

June 2024

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Recommended Citation

Tawfik Abedali, *Inpatient Care: Why AI Must Be Kept Out Of Hospitals*, 9 U. Cin. Intell. Prop. & Comput. L.J. (2024)

Available at: <https://scholarship.law.uc.edu/ipclj/vol9/iss2/5>

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INPATIENT CARE: WHY AI MUST BE KEPT OUT OF HOSPITALS

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I. INTRODUCTION

A. *Brief Introduction Into Artificial Intelligence (AI) Legal Issues*

The advancement of artificial intelligence (“AI”) within the past few years has arguably been one of the most instrumental changes to society. The developments that AI has made possible across many industries have been seismic.¹ The perceived economic impact is also monumental, as Forbes reported in 2019 that 83% of business executives believed the implementation of AI was an essential next step of furthering the market.² According to Forbes, the greatest asset to companies today is data and AI allows companies to reap the greatest benefit from that data. Through AI, companies can organize and utilize their data in meaningful ways such as enhancing the customer experience by streamlining processes and making them more consumer-friendly, enhancing the hiring process by removing bias, and heightening employee engagement and retention by giving companies a better understanding of individual performance.³

As the use of AI has proliferated, it is being implemented throughout the business, education, technology, and healthcare industries.⁴ However, the potential harms that could arise should not be ignored. The various areas of concern include malicious use to further abuse or hate, copyright infringement, fraud, and inaccuracies with data.⁵ The presented threats are

* Associate Member, 2023-2024, *University of Cincinnati Intellectual Property and Computer Law Journal*. Special thanks to my parents, Layla and Ali, and to my siblings, Zain and Mysk.

1. *Artificial Intelligence (AI)*, U.S. DEP’T OF STATE, <https://www.state.gov/artificial-intelligence/> (last visited Feb. 3, 2024).

2. Falon Fatemi, *3 Ways Artificial Intelligence is Transforming Business Operations*, FORBES (May 29, 2019), <https://www.forbes.com/sites/falonfatemi/2019/05/29/3-ways-artificial-intelligence-is-transforming-business-operations/?sh=71569e816036>.

3. *Id.*

4. Jia Rizvi, *How AI Is Uprooting Major Industries*, FORBES (Mar. 16, 2024), <https://www.forbes.com/sites/jiawertz/2024/03/16/how-ai-is-uprooting-major-industries/?sh=5c2eb57f7d90>.

5. *Consumers Are Voicing Concerns About AI*, FED. TRADE COMM’N,

particularly worrisome in the medical industry because of how protective the industry is of patient data. There are already concerns in the industry about healthcare data because since July 2021 there have been nearly 900 unsecured protected health information data breaches that affected more than 500 people for each breach.⁶ As of now, that is over 450,000 breaches involving personal healthcare information. The potential for further and more unique AI dangers involving patient information or monitoring of their vitals could prove to be catastrophic. Within the hospital setting, the protection of patient health and safety is paramount for treating patients and providing them with the best possible care. To provide quality care to patients, hospitals need to collect a variety of data on their patients, which in turn leaves them with various personal information from patients that must be protected. This means that hospital and health networks need to assess risk with AI as it teeters on the fine line between innovation and complication.

While implementing AI could allow hospitals to streamline care and allow doctors and support staff to better monitor patients' vitals, the risks to patient information posed by AI including the potential for data breaches and mistakes could become disastrous. For example, if patient data is inputted into an AI system and that system makes an error and gives faulty data such as recommending the wrong medication or prescribing an incorrect dosage, this could be fatal to the patients. Hospitals using AI systems could be exposed to medical malpractice lawsuits for claims like misdiagnosis, medication errors, and delayed diagnosis. There could also potentially be negligence tort lawsuits brought in instances when competent human oversight was lacking over the AI system and the AI system made an error that had catastrophic consequences for patients.

However, this is not to say that hospitals are against technical innovations: the implementation of robotics in surgery is proof of that. Recently, more hospitals have partnered with universities to be at the forefront of medical and health innovation, including implementing robotics.⁷ Robotic surgeries allow the surgeon to direct the surgery from a nearby console, as opposed to standing directly over the patient the whole time.⁸ Instead, the doctor makes small incisions into the patient's body at the beginning of the surgery, inserts the robotic instruments and

<https://www.ftc.gov/policy/advocacy-research/tech-at-ftc/2023/10/consumers-are-voicing-concerns-about-ai> (last visited Feb. 3, 2024).

6. *Breach Portal: Notice to the Secretary of HHS Breach of Unsecured Protected Health Information*, U.S. DEP'T OF HEALTH AND HUM. SERV. OFF. FOR CIV. RTS., https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf (last visited Feb. 10, 2024).

7. *What is Robotic Surgery*, UCLA HEALTH, <https://www.uclahealth.org/medical-services/robotic-surgery/> (last visited Feb. 19, 2024).

8. *Id.*

camera and then proceeds to do the surgery at the console, with the robot instruments responding to the human-operated console commands.⁹ While there were initial concerns about the risk of robotic malfunction, these circumstances are extremely rare, only occurring approximately 0.38% of the time.¹⁰ The benefits outweigh these concerns; including less pain during recovery, lower risk of infection, reduced blood loss, shorter hospital stays, and smaller scars for patients.¹¹ While there are arguments for AI to be utilized in hospitals, as robotics have, the consequences of AI should not be overlooked because there is no set guide to implementation. The risks presented by robotics in surgery are lesser and more manageable than the possible catastrophes that could occur with AI in hospitals.

