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The Expected Medical Liability as a result of the Health Sector's Interaction with Artificial Intelligence – A Foresight-led, Analytical, and Comparative Study*[1]

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Abstract

The research focuses on medical liability in the context of AI. Considering that AI is a game-changer, it is a system that produces accurate outputs that may surpass doctors' abilities. However, this technology is not risk-free. This puts doctors and hospitals in a complex situation regarding liability that arises from their interactions with AI. Therefore, it was necessary for the research to review medical legislation that preserves its traditional character in regulating medical liability, such as the Kuwaiti and American legislation. As well as to explore proposals that regulate AI and liability for the damage that results from the use of AI, such as the AI Act proposal and the AI liability directive proposal, which were both issued by the EU Commission.The research aims to highlight the deficiencies in the aforementioned legislation and proposals, and provide suitable rules regarding medical liability and AI.

This research adopts foresight, analytical, and comparative approaches and has reached several results, the most important of which is that under current Kuwaiti and American legislations, doctors must apply the traditional standard of care, which does not include AI, to shield themselves from liability. The research also reached several recommendations, the most important of which is that physicians must have two standards of care in the EU, Kuwaiti, and American legislation. The first is the medical standard that obligates the use of AI, and the second is the AI user standard.

Keywords: Standard of Care; Artificial Intelligence; User; Vicarious Liability; Direct liability; AI

1* This article is derived from the author's master thesis titled 'The Civil Liability of Medical Malpractice Related to Artificial Intelligence' supervised by Dr. Ahmad Abdul-Aziz, and submitted to the Kuwait International Law school in 2023.

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المسؤولية الطبية المتوقعة كنتيجة لتفاعل القطاع الصحي مع الذكاء الاصطناعي – دراسة استشرافية تحليلية مقارنة[1]*

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ملخص

يتمحور هذا البحث حول المسؤولية الطبية في ظل وجود الذكاء الاصطناعي. مع الأخذ بالحسبان أن الذكاء الاصطناعي يعدّ نظامًا استثنائيًا خارجًا عن المألوف؛ فهو نظام تكنولوجي ينتج مخرجات دقيقة قد تفوق قدرات الأطباء. ومع ذلك، فإنه لا يخلو من المخاطر، مما يجعل الأطباء والمستشفيات في وضع معقد من حيث المسؤولية الناتجة عن التعامل مع الذكاء الاصطناعي. لذلك كان لزامًا على هذا البحث مراجعة التشريعات التي تحافظ على صبغتها التقليدية في تنظيم المسؤولية الطبية مثل التشريعين الكويتي والأمريكي، واستكشاف المقترحات التي تنظم كل من الذكاء الاصطناعي والمسؤولية عن الأضرار الناجمة عن استخدام الذكاء الاصطناعي، مثل مقترح قانون الذكاء الاصطناعي ومقترح توجيه مسؤولية الذكاء الاصطناعي الصادرين عن مفوضية الاتحاد الأوروبي.

يهدف هذا البحث إلى تسليط الضوء على أوجه القصور في التشريعات والمقترحات سالفة الذكر، كما يهدف إلى تقديم قواعد مناسبة فيما يتعلق بالمسؤولية الطبية والذكاء الاصطناعي. يتبنى البحث المنهج الاستشرافي والتحليلي والمقارن، وقد توصل إلى نتائج عدة؛ أهمها أنه بموجب التشريعات الكويتية والأمريكية الحالية يجب على الأطباء تطبيق المعيار التقليدي للرعاية، الذي لا يشمل الذكاء الاصطناعي، حماية لأنفسهم من المسؤولية القانونية. كما توصل البحث إلى عدة توصيات؛ أهمها ضرورة أن يكون لدى الأطباء معياران للرعاية في التشريعات الأوروبية والكويتية والأمريكية؛ الأول المعيار الطبي الذي يفرض استخدام الذكاء الاصطناعي، والثاني معيار مستخدم الذكاء الاصطناعي.

الكلمات المفتاحية: معيار الرعاية، مستخدم الذكاء الاصطناعي، مسؤولية المتبوع عن عمل تابعه، المسؤولية المباشرة، الذكاء الاصطناعي

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Introduction

At the outset, and before examining AI and healthcare from a legal perspective, this research briefly tackles the concept of AI and how it is incorporated into healthcare. The EU Commission AI Act regulation proposal defines AI as software that is made through certain techniques, which provides outputs like 'content, predictions, recommendations, or decisions' based on goals determined by humans to impact a certain environment.[1] The American computer scientist John McCarthy defines artificial intelligence as the science that focuses on making computer programs intelligent. Noting that such intelligence means the computational capacity to reach results.[2] Artificial intelligence has a family (sub-sets) consisting of a son, a grandson, and a great-grandson, each branching off from the other. The son is machine learning; its most notable feature is relying on datasets labeled by a human expert for learning. The grandson is a neural network that simulates the human brain by passing data in layers that it consists of under certain conditions. The great-grandson is deep learning, which can learn from both labeled and raw data, thus it does not require expert intervention.[3]

AI started to exist in the medical field at the beginning of the 1970s. As AI was used to solve healthcare problems, research related to such matters started to increase. This led to the establishment of the Journal of Artificial Intelligence in Medicine in 1980, a worldwide journal, and the American Association for Artificial Intelligence, which included a subdivision, concerned with medical AI applications. In 2017, medical AI became the most important AI application in terms of aggregate equity funding.[4]

There are various applications of AI in the medical field; this research will indicate some of them. The first is image-diagnosing apps, as it was found in published studies from Google, Stanford University, and countries that participated in the Cancer Metastases in Lymph Nodes Challenge 2016 competition that AI was better and more precise than human physicians were in this regard. Noting that studies involved different types of diseases, such as diabetic retinopathy, skin cancer, and metastases in lymph nodes.[5]

The second is surgical robots. In this field, AI can make complicated decisions related to surgery and its consequences that are beyond the capabilities of most surgeons.[6] Noting that there are five levels

1 Commission, 'Proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence and Amending Certain Union Legislative Acts (Artificial Intelligence Act)' COM(2021) 206 final, art 3 (1).

