues involved with using anesthesia.¹¹¹ Thus, “[a]nesthesiologists have a duty to disclose material information” associated with the use and risks of anesthesia.¹¹²

There was a similar awareness of risks among physicians in the early days of X-ray technology. The effects of radiation exposure and the potential risk of cancer led physicians to endorse clinical guidelines for X-ray usage.¹¹³ Today several medical professional organizations, including the Society of Radiographers, the Association for Radiologic and Imaging Nursing, and the American College of Radiology, have established disclosure and consent requirements for physicians using X-rays to diagnose or treat patients.¹¹⁴

¹⁰⁶ *Opinion 2.1.1: Informed Consent*, AMA, <https://code-medical-ethics.ama-assn.org/ethics-opinions/informed-consent#:~:text=Informed%20consent%20to%20medical%20treatment,well%2Dconsidered%20decisions%20about%20care> (last visited Apr. 25, 2024).

¹⁰⁷ See generally Claire Wallace, *The Newest Physician Threat: AI Malpractice Lawsuits*, BECKER’S PHYSICIAN LEADERSHIP (June 6, 2023), <https://www.beckersphysicianleadership.com/news/the-newest-physician-threat-ai-malpractice-lawsuits.html>.

¹⁰⁸ Daniel H. Robinson & Alexander H. Toledo, *Historical Development of Modern Anesthesia*, 25 J. INVESTIGATIVE SURGERY 141, 142 (2012).

¹⁰⁹ See David B. Waisel & Robert D. Truog, *Informed Consent*, 87 ANESTHESIOLOGY 968, 970 (1997).

¹¹⁰ *Guidelines for the Ethical Practice of Anesthesiology*, ASA COMM. ON ETHICS (last amended Dec. 13, 2020), <https://www.asahq.org/standards-and-practice-parameters/guidelines-for-the-ethical-practice-of-anesthesiology>.

¹¹¹ *Id.*

¹¹² Waisel & Truog, *supra* note 109, at 971.

¹¹³ See Joel D. Howell, *Early Clinical Use of the X-Ray*, 127 TRANSACTIONS OF THE AM. CLINICAL & CLIMATOLOGICAL ASS’N 341, 345–47 (2016). See also Kaustubh Sansare et al., *Early Victims of X-Rays: A Tribute and Current Perception*, 40 DMFR 123 (2011).

¹¹⁴ See *Consent for Radiographers and Sonographers*, Soc’y of Radiographers (May 4, 2020), <https://www.sor.org/news/scor/consent-for-radiographers-and-sonographers>; Sharon Lehmann, *Clinical Practice Guideline: Informed Consent for a Radiology Procedure*, ASS’N FOR RADIOLOGIC & IMAGING NURSING (Jan. 2009), https://www.arinursing.org/ARIN/assets/File/public/practice-guidelines/q_Informed_Consent_for_a_Radiologic_Procedure.pdf; *ACR-SIR-SPR Practice Parameter on Informed Consent for Image-Guided Procedures*, Am. College of Radiology (last amended 2023), <https://www.acr.org/-/media/ACR/Files/Practice-Parameters/InformedConsent-ImagGuided.pdf>. In the UK, the requirement to inform a patient about the risks of radiology have been enshrined in law. See *Ionising Radiation (Medical Exposure) Regulations 2017*, no. 1322 (UK).

Performing a radiology scan on a patient without first communicating the potential risks of radiation exposure “is akin to ordering any other procedure or medication without knowing its risks.”¹¹⁵

Although these examples may be distinguished from medical AI/ML on the basis of their physical nature and direct interaction with patients, the similarity rests in the newness of the innovation. AI/ML systems have presented serious risks to patients in their relatively short clinical utility.¹¹⁶ Dangers to patient safety following the integration of anesthesia and X-ray technology in medicine was the impetus for discussions of their associated risks between physicians and patients. The same discussions are necessary for diagnoses and treatments involving medical AI/ML because, after all, “[m]odels for understanding and holding systems accountable have long rested on ideals of transparency.”¹¹⁷

IV. WHAT TO TELL THE PATIENT

The import of thorough physician-patient communication cannot be understated—30 percent of medical errors are due to communication failures.¹¹⁸ This Comment argues that the use of AI/ML to diagnose and administer medical care is material to a patient’s medical judgment.¹¹⁹ Accordingly, a physician’s use of AI/ML should be a required disclosure under the doctrine of informed consent. The animating question left to be answered is what should a physician tell a patient?