Implementing robotics into hospitals has been a nearly seamless transition that has yielded few errors or concerns. However, it has not been a completely perfect transition. This is never clearer than in the case *Sultzzer v. Intuitive Surgical, Inc.* This wrongful death lawsuit was filed recently in Florida on February 6, 2024, and should serve as a reminder of why technology use in hospitals needs to be monitored as closely as possible.¹² The plaintiff's wife died in February 2022 as a result of a small intestine injury, which the plaintiff claims was a result of the robotics device burning and tearing his wife's small intestines while she was undergoing surgery for colon cancer in September 2021.¹³ The plaintiff brought claims against the maker of the surgical device because the plaintiff alleges they knew there were insulation issues that could lead to the burning of internal organs.¹⁴ Even more alarming than the lack of oversight from device makers is the torrid history of Intuitive Surgical dating back a decade, which includes being named as defendants in ninety-three different lawsuits where the family members of the plaintiffs suffered injuries or death during surgeries using the surgical device designed by Intuitive Surgical.¹⁵ This case should serve as a warning to hospitals introducing new technology to do the due diligence in training their staff to operate the technology, doing the research when purchasing the equipment, and ensuring there is little to no room for error.

9. *Id.*

10. Sero Andonian, et al., *Device failures associated with patient injuries during robot-assisted laparoscopic surgeries: a comprehensive review of FDA MAUDE database*. 15 CAN. J. UROL. (2008).

11. *Robotic Surgery*, CLEVELAND CLINIC <https://my.clevelandclinic.org/health/treatments/22178-robotic-surgery> (last visited Feb. 19, 2024).

12. Complaint at 1-4, *Sultzzer v. Intuitive Surgical, Inc.*, (S.D. Fla. Feb 06, 2024) (No. 9-24-CV-80137).

13. *Id.*

14. *Id.*

15. Aria Bendix, *Robotic Device Burned a Woman's Small Intestine During Surgery, Lawsuit Alleges*, NBC NEWS, (Feb. 8, 2024). <https://www.nbcnews.com/health/health-news/robotic-device-burned-womans-small-intestine-surgery-lawsuit-alleges-rcna137998>.

Recent litigation has also raised major concerns about the dangers that AI presented in the medical field, more specifically within hospital settings.¹⁶ In November 2023, a class action lawsuit was filed against UnitedHealth over their use of AI.¹⁷ The lawsuit, with over 100 members across 21 states, alleges that the AI used by UnitedHealth was faulty and that its algorithm made mistakes that incorrectly denied elderly patients coverage for extended post-acute care and treatments that their doctors felt were vital.¹⁸ The claims included a breach of contract, breach of the implied covenant of good faith and fair dealing, unjust enrichment, violation of an insurance claim settlement practice, and insurance bad faith.¹⁹ This is yet another instance of when AI in the healthcare industry could harm others and deny patients the care they need from the hospitals. With the fact that new AI is developing almost too quickly in the medical field, the issues that have been brought up in the lawsuits should be warning signs to hospitals, health networks, and providers interested in implementing an AI system.

Another recent lawsuit that further illustrates the dangers that the use of AI in hospitals raises is *Dinerstein v. Google, LLC*. This was a class action lawsuit brought by a group of patients, arising out of a breach that occurred during a research collaboration between the University of Chicago Medical Center and Google.²⁰ The two organizations were researching to create an AI system that would be inputted with patient data to create health models to theoretically help prevent patients from the need of repeat visits to the hospital.²¹ The lead class member was a patient who found out their information was being inputted into the system and brought the suit against both the hospital and Google, claiming the practice of inputting the data into the AI system violated the Health Insurance Portability and Accountability Act (HIPAA) and that people could be identified through their health data.²² This lawsuit overlaps into several different areas of the law because with joint ventures, there are inevitable crossovers into intellectual property (IP) law, as it often crosses into copyrights and patents.²³ This case is going to be instrumental for the future of AI uses in the both the hospital and healthcare industry.

The uses of patents in the healthcare and hospital industry are

16. *Dinerstein v. Google, LLC*, 73 F.4th 502 (7th Cir. 2023).

17. Complaint at 1-5, *The Estate of Gene B. Lokken and the Estate of Dale Henry Tetzloff, et al. v. UnitedHealth Group, Inc.*, (D. Minn. Nov. 14, 2023) (No. 0-23-cv-03514).

18. *Id.*

19. *Id.*

20. *Dinerstein*, 73 F.4th at 502.

21. *Id.*

22. *Id.*

23. *Id.*

widespread, from medical devices to healthcare information technology, and to medical and surgical methods. In fact, between 2009 and 2014, there was a 170% increase in the medical device patents that were granted in the United States.²⁴ When it comes to the systems and the technology being used in these joint ventures, the IP law interest is present since each party needs to protect their own technology and secrets. These joint ventures open the possibilities of advancements in technology, however that is countered with a greater risk of IP infringement.²⁵ In understanding the importance of technology and its uses in the medical setting, there are always going to be concerns about mistakes that can cause both direct and indirect harm to patients, and open healthcare providers up to liability.

While AI is an attractive tool that can be used in the medical industry to streamline and complement doctors' care of patients, the mishaps that it causes are often too risky to be allowed to deal with patient information. Patients should not have to worry about their insurance claims for hospital treatment being rejected by faulty AI. Because UnitedHealth implemented faulty AI systems, patients had their claims erroneously rejected when they should have been accepted. There was no clear explanation nor accountability for these errors have occurred.²⁶ These are still the early days of AI being introduced into the healthcare setting. Already, there are lawsuits against insurance providers erroneously denying patients coverage, which leads to dying patients not being able to receive the care they need.²⁷ If AI is not kept out of the healthcare industry, more lawsuits like the ones filed against UnitedHealth and Google will follow and fill the courts with a logjam of medical malpractice, wrongful death, and negligence lawsuits due to the use of AI systems.

II. BACKGROUND

A. *The Lack of Human Supervision in Hospital AI May Lead to Legal Consequences*

Technology used in hospital settings is usually supervised by humans because of the potential risks if left unmonitored. The dangers and risks associated with AI are arguably too great for it to be fully implemented in

24. Denise L. Mayfield, *Tracking Patents and Mapping Medical Device Innovation*, 113 MO. MED. 456-462 (2016).

25. Martha Rumore, *Intellectual property: What Every Medical Practice Needs To Know*, MED. ECON., <https://www.medicaleconomics.com/view/intellectual-property-what-every-medical-practice-needs-to-know> (last visited Mar. 12, 2024).