2 John McCarthy, 'What is Artificial Intelligence' (Stanford, 12 November (2007). <http://jmc.stanford.edu/articles/whatisai/whatisai.pdf> accessed 8 July 2024.

3 IBM, 'What is Machine Learning'. <www.ibm.com/topics/machine-learning> accessed 4 July 2024.

4 Daniel Quest, et al., 'Demystifying AI in Healthcare: Historical Perspectives and Current Considerations' (2021) 8 Physician Leadership Journal 59.

5 Tokio Matsuzaki, 'Ethical Issues of Artificial Intelligence in Medicine' (2018) 55 California Western Law Review 255, 263.

6 R Mirnezami and A Ahmed, 'Surgery 3.0, Artificial Intelligence and the Next-Generation Surgeon' (2018) 105 British Journal of Surgery 463,463.

of surgeon robots, differing in the amount of automation and doctor intervention.[7] The third is intelligent personal records, such as wearable health devices, like watches or a band that enable users to monitor their health by providing signs. Another example is natural language processing, which is used for translating doctors' natural speech and analyzing data in electronic medical records.[8] This leads the researcher to believe that AI could play a significant role in resolving future health crises, such as COVID-19, where human existence is threatened and all activities are postponed.[9]

What sparked the curiosity of this research is the question: What will be the fate of doctors and hospitals in terms of medical liability in the presence of AI? Noting that AI may behave independently in producing outputs, as complete control of it may be impossible. However, AI can provide results that are more accurate than some doctors, which makes its application and contributions to the medical field a necessity. Therefore, how could doctors use such technology and stay legally secure?

The importance of this research lies, on the one hand, in explaining the application of law in medical cases that involve AI. For example, the research explored the relevant EU, Kuwaiti, and American legislation and explained how general medical rules, such as those in Kuwaiti and American legislation, and special rules that relate to AI users, such as those in the EU legislation, would apply. On the other hand, what may further demonstrate the importance of the research is providing what could possibly be considered solutions, such as suggesting a new standard of care, excluding some general rules from application, and altering deficiencies in the explored legislation as per the scope of this research.

This research adopts foresight, analytical, and comparative approaches. It looks for legislation, whether it is in the form of acts or cases, in Kuwaiti and American legislation. It also investigates the relevant proposals that are produced by the EU Commission to analyze and compare all the above to foresee possible solutions to such an international issue. Noting that this research is divided into two main headings, which are:

1. The development of the standard of care,
2. Hospitals' liability with the incorporation of AI.

1. The Development of the Standard of Care

Under this topic, the research will discuss two main headings. The first is medical malpractice under the US and Kuwaiti legislation. While the second will address physicians' liability under the EU legislation.

7 Aimun AB Jamjoom, Ammer MA Jamjoom & Hani J Marcus, 'Exploring Public Opinion About Liability and Responsibility in Surgical Robotics with the Irobotsurgeon Survey' (2020) 2 Nature Machine Intelligence <https://discovery.ucl.ac.uk/id/eprint/10096389/3/Marcus_1517_0_attach_6_12933_%20AJ%20edits.pdf> accessed 5 July 2024; See also Fosch Villaronga and others, 'A Human in the Loop in Surgery Automation' (2021) 3 Nature Machine Intelligence <www.researchgate.net/profile/EduardFoschVillaronga/publication/351462735_A_human_in_the_loop_in_surgery_automation/links/609b65b8299bf1ad8d955086/Ahumanintheloopinsurgeryautomation.pdf?_sg%5B0%5D=started_experiment_milestone&_sg%5B1%5D=started_experiment_milestone&origin=journalDetail> accessed 5 July 2024.

8 Adam Bohr and Kaveh Memarzadeh (eds), 'The Rise of Artificial Intelligence in Health Care' *Artificial Intelligence in Healthcare* (Academic Press, 2020) 39-41.

9 Abderraaouf Elloumi, 'Justice in a Time of Health Crisis – A Comparative Study' (2023)12 International Review of Law,57, 59

1.1. Medical Malpractice under the US and Kuwaiti Legislation

Four essential elements need to be proven in a successful medical malpractice case. They are: (1) the existence of the doctor's obligation of duty of care towards the patient, (2) the breach of such a duty by the doctor through deviating from the standard of care, (3) the patient's damages, and (4) the causation between such damages and the doctor's breach to his duty.[10] Therefore, the research will analyze those elements, as well as how they apply to medical AI. Similarly, the analysis will entail the application of the learned intermediary doctrine on AI under this requirement.

1.1.1. Duty of Care and Breach of Duty

In American legislation, the duty of care is related to the establishment of the doctor-patient relationship. Noting that such a link does not have to be formal where no contract is demanded to establish it. Moreover, in one case, an appeals court ruled that the duty of care does not have to be done through physical contact. For instance, if a doctor prescribes a certain medication for a patient over the phone, the relationship is considered established.[11] Similarly, the Kuwaiti Medical Law considers whoever practices medical activities like diagnosis or treatment, whether in person, through third parties or by any other means as a doctor.[12] This leads the researcher to believe that Kuwaiti law implicitly admits that a doctor's duty starts once the doctor-patient relationship is established through the phone such in the previous example, email, or any other means, whereby considering that a person who performs a medical activity by any means as a doctor, the law is suggesting that his duty has started.