The simple and straightforward answer is that a physician should tell the patient that they used AI/ML to help diagnose or curate the patient’s medical care. Patients should then have the opportunity to ask questions related to the physician’s decision making to dispel or confirm the patient’s own knowledge and expectations of AI/ML.¹²⁰ A physician should be able to understand AI/ML technology and have access to certain information in order to participate in interactive discussions with the patient.¹²¹ Guidance from the AMA suggests that AI/ML developers ought to tell physicians the following information so they may appropriately address patient inquiries: a general explanation of how the program works, its regulatory approval status, a description of the data used to train the program, information about any safeguards that have been enacted, validation data, and the program’s data use and privacy policies.¹²² A physician may also need to describe their experience using the AI/ML program, the risks versus benefits of the technology compared to human accuracy, and the different roles and responsibilities between machines and humans in diagnosing and treating patients.¹²³

Establishing these requirements for physicians could be achieved in a number of ways.¹²⁴ First, a state legislature could enact or modify new standards of care for healthcare professionals.¹²⁵ This could involve introducing a bill that outlines specific requirements or guidelines for medical practice. Second, state health departments or medical boards have regulatory authority over physicians and can establish rules and

¹¹⁵ Kay Denise Spong Lozano, *Medicine and Society*, 9 *AMA J. OF ETHICS* 769, 771 (2007). *See also Informed Consent in Radiology: A Technologist’s Guide*, *MED. PROS.* (Nov. 1, 2022), [HTTPS://WWW.MEDICAL-PROFESSIONALS.COM/EN/INFORMED-CONSENT-IN-RADIOLOGY/#:~:TEXT=PATIENTS%20OVER%20THE%20AGE%20OF,OR%20NOT%20HAVING%20THE%20EXAM](https://www.medical-professionals.com/en/informed-consent-in-radiology/#:~:text=PATIENTS%20OVER%20THE%20AGE%20OF,OR%20NOT%20HAVING%20THE%20EXAM) (“A patient must be given every opportunity to understand the potential benefits and risks of undergoing a medical imaging exam . . .”).

¹¹⁶ *See* discussion *supra* Section II.B.

¹¹⁷ KATE CRAWFORD, *THE ATLAS OF AI: POWER, POLITICS, AND THE PLANETARY COSTS OF ARTIFICIAL INTELLIGENCE* 12 (2021).

¹¹⁸ OECD, *AI IN HEALTH, HUGE POTENTIAL, HUGE RISKS*, 3 (2024).

¹¹⁹ *See* discussion *supra* Section III.B.

¹²⁰ Cascella, *supra* note 64.

¹²¹ *Principles for Augmented Intelligence*, *supra* note 60.

¹²² *Id.*

¹²³ Cascella, *supra* note 64.

¹²⁴ A detailed discussion on the various mechanisms to establish physician standards of care is beyond the scope of this Comment. A brief summary of some of the methods will suffice for illustration purposes.

¹²⁵ *See* discussion *supra* Section II.C.

define standards of care within their jurisdiction.¹²⁶ Third, medical associations and specialty boards play a significant role in establishing professional standards of care for physicians. These organizations often adopt or develop clinical practice guidelines and ethical codes that reflect best practices.¹²⁷ Finally, court decisions and legal precedents can shape the standard of care for doctors by establishing legal principles and interpretations of medical negligence.¹²⁸ Regardless of the manner, creating physician guidelines for the use of medical AI/ML will ensure that these programs will benefit patients, physicians, and the healthcare community.

V. CONCLUSION

The result does not change if the facts of the airplane hypothetical posed at the beginning of this Comment¹²⁹ are switched to reflect a patient's consultation with a physician—the passenger becomes the patient, the pilot becomes the physician, and the automated flight control system becomes the medical AI/ML system. The disclosure of the system in both scenarios is critical.

Medical AI/ML is proving to be a valuable tool in the administration of healthcare, but its risks present concerns for patient safety.¹³⁰ Interactive and thorough discussions between a physician and patient is the key to understanding treatment risks in general and is typified by the doctrine of informed consent. Physician-patient communication is so important that the law imposes certain disclosure requirements on physicians regarding a patient's medical care. A physician's use of AI/ML to diagnose or treat patients is material to a patient's medical judgment and should be a required disclosure prior to any treatment or procedure occurs.

Disclosing a physician's use of medical AI/ML is best practice and protects the patient and physician. A patient aware of the fact that the physician has used AI/ML in their medical diagnosis or treatment has the opportunity to ask questions and seek additional information before consenting. Additionally, a physician that properly discloses their use of AI/ML to patients effectively puts on armor against a patient's action for lack of informed consent. This balance of liability promotes patient safety and physician protection as society navigates through the promising yet uncertain future of AI/ML.

¹²⁶ See Drew Carlson and James N. Thompson, *The Role of State Medical Boards*, 7 ETHICS J. AM. MED. ASS'N 311 (2005).

¹²⁷ See discussion *supra* Section III.D.

¹²⁸ See discussion *supra* Section III.B.

¹²⁹ See introductory hypothetical *supra* Section I.

¹³⁰ See discussion *supra* Section II.B.