26. Complaint, *UnitedHealth*, *supra* note 17, at 5.

27. *Id.*

the hospital, and the possibility of partial implementation with constant supervision has not been fully explored. AI should largely be kept out of the hospital settings due to the severity of the risks it poses. AI, either by design or inadvertently, takes the necessary human factor out of medicine.

1. Benefits of AI Use in Hospitals Include Earlier Diagnosis and More Personalized Treatment Plans

AI implementation in hospitals would allow for early detection and diagnosis of diseases.²⁸ With how far AI is advancing, theoretically, AI systems would enable doctors to more readily diagnose the very early onset of diseases or conditions.²⁹ By analyzing certain patient data, the AI system could potentially lead to diseases being diagnosed much earlier, such as indicating a high white blood cell count, with the potential that it could be leukemia. It would be in the patient's and the doctor's best interest to diagnose it as early as possible to help them combat it via chemotherapy. The possibility that doctors could use AI tools to diagnose diseases such as cancers or Parkinson's would allow doctors to begin treating these debilitating diseases before they start severely attacking patient health.³⁰ A somewhat recent example where doctors used AI to help treat diseases occurred in a 2020 study where researchers and doctors worked together to assess diabetic risks in patients.³¹ They input data based on patient lifestyle, daily routines, health problems and concerns into the AI system to receive indicators on which of the 952 patients used in the study were close to diabetic risk.³²

AI in hospitals could also be a possible tool in helping with the enhancing and processing medical images, x-rays, magnetic resonance images (MRIs) and computed tomography (CT) scans.³³ To illustrate why the healthcare industry might be interested in using AI to help with medical imaging, in a study done on the scanning of oral primary carcinomas, the accuracy for the MRI scans ranged from 67% to 83%. In contrast, CT scans stood at a 75% accuracy mark.³⁴ This means the truth of MRI scans are accurate at least two-thirds of the time, and for CT scans

28. Jesse Corn, *Balancing the Pros and Cons of AI in Healthcare*, FORBES (Dec. 1, 2023), <https://www.forbes.com/sites/forbesbusinesscouncil/2023/12/01/balancing-the-pros-and-cons-of-ai-in-healthcare/?sh=7f8fd03b752b>.

29. *Id.*

30. *Id.*

31. Neha Perna Tigga & Shruti Garg, *Prediction Of Type 2 Diabetes Using Machine Learning Classification Methods*, 167 *PROCEDIA COMPUT. SCI.* 706-716 (2020)

32. *Id.*

33. *Id.*

34. Fernanda Scotti, et al., *Accuracy of MRI, CT, and Ultrasound Imaging On Thickness and Depth Of Oral Primary Carcinomas Invasion: A Systematic Review*, 51 *DENTOMAXILLOFAC RADIOL.* (2022).

at least 75% of the time. There is always room to improve the accuracy and clarity of these medical images to give doctors a clearer picture of what they can do to help patients further and to ensure they are being diagnosed correctly. The potential of AI systems in the hospitals could potentially help streamline and improve these accuracy marks and could lead to clearer imaging, which means more accurate diagnoses. The possibilities of what AI could do in the hospital systems appear to be filled with benefits that could further health, science, and, most importantly, potentially extend the patients' lives.

The strides and improvements made by AI in the hospital setting can come to fruition due to the collaboration between research institutions and hospitals. This includes a recent study by Kin Wai Lee and Renee Ka Yin Chin, Faculty of Engineering at the Universiti Malaysia Sabah, the twelfth-ranked research hospital in Malaysia, about the benefits of AI use in assisting with imaging lungs to diagnose and monitor COVID-19.³⁵ The authors and leads of the study found that the AI system produced scenarios that would create synthetic images that were nearly identical to authentic life images.³⁶ The success of the AI-assisted images being nearly identical to images produced by current technology gives early optimism for the results of AI in hospital-university collaboration.

AI in hospitals would also be used to help create personalized treatment plans that are automated to the data doctors' input about their patients. This would be implemented in a variety of ways, such as the possibilities to enhance the imaging of MRI scans, CT scans and ultrasounds, as recent studies have been undertaken to review the sensitivity, specificity, and accuracy of such scans.³⁷ The potential of AI to help hospital staff in the monitoring of patient vitals and then give personalized treatment plans specifically engineered for the patient is an intriguing prospect. Theoretically, this system could offer a more streamlined and efficient treatment and would decrease the burden on both doctors and hospital support staff.

2. The Risks of Allowing AI in the Hospital and Medical Settings Include Privacy Issues and Potentially Grave Mistakes by AI Algorithms

One of the major risks of allowing AI in the hospital and the medical setting are the questions of accountability arising out of unclear liability.

35. Kim Wai Lee & Renee Ka Yin Chin, *Diverse COVID-19 CT Image-to-Image Translation with Stacked Residual Dropout*, 9 *BIOENGINEERING*, 698 (2022).

36. *Id.*

37. *See* Scotti, et al., *supra* note 34.

If a doctor makes a mistake and their patient decides to bring suit, the patient may sue the doctor, the hospital, and the healthcare network. If a mistake is made using an AI algorithm and causes the doctor or support staff to make a mistake in care, it is now difficult to decipher who should be held liable: the AI system or the doctor. While the doctor or support staff administered the care to the patients, there is an argument to be made that they based their decision on the recommendation of the AI system.