In many states, for a doctor to breach their owed duty of care to the patient, courts must find that the doctor failed to practice certain elements, such as providing care and skill of a reasonably prudent doctor. Courts investigate this matter by comparing the defendant doctor's conduct with the conduct of another doctor in the same state; other states apply a stricter standard of care, where the defendant doctor's conduct is compared with the conduct of a specialist and not a general practitioner. Noting that experts play a major role in determining whether the defendant's conduct is irregular.[13] Similarly, the adopted standard of care in Kuwaiti Medical Law tends to be strict, requiring the comparison of similar specialist conduct.[14] It is noteworthy to indicate that the discussed standards of care are not detailed in a certain list, but they are the best practices embraced by physicians through applying their training,

10 Benedict See, 'Paging Doctor Robot: Medical Artificial Intelligence, Tort Liability, and Why Personhood May Be the Answer' (2021) 87 Brooklyn Law Review 417, 426.

11 Tort Law: The Rules of Medical Malpractice' (Lawshelf, 21 October 2020) <www.youtube.com/watch?v=4hvGIETLfkM&t=311s> accessed 6 July 2024.

12 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health Facilities, art 2 <https://www.amr.gov.kw/ar/law70-2020.php> accessed 21 September 2024.

13 Lawshelf, 'Tort Law: The Rules of Medical Malpractice' 21 October (2020). <www.youtube.com/watch?v=4hvGIETLfkM&t=311s> (accessed 6/7/2024).

14 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health Facilities, art 34 2 <https://www.amr.gov.kw/ar/law70-2020.php> accessed 21 September 2024.

education, and protocols.[15]

However, when technology is integrated into the health field, changing the standard of care follows, such as changing the standard of care of anesthesiologists through establishing 'new methods monitoring oxygen levels during surgery', which resulted from misusing anesthesia that caused a massive amount of deaths and injuries in the 1980s.[16] Noting that AI as a technology is providing outstanding solutions in the medical field, this led to the belief that it would even heal cancer. However, AI may be mistaken. Therefore, the question of whether and how AI can change the standard of care becomes essential.[17]

According to the last paragraph, scholars' opinions were divided into four, respecting the matter of the standard of care, as the first opinion focused on the reasonableness of doctors' judgment, which encompasses their decisions of whether or not to utilize AI. For example, one scholar perceives that the standard of care may change to recognize tumors as radiologists, regardless of the instruments utilized. In the same context, the South California Supreme Court in McCourt ex rel. McCourt v. Abernathy emphasized that the matter of adopting a certain approach is not enough to impose liability, as treatment may be a result of varied approaches, so long as a comparable reasonable prudent doctor can exercise them in similar circumstances. Therefore, the application of the principle that resulted from this trend would compare the diagnosis, treatment, and decision to use AI with that of a reasonable, prudent doctor, as the mere decision of whether or not to utilize AI would not hold physicians liable.[18]

The second opinion holds that the influence of technology governs the standard of care change. This opinion believes that not using AI would probably hold doctors liable, given that AI provides more data to doctors for diagnosis and treatment, which makes prescribing medicine through its use much better than the doctor's sole decision. Therefore, using AI would become an obligation, just as in 'using X-rays or automated external defibrillators'. Noting that by adopting the use of AI as the standard of care, the required reasonableness will change, where it will be considered that it is 'unreasonable, per se, not to use medical AI'. However, this opinion believes that the matter of whether to follow the recommendation of AI should be left to the court to determine its reasonableness. Noting that AI might provide an unforeseen recommendation due to its black-box issue, which is a lack of understanding of how the AI reached its results,[19] or what is known to be called 'hallucinations', which is a condition in which AI produces outputs that are disproportionate to user inputs.[20]

The third opinion believes that AI might become the standard of care over time, where the physician

15 'What Do You Need to Know About the Standard of Care?' (Miller Wagner, 10 April 2020) <www.miller-wagner.com/articles/standard-of-care/> accessed 6 July 2024

16 Benedict See, 'Paging Doctor Robot: Medical Artificial Intelligence, Tort Liability, and Why Personhood May Be the Answer' (2021) 87 Brooklyn Law Review 417, 427.

17 Iria Giuffrida and Taylor Treece, 'Keeping AI Under Observation: Anticipated Impacts on Physicians' Standard of Care' (2020) 22 Tulane Journal of Technology & Intellectual Property 111, 112.

18 Ibid 114-116.

19 Ibid 116-118.

20 David O. Shumway, Hayes J. Hartman, 'Medical Malpractice Liability in Large Language Model Artificial Intelligence: Legal Review and Policy Recommendation' (2024) 124 Journal of Osteopathic Medicine 287, 287.

will be liable in case he does not follow the AI recommendation, regardless of the accuracy of the AI output, whether it was right or wrong. Therefore, the physician should follow the AI recommendation to shield himself against liability.[21]

Given this, the researcher believes that the first opinion overlooked the capabilities of AI. For example, it was mentioned in the introduction of this research that AI provided results better than human physicians in image diagnosis and can make surgical decisions better than human doctors,[22] which leads the researcher to believe that the necessity of adopting AI as an approach becomes a fact. Therefore, this research disagrees with the first opinion.

On the contrary, this research believes that the third opinion strongly adopts the idea of AI superiority, relying on that AI can 'perform better than even the best physicians',[23] passing the fact that AI is not risk-free, as mentioned earlier that AI may provide incomprehensible recommendations due to the black-box problem. Therefore, the researcher disagrees with this opinion and believes that doctors cannot follow AI recommendations without monitoring, assessment, or intervention.