Further studies abroad seek to comprehend the capabilities of AI systems in hospital use. One such study was conducted by an AI research group at the Department of Radiology at Bispebjerg-Frederiksberg University Hospital, the sixth-ranked Danish research hospital, located in Copenhagen, Denmark.³⁸ The AI system was input with data and information to recognize and diagnose knee osteoarthritis binary scoring.³⁹ The AI algorithm had a 13% error rate, higher than what was considered acceptable for what the doctors would feel safe to use with patients, which was around the 3% to 6 % range.⁴⁰ The implications of an incorrect diagnosis are grim, as there could be adverse health, mental, and financial consequences that could harm patients.⁴¹ People are better suited for critical thinking than AI because people can learn from mistakes they make in the hospital setting, whereas some of the Federal Drug Administration (FDA)-approved AI medical devices have certain algorithms that are locked before marketing.⁴²

Hospitals and healthcare networks need to remain diligent and wary about the implementation of AI systems because they could potentially cost millions in liability damages. There are concerns for data privacy law, as the use of AI in hospitals would require inputting patient information into the system, and a breach could result in the misuse of personal information.⁴³ The potential of AI may be limitless, but so too would the liability of the hospitals and administration. The costs of lawsuits and settlements involving hospitals and healthcare networks can be exorbitant, depending on the severity and nature of the violations. A prime example of when healthcare networks have been on the hook for

38. Matias Willadsen Brejneboel et al., *External validation of an artificial intelligence tool for radiographic knee osteoarthritis severity classification*, 150 EUR. J. RADIOL. (2022).

39. *Id.*

40. *Id.*

41. *Id.*

42. *DA Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback* (April 2, 2019), U.S. FOOD AND DRUG ADMIN., <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf>.

43. Neel Yadav et al., *Data Privacy in Healthcare: In The Era of Artificial Intelligence*, 14 INDIAN DERMATOLOGY ONLINE J. 788–792 (2023).

data privacy leaks includes when healthcare network Inmediata was ordered to pay \$1.4 million in settlements due to exposing protected health information of 1.5 million consumers.⁴⁴ Hospitals need to consider the fact they could have to face millions in settlements if an AI system they use is compromised and ends up misusing or misappropriating patient data.

3. The Laws That Govern Hospitals and the Medical Field and How This Can Lead to AI Litigation

Within the medical field, and hospitals specifically, there are several laws and regulations that govern the implementation of AI systems. In particular, the Health Insurance Portability and Accountability Act (HIPAA), requires the protection of confidential patient healthcare information.⁴⁵ The act details how hospitals and medical providers are to store, use, and disseminate patient healthcare information and provides the penalties for violations.⁴⁶ There is also the HITECH Act, the sharp teeth of HIPPA, which requires audits of healthcare providers to ensure they are HIPPA compliant.⁴⁷ The HITECH Act sets high standards of information protection and requires financial backing from the providers to show they are taking the steps to protect patient information.⁴⁸ The act also imposes severe penalties for healthcare providers to protect patient information and to ensure that the providers will be responsible and diligent with patient information.⁴⁹ These penalties have four categories of violations reflecting the increasing levels of culpability, minimum penalty amounts, and a maximum penalty amount of \$1.5 million.⁵⁰ Altogether, these acts require that hospitals be careful when it comes to patient information. Wanting to implement technology that would improve and advance care of patients is a noble goal. However, it is imperative that these laws be in place because of the importance of keeping patient information private. Patients are entrusting hospitals with

44. *AG Yost Announces Data Breach Settlement with Health-Care Clearinghouse*, OHIO ATT'Y GEN. (Oct. 17, 2024), <https://www.ohioattorneygeneral.gov/Media/News-Releases/October-2023/AG-Yost-Announces-Data-Breach-Settlement-with-Heal#t>.

45. *Summary Of The HIPAA Privacy Rule*, U.S. DEP'T OF HEALTH AND HUM. SERV., <https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html> (last visited Feb. 20, 2024).

46. *Id.*

47. *HITECH Act Enforcement Interim Final Rule*, U.S. DEP'T OF HEALTH AND HUM. SERV., <https://www.hhs.gov/hipaa/for-professionals/special-topics/hitech-act-enforcement-interim-final-rule/index.html> (last visited Feb. 20, 2024).

48. *Id.*

49. *Id.*

50. *Id.*

their lives and the laws reflect the severity of the situation.

The laws and regulations do not just end there, as the Emergency Medical Treatment and Labor Act is a federal law that requires hospitals to provide treatment for anyone who comes to them, regardless of whether the patients have insurance or can pay.⁵¹ There are also the federal anti-kickback laws that prevents the abuse of the healthcare system for financial gain.⁵² And, there are federal Stark laws; a set of healthcare and abuse laws preventing physicians from recommending those on Medicare to another provider with whom they have a financial relationship.⁵³ Finally, there is the Patient Safety and Quality Improvement Act (PSQIA), which protects workers from unsafe conditions but further encourages the reporting of medical errors while maintaining patient confidentiality.⁵⁴ Therefore, while there are certain benefits and laws in place to protect patient data, the potential for AI systems to make mistakes, be breached by cyber-attacks, and lose confidential patient data are valid concerns that must be evaluated when determining whether to allow AI systems in the hospitals. In the hospital setting, everything could be a matter of life or death.

B. Administrative Actions of the U.S. Government Guide Hospitals' Integration of AI

Because AI is such a new technological innovation, few laws within the United States exist to regulate it. Before looking to the administrative actions of what the U.S. government has undertaken, it would be prudent to gain an understanding of what other countries have done because the rest of the world has already begun making strides in implementing AI regulations. So far, the European Parliament has voted to adopt an Artificial Intelligence Act, which would ban and limit high-risk applications of AI that could be used to impersonate people and potentially cause people to fall for scams.⁵⁵ Similarly, Canada and Singapore both have laws in place that regulate the use of AI, as a part of

51. *Emergency Medical Treatment and Labor Act (EMTALA)*, CTR. OF MEDICARE AND MEDICAID SERV., <https://www.cms.gov/medicare/regulations-guidance/legislation/emergency-medical-treatment-labor-act> (last visited Feb. 20, 2024).

52. *Fraud and Abuse Laws*, U.S. DEP'T OF HEALTH AND HUM. SERV., <https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/> (last visited Feb. 21, 2024).

53. *Id.*

54. *The Patient Safety and Quality Improvement Act of 2005*, U.S. DEP'T OF HEALTH AND HUM. SERV., <https://www.hhs.gov/hipaa/for-professionals/patient-safety/patient-safety-quality-improvement-act-2005/index.html> (last visited Feb. 21, 2024).

55. *US federal AI governance: Laws, policies and strategies*, INT'L ASS'N OF PRIV. PROFESSIONALS, <https://iapp.org/resources/article/us-federal-ai-governance/#s> (last visited Feb. 21, 2024).

broader information privacy laws schemes to protect citizens' personal information.⁵⁶

Conversely, the United Kingdom (UK) has also begun making strides to get ahead of the curve and implement policies overseeing and supporting AI. Recently, the Secretary of State for Science, Innovation and Technology released a statement highlighting a hope of establishing the UK as an AI superpower.⁵⁷ However, the implications AI would have in the healthcare industry in the UK would fall under direct government scrutiny as healthcare is public under the National Health Services.⁵⁸ This makes the situation in the United Kingdom much more unique in that it offers a potential avenue for the government to be accountable for introducing AI into healthcare. By seeing the implementation of AI systems in hospitals, the UK government would be able to oversee its capabilities and control its limits.

While these legislations regulate AI use generally, there is currently no explicit AI law regarding hospitals and healthcare. However, steps are being made by AI companies themselves to implement voluntary safeguards, as these companies have begun to feel pressure from President Biden.⁵⁹ These companies are Amazon, Anthropic, Google, Inflection, Meta, Microsoft, and OpenAI, billion-dollar corporations that can afford to voluntarily put safeguards on themselves. Due to pressure from President Biden and the federal government, it is likely that there will be further regulations on the use of AI in the U.S. healthcare system.⁶⁰ To preempt this, the groups mentioned above, including Google and OpenAI, made commitments to increasing the standards for safety, security, and trust.⁶¹ While these self-imposed policies would leave the corporate giants protected from liability theoretically, there needs to be just as strong safeguards for the hospitals and the healthcare industry.

Within the United States, there have been initial steps from government agencies such as the Consumer Financial Protection Bureau (CFPB), Department of Justice (DOJ), Federal Trade Commission (FTC), and Equal Employment Opportunities Commission (EEOC) to address AI concerns.⁶² In a joint statement made by all four agencies, they made it

56. *Id.*

57. *Id.*

58. *Id.*

59. Michael D. Shear, at al., *Pressured by Biden, A.I. Companies Agree to Guardrails on New Tools*, THE N.Y. TIMES, (Jul. 21, 2023), <https://www.nytimes.com/2023/07/21/us/politics/ai-regulation-biden.html>.

60. *Id.*

61. *Id.*

62. *Joint Statement on Enforcement Efforts Against Discrimination and Bias in Automated Systems*, FED. TRADE COMM'N, https://www.ftc.gov/system/files/ftc_gov/pdf/EEOC-CRT-FTC-CFPB-AI-Joint-Statement%28final%29.pdf (last visited Feb. 21, 2024).

clear all the government agencies involved wanted to see the widespread application of AI, but with practically enforceable standards that would not cause harm to citizens.⁶³ The reason all four collaborated on this joint statement of intent about AI application is that their agencies all have a direct interest in how AI is applied and have a responsibility to oversee its safe implementation in everyday use. The CFPB is involved because the agency oversees, regulates, and enforces federal consumer financial laws, intending to protect people from fraud.⁶⁴ The DOJ enforces constitutional provisions and federal statutes.⁶⁵ The agency is beginning to take a more active interest in AI.⁶⁶ This interest was evident when the agency offered a statement in federal court that the Fair Housing Act applied to AI-based tenant screening services.⁶⁷ The EEOC enforces federal laws that make it illegal for employers to discriminate against applicants or employees.⁶⁸ This enforcement would be applied to AI because the agency's interest is related to the AI services which could be used for screening and discrimination. The FTC protects consumers from deceptive and unfair business practices, and the agency's interest in AI is based on the belief that discrimination via AI could be a violation of the FTC Act.⁶⁹ These agencies all have a vested interest in the advancement of AI. They will play key roles in regulating its use and the limits of how industries can utilize AI systems in the foreseeable future.

While this is a step in the right direction for general AI use in the United States, the exception must be made for the medical industry, as there are too many possibilities and risks. The AI industry is too new and untapped to truly understand the scope of what is possible, both positive and negative. The appropriate course of action is to keep AI out of hospitals to ensure patient health because the AI system would require constant supervision and oversight to ensure that no errors would be made. While this would seem like a positive at first glance, the focus in hospitals should be on the patients, and taking away attention and resources to focus on the data could lead to problems down the line

1. How Medical Risks Have Become Legal Risks: An Analysis of the Claims of Patients and Providers

A major medical risk with the implementation of AI in the hospital

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Id.*

68. *Id.*

69. *Id.*

setting is the potential for misdiagnosing patients, which is being balanced with excitement over the possibilities of improved efficiency in diagnostics.⁷⁰ However, the dangers of implementing AI in hospitals become clear when it is used in areas of diagnoses because while the AI systems can be used for early onset diagnosis, there remains a chance that the algorithm makes a mistake, misdiagnoses someone, and they begin receiving treatment for a disease or condition they do not have. Or, if AI is measuring the vitals and giving indications to the doctors based on the data entered in the system and gives wrong information or creates a false indicator for the attendings, this could cause them to treat the patients in a way that does not actually help them. These dangers have not stopped early steps to introduce AI into hospitals, such as the Houston Methodist Hospital implementing its AI vital tracker system BioButton.⁷¹ If AI measures the vitals and gives indications to the doctors based on the data entered in the system and gives wrong information or creates a false indicator for the attendings, this could cause them to treat the patients in a way that does not help them.