Accordingly, the researcher agrees with the second opinion. Doctors are obligated to use AI; however, the reasonableness of following or not following its recommendation is a matter that is left to the court examination on a case-by-case basis. Notwithstanding, supporters of the third opinion who see the idea of following AI as the proper standard of care may argue that the trend, such as in the EU Commission AI Act regulation proposal, which regulates AI in general and states varied provisions to reach a trustworthy AI, is to impose legal requirements on high-risk AI systems, like 'data and data governance, documentation and recording keeping, transparency and provision of information to users, human oversight, robustness, accuracy, and security'.[24] This, in return, would overcome the black-box problem, along with other possible problems, which makes the idea of changing the medical standard of care to follow AI as the best one. In contrast, this research believes that such requirements aim to mitigate risks and not end them as stated in the EU AI Act regulation proposal.[25] Noting such requirements would help doctors in interpreting and assessing the AI output, which most probably matches the idea of changing the standard of care to using AI with no obligations to follow.

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21 W Nicholson Price II, Sara Gerke and I Glenn Cohen, 'Potential Liability for Physicians Using Artificial Intelligence'(2019) 322 Journal of the American Medical Association 1765, 1765; See also Sara Gerke, 'Legal Issues of Artificial Intelligence in Healthcare in the U.S' (Oxford law Faculty, 28 May 2021) <www.youtube.com/watch?v=zwONJAxK_AA> accessed 6 July 2024.

22 Tokio Matsuzaki, 'Ethical Issues of Artificial Intelligence in Medicine' (2018) 55 California Western Law Review 255,263; See also R Mirnezami and A Ahmed, 'Surgery 3.0, Artificial Intelligence and the Next-Generation Surgeon' (2018) 105 British Journal of Surgery 463, 463.

23 W Nicholson Price II, Sara Gerke and I Glenn Cohen, 'Potential Liability for Physicians Using Artificial Intelligence' (2019) 322 Journal of the American Medical Association 1765.

24 Commission, 'proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence and Amending Certain Union Legislative Acts (Artificial Intelligence Act)' COM(2021) 206 final, s 5 (5.2) (5.2.3).

25 Ibid s 2 (2.3).

Moreover, supporters of the third opinion may argue that if the standard of care follows AI, doctors could still avoid liability in case they deviate from the AI recommendation by applying the respectable minority doctrine that allows doctors not to use AI.[26] The respectable minority doctrine is where the defendant doctor demonstrates that although his conduct differs from another practitioner's conduct, it is still 'accepted by a respectable minority of practitioners', and this may lead the jury to decide that the defendant doctor's conduct, which belongs to the minority standard is the correct standard to follow.[27] Similarly, this argument may be presented in Kuwaiti courts, noting that the Medical Law allows doctors to deviate from similar specialist conduct, provided that the deviated conduct complies with the medical principles.[28]

However, the researcher believes that when changing the standard of care to adopting AI, the doctor would have no motive to deviate from an inappropriate AI recommendation, as they are protected anyway by only applying it. In this way, making the correct decision would be left to the doctor's conscience. In addition, doctors may find themselves defendants in any case, and here, justifying and proving that a respected minority accepts their conduct would be more complicated than proving that they adopted AI. The researcher also believes that this view is hasty in adopting AI as the only standard of care, leaving out the opinion of some scholars such as Dreyfus, Searle, and Penrose, who argue that AI is unable to think like humans, which elaborates the necessity of human intelligence.[29] In contrast, altering the standard of care to use AI without the obligation to follow its recommendations would push doctors to intervene and make the right decision, as their role still affects the outcome of whether or not there is a liability; unlike adopting AI, which excludes the role of the doctor. Noting that law, in general, is about governing persons' actions rather than eliminating them.

The fourth opinion was found in an empirical study, where potential jurors composed of 2,000 persons showed that following the traditional standard of care or AI advice, regardless of deviating from the traditional standard of care and causing injury to the patient, would shield doctors from liability, noting that potential patients tended to see that adopting AI is more reasonable and important than applying the traditional standard of care.[30]

However, the researcher disagrees with what might turn out to be with potential jurors. Such an

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26 W Nicholson Price, Sara Gerke and I Glenn Cohen, 'Liability for Use of Artificial Intelligence in Medicine' [2022] Law & Economics Working Papers 1, 7.

27 'Standard of Care' (The Climate Change and Public Health Law Site) <https://biotech.law.lsu.edu/books/lbb/x131.htm> accessed 7 July 2024.

28 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health Facilities, art 34 (6).

29 Mahmoud Dhaouadi, 'An Exploration into the Nature of the Making of Human and Artificial Intelligence and the Qur'anic Persepective' (1992) 9 American Journal of Islamic Social Sciences 465, 467-468.