For example, Ohio, like all other states, has a designated section of its code that reviews and clarifies what is medical malpractice and the requirements of commencing such an action, as well as outlines negligence in the medical field.⁷² Within those confines, the Ohio Revised Code breaks down section by section what can be considered malpractice, and who can be considered liable, including but not limited to the hospitals, and all the associated physicians or staff involved in that treatment.⁷³ This is important to note because if Ohio hospitals seek to introduce AI into their everyday procedures, they would have to comply with the guidelines of the Ohio Revised Code. The AI system would then be included as in the same vein as hospitals, doctors, health networks, and staff if malpractice occurs per the guidelines. Complications arise because patients cannot as readily hold the technological AI system at fault. In that case, the patients' only choice is to hold the people and hospitals who did not oversee the AI system liable.

70. Rana Abdullah & Bahjat Fakieh, *Health Care Employees' Perceptions Of The Use Of Artificial Intelligence Applications: Survey Study*, 22 J. MED. INT. RES. 1-8 (2020).

71. *Future Bet: Remote Patient Monitoring*, HOUSTON METHODIST, <https://www.houstonmethodist.org/center-for-innovation/our-work/remote-patient-monitoring/> (last visited May 24, 2024).

72. OHIO REV. CODE ANN. § 2305.113.

73. *Id.*

2. How the Errors In the AI System Can Lead to a Downward Spiral

For example, if a patient with hemophilia was incorrectly noted by the AI system as not having it, this error would affect not just the patient. The error would also affect hospital staff trying to treat the patient. If the AI system gives an inaccurate response to the hospital staff and then they are left scrambling or unaware of conditions the patient may have, this creates larger margins of error in care. More seriously, if the AI system made a mistake in not identifying the patient as a hemophiliac, a doctor may prescribe medicine that would be detrimental to hemophiliacs. There are also the possibility complications arise in surgery, with surgeons having to deal with deep internal bleeding when trying to operate on a patient with hemophilia without being properly prepared. A small error can quickly become a very large problem, and hospitals need to be aware of that potential. Hospitals may underestimate how costly a lackluster approach can be and how this would create long-term liability issues for all involved.

III. DISCUSSION OF ANTICIPATED AND UNFORESEEN POTENTIAL LEGAL ISSUES WITH AI IN THE MEDICAL FIELD

A. *Ethical Dilemmas Unique to AI in the Hospital Setting*

When an AI system produces information that a doctor disagrees with, doctors face issues on how to proceed. This dilemma creates a conflict of a doctor's instincts forged through the years of learning and real-world experience versus the algorithm. These are issues that doctors would have to face when AI is implemented within the hospital setting. More experienced healthcare providers are bound to trust their own understanding and familiarity about certain health issues than they would an AI system recommendation.⁷⁴ This may be related to the provider's distrust of the system and the possibility of losing autonomy when the AI is recommending a solution that is not compatible with what the doctor would recommend.

There should be, and likely will be, a medical and legal duty to monitor and develop the program, which could be rolled out in stages. First, healthcare networks have a medical duty to develop the program because the main goal of a hospital is to provide the best possible care it can to its patients safely while ensuring the duty of care is adhered to. These

74. Sophie Isabelle Lambert, et al., *An Integrative Review On The Acceptance Of Artificial Intelligence Among Healthcare Professionals In Hospitals*, 6 NPJ DIGIT. MED. 111 (2023).

healthcare networks also have a legal duty to ensure their steps do not expose the hospital and healthcare network to any potential forms of liability. Hospitals have this duty to ensure they take all the necessary precautions to protect themselves from liability and, more importantly, to protect the patients. A nurse's or doctor's duty has always been about patient care, not data analysis, and fulfilling an additional data analysis duty would be too time consuming. Time is one of those commodities that healthcare professionals do not have the privilege of having an abundance of, as they work long hours in their official capacity and do not have the time to learn about AI technology in their free time.⁷⁵ Nonetheless, training requires time and several studies have reported that healthcare professionals lack the time outside their official duty hours to learn how to use the new AI-based technology. Thus, it is an organizational duty to not only offer training for potential users of the AI systems but also to provide staff with the opportunity to take part in this training to foster acceptance.

B. Legal and Ethical Considerations Recapitulated: Who is Responsible?

On the one hand, there is pressure for the implementation of AI systems in hospitals due to the increasing patient demand, chronic diseases, and resource constraints of the healthcare systems.⁷⁶ According to the Centers for Disease Control and Prevention (CDC), six in ten adults in the United States have chronic diseases, with four in ten having two or more chronic diseases.⁷⁷ Consequently, chronic conditions are one of the leading drivers in the annual health care cost being around \$4.1 trillion.⁷⁸ If the AI systems were harnessed correctly, digital health technologies could focus on the causes of illnesses and track the success of preventive measures and interventions.⁷⁹ The Department of Health and Human Services (DHHS) monitors how many hospitals and health networks are under investigation for data breaches involving more than 500 patients whose information was breached.⁸⁰ When these breaches occur, the patients seeking to bring suit want to know who is responsible for their

75. *Id.*

76. Nithesh Naik, et al., *Legal and Ethical Consideration in Artificial Intelligence in Healthcare: Who Takes Responsibility?* FRONT. SURG. (2022)

77. *Chronic Diseases in America*, CTRS. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/chronicdisease/resources/infographic/chronic-diseases.htm>, (last visited Mar.13, 2024).

78. *Id.*

79. *Id.*

80. U.S. DEP'T OF HEALTH AND HUM. SERV. OFF. FOR CIV. RTS., https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf (last visited Feb. 10, 2024).

protected personal and health data being leaked. The capacity to trace culpability back to the maker or operator would be threatened by the machines that could operate by unfixed rules and new patterns of behavior.⁸¹ The extent of the danger would be unknown, and there would be a lack of accountability because there could and would be arguments and conflicts surrounding the fact was the machine who learned the behavior.⁸²

1. Revisiting *Dinerstein v. Google* and Breaking Down How Google was Able to Avoid Liability

Looking back at the case *Dinerstein v. Google*, the United State Court of Appeals for the Seventh Circuit stated that the plaintiff did not have standing to sue defendants for alleged breach of privacy because the plaintiff acknowledged that the challenged medical record transfer was proper according to the data use agreement.⁸³ The class action lawsuit was brought against Google, who was collaborating with UChicago.⁸⁴ The two were working to create AI software capable of anticipating the patients' future healthcare needs with the goal of reducing medical complications, eliminating unneeded hospital stays, and improving healthcare outcomes.⁸⁵ The class, made up of patients who believed their data was being misappropriated by the AI system designed by Google, claimed that UChicago had breached either an express or an implied contract traceable to a privacy notice the patients received and an authorization they signed upon each admission to the medical center.⁸⁶ Alternatively, the plaintiffs asserted a claim for unjust enrichment, citing the same notice and authorization.⁸⁷ The plaintiffs also alleged that UChicago had reneged on its promise of patient confidentiality.⁸⁸

This lawsuit, arising out of what was supposed to be an AI-driven innovation for healthcare and hospitals, does not bode well for the integration of AI into the hospital systems. In breaking down each area of the law, the breach of contract claims seeks to hold the hospital liable for violating the agreement and authorization form plaintiffs signed when they were admitted to the hospital, which created a contractual obligation

81. See Naik, et al., *supra* note 76.

82. *Id.*

83. *Dinerstein*, 73 F.4th at 502.

84. *Id.*

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

for the hospital to safeguard the patient's medical information.⁸⁹ However, the court made clear that the plaintiff was trying to mislabel an injury of law as an injury of fact, which, without showing any actual harm, falls short of the breach of contract requirements for lawsuits in federal court.⁹⁰ This shows some of the ways that these entities circumvent liability for the issues that arise from AI systems being implemented into hospitals.⁹¹

Constitutional law applies in this situation when it comes to the privacy concerns of the hospital based on the Notice of Privacy Practices the patients received and the Admission and Outpatient Agreement and Authorization patients signed when they checked in.⁹² The agreements permit hospitals to gather patient information for research purposes with AI systems to be implemented in the hospital.⁹³ The court in *Dinerstein* made it clear that the plaintiff was using the privacy claim strictly in the medical confidentiality sense, which required them to show if there was either past or future harm.⁹⁴ The court ruled that because the agreement the hospital had with Google made it clear that Google's purpose in obtaining the medical data was not to identify patients but to keep a record for the patients, they did not technically violate the terms of the agreement and confidentiality.⁹⁵ The court further states that first because the hospital took the steps once they received the patient information to de-identify patients before importing the information into the AI system and the plaintiff agreed that the hospital met its obligation to de-identify, the basis of the claim of past harm was a hypothetical and does not suffice.⁹⁶ De-identification occurs when the hospital staff and AI administrators take the necessary steps and due diligence of going through reports and systems and remove any identifying patient information.⁹⁷ These steps are important to note in the fact that by going through the motions of de-identification, Google freed itself from being on the hook for liability for breaching patient privacy laws. By removing all the patient's identifying information, Google found a way to streamline the health information and convert it into data.

The second step Google took in de-identification also helped the company in the *Dinerstein* litigation. Google explicitly agreed not to

89. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

97. *5 steps for removing identifies from datasets*, JOHNS HOPKINS Univ., https://guides.library.jhu.edu/protecting_identifiers/de-id_steps (last visited Mar. 13, 2024).

identify any patient with the information they were given.⁹⁸ The court felt that was enough to show the risk of future harm would not come to be and that the steps Google took with the process of de-identifying the data were enough to ensure this.⁹⁹ Therefore, the plaintiff's claim failed to hold the hospital and Google liable because both entities took the necessary steps to protect the patient information, even when being used in curating and working with AI systems.¹⁰⁰ This case is significant because it details the extreme attention to detail and precise steps needed to allow for this limited implementation and feeding of patient data into the AI system used by UChicago. While universities have always been the linchpin of research and collaboration between medical research and application, legal limits must be adhered to. As a relatively recent innovations, AI systems are still being slowly integrated and introduced into healthcare systems. While Google was able to escape without being found liable to patients of UChicago, the lawsuit should serve as a warning sign to technology companies and hospital systems alike as a reminder of how much value people place in their healthcare data and information.

C. The Healthcare Industry is Seeking to Implement AI in a More Widespread Capacity and Could Follow the Suit of the Legal Industry

In looking at the legal implications posed by AI in the similarly protective legal industry, there has been a more active interest in trying to turn the AI's capability of learning law from its use as a knowledge-supplement tool. Compare this with the more machine-learning-based approach that is more widely seen today in everyday life and the possibilities seem appealing.¹⁰¹ From helping lawyers with citations to helping edit papers to helping with the writing of memos and articles, the possibilities of AI use in the legal field are widespread.¹⁰² While the possibilities seemed numerous and attractive, the possibilities are not limitless.

With the two high stress industries, the industries are feeling pressure to introduce both into everyday practices. Already, this seems to be an adding pressure to the lives of doctors and lawyers. Doctors and lawyers already must get certified to practice in states by state medical boards and

98. *Id.*

99. *Id.*

100. *Id.*

101. Harry Surden, *Artificial Intelligence and Law: An Overview*, GA. ST. UNIV. L. REV., <https://readingroom.law.gsu.edu/cgi/viewcontent.cgi?article=2981&context=gsulr> (last visited Feb 22, 2024).