30 W Nicholson Price II, Sara Gerke and I Glenn Cohen, 'How Much Can Potential Jurors Tell Us About Liability for Medical Artificial Intelligence?' (2021) 62 Journal of Nuclear Medicine 15,15; See also Sara Gerke, 'Legal Issues of Artificial Intelligence in Healthcare in the U.S' (Oxford law Faculty, 28 May 2021) <www.youtube.com/watch?v=zwONJAxK_AA> accessed 6 July 2024.

opinion may leave doctors with the option of either leaving the excellent results of AI behind or adopting AI unthinkingly, and both cases would result in no liability. This research is curious to know if the patient group targeted for the study was introduced to the risks of AI or the impact of AI on healthcare, such as the controversy of whether AI would improve or reduce the patient-doctor relationship. Noting that according to the report 'Crossing the Quality Chasm', which is published by the American Institute of Medicine, such a relationship is crucial to enhance the healthcare system in general, [31] or whether the targeted patient group was introduced to the issue of AI hallucinations, or the issue of wrong AI outputs that rest on biased data that relates to race, gender, and socioeconomic condition.[32]

It is noteworthy to mention that an opinion believes that with the emergence of fully autonomous AI medical devices, their legal status of deserving legal personality would be reconsidered, as the same opinion discussed applying medical malpractice elements to the fully autonomous AI medical devices. In fact, it was stated that it would be easier to prove elements such as the existence of a duty of care, causation, and damage through looking into the patient›s electronic medical records.[33] However, the researcher believes that the hypothesis of vague, wrong, and biased decisions still stands with fully autonomous AI medical devices, as it is similar to the previous opinion of following AI without any human intervention. This leads the researcher to believe that excluding human doctors and leaving the mission to fully autonomous AI medical devices is not necessarily a development, where the ultimate goal is to provide the best care for patients as this matter is realized through the efforts of both AI and human doctors as explained previously.

Nevertheless, meanwhile, under the current standard of care in Kuwaiti and American legislation, a physician who relies on AI recommendations could still face liability if his/her conduct deviates from the current traditional standard of care and results in an injury.[34]

For example, the first scenario would be that the traditional correct dosage for a person who is diagnosed with ovarian cancer is '15 milligrams per kilogram every 3 weeks of a particular chemotherapeutic agent'. Noting that it is the traditional standard of care dosage, and the AI recommended the same dosage. If the doctor follows such a recommendation, there would not be an injury, and he would not be liable. In contrast, if the doctor rejects the recommendation, he/she will

31 Matthew Nagy and Bryan Sisk, 'How Will Artificial Intelligence Affect Patient-Clinician Relationship?' (2020) 22 American Medical Association journal of ethics 395, 395-396.

32 George Benneh Mensah, 'AI and Medical Negligence' (2024) 1 Africa Journal of Regulatory Affairs 46, 49.

33 Ahmed Eldakak and others, 'Civil Liability for the Actions of Autonomus AI in Healthcare: An Invitation to Further Contemplation (2024) 11(1) Humanities and Social Sciences Communications 1, 2-4.

34 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health Facilities, art 34 <https://www.amr.gov.kw/ar/law70-2020.php> accessed 21 September 2024; See also W Nicholson Price II, Sara Gerke and I Glenn Cohen, 'Potential Liability for Physicians Using Artificial Intelligence'(2019) 322 Journal of the American Medical Association 1765, 1765; See also Sara Gerke, 'Legal Issues of Artificial Intelligence in Healthcare in the U.S' (Oxford law Faculty, 28 May 2021) <www.youtube.com/watch?v=zwONJAxK_AA> accessed 6 July 2024.

cause harm to the patient, as he/she will be liable for deviating from the traditional standard of care. However, let us imagine that such a dosage is inaccurate, which means that the traditional standard of care and AI are both wrong. If the doctor had adopted the AI recommendation and harmed the patient, he would not be liable, as he had followed the traditional standard of care. However, if the doctor decides to reject such a recommendation, he/she may also not be liable due to the nonexistence of the harm despite deviating from the traditional standard of care.[35]

In the second scenario, the AI recommends a different dosage that does not comply with the standard of care dosage, such as '75 milligrams per kilogram every 3 weeks of a chemotherapeutic agent'. Noting that the AI recommendation is the correct dosage, unlike what is perceived in the traditional standard of care, especially since personalizing care is one of the medical AI's aims. If the doctor follows such a recommendation, he/she will not harm the patient. Therefore, he will not be liable despite deviating from the traditional standard of care. In addition, if the doctor rejects such a recommendation, he will still not be liable, despite the harm done to the patient, because he adopted the traditional standard of care. Notwithstanding, suppose this non-standard dosage provided by AI was incorrect as the doctor followed it. In that case, he will cause harm to the patient and will be considered liable due to not following the traditional standard of care and causing harm. In contrast, if the doctor rejects the AI recommendation, he/she will not harm the patient and will not be considered liable.[36]

1.1.2. Causation

According to American law, the plaintiff must prove two elements of causation. First, cause in fact, which means that if it was not for the doctor's negligence, the harm would not exist. Second is proximate causation, which means that the harm is an expected result of the doctor's negligence.[37] Noting that causation is proved through experts 'or a similar state law standard'.[38]

For example, in the Bramlett v. Charter case, a psychiatrist moved a patient with anxiety to a less stringent observation, which resulted in the latter's suicide. The patient's widow proved that if it were not for the psychiatrist's decision, her husband would have been alive. She also proved that suicide is an expected result of not suitably observing a patient with such an illness.[39]

As for the Kuwaiti Medical Law, proving medical malpractice is assigned to the body of medical liability, which is a governmental institution that encompasses experts who determine whether the

35 Price II, Gerke and Cohen, Ibid; See also, Sara Gerke, Ibid.

36 Ibid.

37 Tort Law: The Rules of Medical Malpractice' (Lawshelf, 21 October 2020) <www.youtube.com/watch?v=4hvGIETLfkM&t=311s> accessed 6 July 2024.

38 Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 Health Matrix: The Journal of Law-Medicine 65, 100.