102. *Id.*

bar associations, respectively.¹⁰³ Nowhere in either profession was the requirement of becoming a computer or AI system expert ever written in, and pressuring these individuals to do so only adds extra stress and work into industries filled with overworked individuals.

There are limitations to how AI is being used in the legal industry. The AI systems do not and should, not have the final say on what cases are used in legal research or determining the relevance of documents in the legal community.¹⁰⁴ This should be left to the human professionals, certified in their fields by their respective state boards, to ensure that the AI does not fabricate cases that are not real nor that the system does not gleam over possible relevant cases that could help attorneys.

Initial studies have begun taking place to determine what implementing of AI systems in hospitals would look like. In studies conducted by the Departments of Radiology at Istinye University MedicalPark Gaziosmanpasa Hospital and Hisar Intercontinental Hospital, two of the top-ranked research hospitals in Istanbul, Turkey, simulations of hospital settings with the implementation of AI systems were conducted to see how they would affect productivity of staff and doctors.¹⁰⁵ The study found that the AI system being used showed that it induced errors in emergency care settings, which defeated the purpose of having the AI system help streamline the care to patients.¹⁰⁶ At the same time, while some physicians found the alerts the AI system provided could be useful in certain scenarios, there were still concerns about how useful it would prove to be.¹⁰⁷

A study involving multiple health departments overseas in Italy and the Cambridge Centre for Health Services Research (CCHSR), Department of Public Health and Primary Care, at the University of Cambridge School of Clinical Medicine found there were extensive barriers of using the AI in the hospital.¹⁰⁸ In fact, the researchers in the study noted that the AI-developed technologies that created alerts caused the physicians and nurses to feel fatigued from the excessive alerts.¹⁰⁹ The parties found it to

103. *Licensure*, U.S. DEP'T OF HEALTH AND HUM. SERV., <https://telehealth.hhs.gov/licensure/getting-started-licensure> (last visited March 25, 2024).

104. *Id.*

105. Isil Yurdaisik & Suleyman Hilmi Aksoy, *Evaluation Of Knowledge And Attitudes Of Radiology Department Workers About Artificial Intelligence*. ANN. CLIN. 12 ANAL. MED., 186–190 (2021).

106. Sophie Isabelle Lambert, et al., *An Integrative Review On The Acceptance Of Artificial Intelligence Among Healthcare Professionals In Hospitals*. 6 NPJ DIGIT. MED. 111 (2023).

107. *Id.*

108. Elisa G. Liberati, et al., *What Hinders The Uptake Of Computerized Decision Support Systems In Hospitals? A Qualitative Study And Framework For Implementation*. 12 IMP. SCI. (2017).

109. *Id.*

be excessive and that some physicians dismissed alerts.¹¹⁰ Only 12 % of the radiology department in a Turkish study felt that AI would always be used with confidence soon.¹¹¹ This is because the doctors felt that, because of how new AI is and because of their confidence in their abilities, doctors trusted their judgment more than what the AI systems proposed.¹¹² Despite how the research looks at these issues, doctors are still incredibly reluctant to speak out about this issue publicly for fear of losing their jobs.¹¹³

Potential issues with AI systems and distractions caused by constant AI-induced alerts would most likely become a legal problem because it creates situations where the people taking care are becoming more tired and fatigued.¹¹⁴ Because of this fatigue, this would leave the doctors more open to making mistakes that could harm the patients, which would then open the doctor, the hospital and the health network up for liability on grounds of negligence.¹¹⁵ The UnitedHealth lawsuit is a prime example of how the AI used by insurance firms was faulty and incorrect, and because of this oversight and trust of the AI system, it made mistakes.¹¹⁶ These errors in its algorithm incorrectly denied elderly patients' coverage for extended care that their doctors felt was vital for their health.¹¹⁷ Because of this oversight, both patients were not able to get the care they needed.¹¹⁸ Both died as a result of a computer error, which arguably could have been prevented.

IV. CONCLUSION

While the greatest asset to companies is data and its potential for new pathways, AI has advantages in other areas of society. However, it should be largely kept out of hospitals, especially unless human decisions still have the final say. AI seems to be the answer to allowing companies to benefit from that data, as it would automate and streamline the processes to help get the best and most efficient answers. However, the possibility of errors that could lead to more serious and dire consequences for the hospital staff using the systems and for the patients relying on them is too high to proceed. While the advantages in other fields would help expedite

110. *Id.*

111. *Id.*

112. *Id.*

113. *Id.*

114. *Id.*

115. *Id.*

116. Complaint, *UnitedHealth*, *supra* note 17, at 5.

117. *Id.*

118. *Id.*

certain tasks, the harms and risks are too severe for hospitals to implement this technology without additional legal guidelines. If hospitals were to implement the AI system, they would need to proceed with extreme caution and care. In pursuing AI implementation in hospitals, there needs to be a focus on ensuring that the measures taken reflect the severity of the potential harms and the importance of the personal health data.

Hospitals are meant to be places where people seek care and remedies for their health, and often, this care requires careful, human care. If AI is allowed into hospital procedures, it will almost certainly do more harm than good. Despite the strides of AI in other areas, such as financial data use, research, and algorithms, AI should be kept out of hospitals to protect the patients' health. The implications posed by AI in a similarly protective industry, such as the legal profession, has shown that there is an active interest in turning AI's capability of learning law from its use as a knowledge-supplement tool to a more machine-learning based approach that could be used in hospital settings to help doctors treat patients.¹¹⁹ While there are the benefits AI has provided other industries, such as streamlined research, and more efficient solutions to questions, the dangers that it poses to patient safety should be the main reason to keep AI out of the hospital.

119. Harry Surden, *Artificial Intelligence and Law: An Overview*, GA. ST. UNIV. L. REV., (Jun. 1, 2019), <https://readingroom.law.gsu.edu/cgi/viewcontent.cgi?article=2981&context=gsulr>