39 'Tort Law: The Rules of Medical Malpractice' (Lawshelf, 21 October 2020) <www.youtube.com/watch?v=4hvGIETLfkM&t=311s> accessed 6 July 2024 (citing Bramlette v Charter Med-Columbia 302 SC 68, 393 SE 2d 914 (1990)).

doctor's action constitutes medical malpractice from a technical dimension.[40]

Some believe that proving causation will be more complicated. As attributing the liability of the fault to either the doctor or AI becomes a difficult matter for the jury, expert testimony will be needed.[41] However, the researcher disagrees with the alleged complexity, where it may be inappropriate to compare the human doctor and the medical AI in terms of causing harm when the only qualified defendant in a medical malpractice case is the human doctor, and the factors of such a case apply only to him. Since then, the research argues that the philosophy behind its adoption of using AI as a standard of care was to allow doctors to avoid AI errors. Therefore, for example, causation may be proved by demonstrating that not using AI or adopting its wrong output by the doctor was the reason for the injury, after proving that plaintiffs may sue AI makers under product liability grounds.

1.1.3. Damages

In American law, Damages are divided into (3) categories: 'compensatory damages for economic loss, non-economic damages for pain and suffering, and punitive damages'.[42]

Damages, according to Kuwaiti law, are divided into 2 types: physical, and moral.[43] The Kuwaiti law differs from American law in that it does not impose punitive damages. Noting that the amount of punitive damages exceeds the value of harm, where the goal of punitive damages is deterrence and not remedy.[44]

However, AI may open the door to unusual damages; for example, AI-enabled electronic health records can predict patients who may die soon. This was proven in a study that involved cancer patients. Therefore, overlooking the end-of-life discussions that should take place between doctors and such patients may lead to damage.[45]

1.1.4. Learned Intermediary Doctrine

Under normal circumstances, manufacturers must warn consumers about the product's possible dangers when in use. Notwithstanding, in medical devices, which may include some AIs, the manufacturer's duty is to warn the doctor about such dangers and not the patient, where the latter

40 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health Facilities, art 36-37 and 39 <https://www.amr.gov.kw/ar/law70-2020.php> accessed 21 September 2024; See also Kuwait court of cassation judgment, session 6/11/2022, challenge no 498/2016 civil <https://laalaws.com/KTash/kwtAhkamTameezBySub> accessed 21 September 2024.

41 Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 Health Matrix: The Journal of Law-Medicine 65, 101.

42 'Tort Law: The Rules of Medical Malpractice' (Lawshelf, 21 October 2020) <www.youtube.com/watch?v=4hvGIETLfkM&t=311s> accessed 6 July 2024.

43 Abdul Rasul Abdul Reda and Jamal Alnakkas, *The concise in the General Theory of Obligations: The First Book Sources of Obligation and Proof* (4th ed., House of Books Institution 2014-2015) 240-241.

44 Ghanam Mohammed Ghanam, 'Civil Financial Penalties towards the Penetration of the Idea of Punishment in Civil Law' (2022) 12(80) The Journal of Economic and Legal Research 3, 10.

45 Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 Health Matrix: The Journal of Law-Medicine 65, 101-102.

becomes a learned intermediary. [46] Therefore, the duty of warning patients about the device dangers shifts to the doctors.[47]

The doctrine is accepted by plenty of American courts. Nonetheless, the doctrine has two exceptions from application. The first is when the manufacturer markets the product directly to the consumer. The second is when the doctor's role is considered as passive between the product and the patient.[48]

An example of the second exception manifests in the AI machine vision systems that are designed to read the scan and then present the diagnostic results to the doctor. In this case, misdiagnosing may not be attributed to the doctor, as he would be excluded from liability due to his/her passive role in such a process, and manufacturers cannot benefit from the defense of the learned intermediary doctrine.[49]

In contrast, the researcher believes that there will be no passive roles for doctors when using medical AI as the EU Commission AI Act regulation proposal imposed that AI products should include 'human-machine interface tools' that help doctors oversee, monitor, and assess AI operations and outputs as they allow doctors to intervene and stop the operation of AI when needed.[50] However, the researcher is against applying such a doctrine in cases that include medical AI. As doctors should not bear the liability of the complex AI dangers, the law should protect them in such a matter and provide them with an environment where they can focus on interacting with AI suitably.

As for the Kuwaiti law, the researcher believes that the learned intermediary doctrine is unknown.

1.2. Physician's Liability under EU Proposal

The EU Commission's non-contractual civil liability rules under the Artificial Intelligence Directive proposal (AI Liability Directive), which regulates civil liability if AI is involved in causing damage, consider any legal person who uses AI as a user,[51] where it refers to the definition of the user in the AI Act regulation proposal that was mentioned earlier in this research.[52] Therefore, the research will examine the doctor's liability according to that.

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46 Scott J Schweikart, 'Who Will Be Liable for Medical Malpractice in the Future? How the Use of Artificial Intelligence in Medicine Will Shape Medical Tort Law' (2020) 22(2) The Minnesota Journal of Law, Science & Technology 1, 15.

47 Jason Husgen, 'Product Liability Suits Involving Drug or Device Manufactures and Physicians: The Learned Intermediary Doctrine and the Physician's Duty to Warn' (2014) 111 The Journal of Missouri State Medical Association 478, 479.

48 Zach Harned, Matthew P Lungren and Pranav Rajpurkar, 'Machine Vision, Medical AI, and Malpractice' [2019] Harvard Journal of Law & Technology Digest 2, 9.

49 Ibid.

50 Commission, 'proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence and Amending Certain Union Legislative Acts (Artificial Intelligence Act)' COM(2021) 206 final, art 14.

51 Commission, 'Proposal for a Directive of the European Parliament and of the Council on Adapting Non-Contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive)' COM(2022) 496 final, art 2(4).

52 Commission, 'proposal for a Regulation of the European Parliament and of the Council Laying Down Harmonised Rules on Artificial Intelligence and Amending Certain Union Legislative Acts (Artificial Intelligence Act)' COM(2021) 206 final, art 3(4).

Under this proposal, the causal link between the user's fault and the damage caused by an AI output or the abstention of AI to provide the output is presumed by the court through three major elements combined. First, the user's deviation from a duty of care that is stated at a union or national level, where this is presumed by either that the defendant did not preserve or disclose evidence related to the suspected AI according to the court's order or through the claimant's clarification.[53] However, suppose the defendant is a user of a high-risk AI who is governed by the AI Act obligations in Chapters 2 and 3. In that case, the plaintiff should prove the defendant's deviation from duty of care through the following elements:

a. Not using or monitoring the AI system upon the given directions, or did not interfere to suspend the AI when necessary 'under [Article 29 of the AI Act]; or'

b. '[E]xposed the AI system to input data' that is irrelevant to the AI system's purpose 'pursuant to [Article 29 (3) of the Act]'.[54]

Second, the impact of the user's fault 'reasonably likely based on the circumstances of the case' on the AI output or the abstention of AI to provide the output. Third, claimant's clarification that the damage was caused by the impacted AI output or the AI's failure to provide the output.[55]

According to the above, the duty of care that the doctor is obligated to have is the one that is assigned to the AI user and not the medical standard of care. Since the latter is excluded according to the rule of lex specialis.[56] Noting that such a standard of care does not exist in the Kuwaiti and American legislations.

The researcher believes it is better to impose rules when dealing with AI, such as applying the adopted standard of care for the AI user in the non-contractual civil liability rules to the artificial intelligence proposal. However, this research argues that the proposal should have noticed that AI would probably produce inappropriate outputs despite applying all the requirements. This previously prompted the researcher to adopt the medical standard of using AI, as the reasonableness of following its recommendations is left to the court. Noting that the AI Liability Act proposal strongly relies on the AI Act proposal, which lays down the requirements for high-risk AI systems to reduce risks and not end them. Therefore, the researcher thinks it may be suitable to encourage doctors to adopt two standards of care: the medical standard of care that this research adopts and the AI user standard of care.

2. Hospitals' Liability with the Incorporation of AI

Under this topic, the research will address two main headings. The first is vicarious liability, and the

53 Commission, 'Proposal for a Directive of the European Parliament and of the Council on Adapting Non-Contractual Civil Liability Rules to Artificial Intelligence (AI Liability Directive)' COM(2022) 496 final, art 4(1) (a).

54 Ibid, art. 4(3) (a-b).

55 Ibid, art. 4(1) (b-c).

56 Ibid, art. 1.

second is direct liability of medical facilities.

2.1 Vicarious Liability

In American law, the theory of vicarious liability means that one person is liable for another person's act.[57] Under the doctrine of respondeat superior, the employer is held liable for the employee's negligent act. However, the act of the latter should fall within the scope of employment, which means that the act was committed during the permitted time and zone, the employee was partially or fully motivated to perform their work, and the committed conduct relates to the reason for hiring.[58] Noting that the Minnesota Supreme Court stated that the hospital's control of the employed physicians' conduct is a condition to apply vicarious liability under the doctrine of respondeat superior.[59] Similarly, the Kuwaiti law allows holding the employer liable on behalf of the employee who caused damage, so long as the latter's act occurred during or because of his work.[60]

An example of a hospital's vicarious liability, that involves AI, is when a negligent doctor wrongly interprets the output of a sepsis prediction AI system.[61]

However, if the doctor was not an employee but an independent contractor, alternatively, the doctrine of apparent authority becomes applicable, as it applies when the principal demonstrates that a certain person has the power to act on his behalf, which leads the third party to believe in such power reasonably. Therefore, a hospital may be liable in a case where an independent contractor causes harm to a patient through using AI.[62] In contrast, Kuwaiti law differs from American law in terms of this point, where vicarious liability applies to the principal regardless of whether the other person is a contractor or an employee.[63]

It is worth noting that there is an opinion arguing that the damage caused by AI itself may shield hospitals from being vicariously liable. This is achieved when courts consider AI systems to be completely independent or subject to the control of their maker. In this case, there will be no room to hold hospitals vicariously liable due to the lack of the principal's control. Notwithstanding, it is

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57 J W Neyers, 'A Theory of Vicarious Liability' (2005) 43 Alberta Law Review 287, 289.

58 Benedict See, 'Paging Doctor Robot: Medical Artificial Intelligence, Tort Liability, and Why Personhood May Be the Answer' (2021) 87 Brooklyn Law Review 417, 428.

59 W Nicholson Price, Sara Gerke and I Glenn Cohen, 'Liability for Use of Artificial Intelligence in Medicine' [2022] Law & Economics Working Papers 1, 8.

60 Decree-Law no 67 of 1980 Promulgating Civil Law, article 240 (1) <https://2h.ae/vGrB> accessed 21 September 21, 2024.

61 George Maliha and others, 'Artificial Intelligence and Liability in Medicine: Balancing Safety and Innovation' (2021) 99 The Milbank Quarterly 629, 633.

62 W Nicholson Price, Sara Gerke and I Glenn Cohen, 'Liability for Use of Artificial Intelligence in Medicine' [2022] Law & Economics Working Papers 1, 8-9; See also Samuel D Hodge Jr, 'The Medical and Legal Implications of Artificial Intelligence in Healthcare - An Area of Unsettled Law' (2022) XXVIII Richmond journal of law & technology 405, 459-461.

63 Ibrahim Al-desouqi Abu Al-layl, *Civil Liability and Unjust Enrichment: A Study of the Non-Voluntary Sources of Obligation According to the Kuwaiti Civil Law* (2nd edition, house of books 1998) 150-151.

unknown whether the apparent authority theory would apply to this case, noting that its application does not require the control factor.[64]

Given this, the researcher believes that the past hypothesis considered AI an uncontrolled employee who committed a wrongful act. Noting that to be considered as an employee or an independent contractor, AI must first possess a legal personality. The EU parliament discussed such a matter and concluded that there is no need to grant legal personality to AI.[65] Therefore, this hypothesis is unlikely to happen. However, what could prevent hospitals' vicarious liability is altering the medical standard of care to adopting AI, where physicians will never act wrongly by adopting AI; thus, hospitals won't be liable for that.

2.2 Direct Liability

Hospitals' direct liability means that the hospital administration becomes directly liable due to its negligence regarding doctors' efficiency and patient care. The concept of direct liability obligates hospitals to have a direct duty of care in terms of medical judgment,[66] noting that such a concept has various categories that increase and decrease depending on the state.[67] This leads us to the first opinion which believes that hospitals are governed by two main direct liability theories regarding their decisions towards AI. The first is the negligent selection and retention, and the second is the negligent supervision.[68]

In the first theory, negligent selection and retention, the hospital must ensure the doctor's efficiency and eligibility before accepting him into its workforce, noting that this duty should be repeated every two years. In this context, the Supreme Court of Wisconsin stated that a claimant should demonstrate that the defendant hospital did not practice the level of care that a median hospital usually practices ensuring the doctor's eligibility. Therefore, a claimant may sue a hospital on the basis that it hired rather than purchased AI without reviewing its competency, contrary to what the theory requires. However, courts might not accept the idea of 'anthropomorphizing AI', which may exclude this theory's application. If the court decided to apply the theory, the problem of determining reasonable care would follow, noting that hospitals are beginning to adopt AI.[69]

The second theory, negligent supervision, presumes that hospitals must monitor doctors' decisions at the same time he/she make them daily. However, it is unlikely that courts would apply this theory to

64 W Nicholson Price, Sara Gerke and I Glenn Cohen, 'Liability for Use of Artificial Intelligence in Medicine' [2022] Law & Economics Working Papers 1,9; See also Samuel D Hodge Jr, 'The Medical and Legal Implications of Artificial Intelligence in Healthcare - An Area of Unsettled Law' (2022) XXVIII Richmond journal of law & technology 405, 461.

65 Vagelis Papakonstantinou and Paul de Hert, 'Refusing to Award Legal Personality to AI: Why the European Parliament got it Wrong' (AI-Regulation, 26 November 2020) <https://ai-regulation.com/wp-content/uploads/2020/11/Refusing-to-award-legal-personality-to-AI-Why-the-European-Parliament-got-it-wrong.pdf> accessed 9 July 2024.

66 Julie Dickinson, 'Direct Hospital Liability As A Legal Path to Improve Safety?' (2024) 27 Journal of Health Care and Policy 279, 287.

67 Ibid 288.

68 W Nicholson Price, Sara Gerke and I Glenn Cohen, 'Liability for Use of Artificial Intelligence in Medicine' [2022] Law & Economics Working Papers 1, 10.

69 Ibid.

each AI output or to doctors' decisions that are made accordingly. It is more suitable to apply such a theory to cases that entail gross negligence but not normal negligence, where this would help impose the appropriate obligations on hospitals and would not prevent them from adopting AI.[70]

The researcher believes that the application of both theories essentially revolves around hospital decisions that relate to employees or medical staff. It is unlikely that they will be applied to hospitals for decisions related to the adoption of AI, given that AI does not possess legal personality, as mentioned previously in this research.

However, the researcher agrees with the second, third, and fourth following opinions. The second opinion states that once using AI becomes the standard of care, healthcare facilities may expose themselves to liability if AI is unavailable. Even with this, some AI scholars believe that the extremely high cost of AI would constitute an obstacle for hospitals to provide AI, and in this case, courts might not impose such a duty on hospitals. Others argue that the high-cost obstacle can be solved when using medical AI 'through the cloud as a decentralized service'.[71]

According to the hospital's duty to provide suitable equipment and facilities,[72] the third opinion holds that medical facilities may be held liable when they do not provide care and maintenance of AI.[73] For example, it was claimed in one case that the hospital did not exercise the required maintenance and care for the Mako total knee robot.[74]

In addition, the researcher believes that a fourth opinion was found in the case of Payas v. Adventist Health System/Sunbelt Inc, where the court found that not only the unsuccessful maintenance of the surgeon robot but also the failure to operate it and not teaching the doctors about the appropriate use of it may hold the hospital liable.[75]

In the Kuwaiti Medical Law, the legislator stipulated a special provision in terms of providing healthcare through AI, stating that it is permissible to use AI as per the requirements and controls issued by the health ministry.[76] The researcher believes that such a provision may not only constitute an

70 Ibid 11.

71 Iria Giuffrida and Taylor Treece, 'Keeping AI Under Observation: Anticipated Impacts on Physicians' Standard of Care' (2020) 22 Tulane Journal of Technology & Intellectual Property 112, 117-118.

72 Samuel D Hodge Jr, 'The Medical and Legal Implications of Artificial Intelligence in Healthcare - An Area of Unsettled Law' (2022) XXVIII Richmond journal of law & technology 405,458; See also Hannah R Sullivan and Scott J Schweikart, 'Are Current Tort Liability Doctrines Adequate for Addressing Injury Caused by AI?' (2019) 21 American Medical Association Journal of Ethics 160, 162.

73 Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 Health Matrix: The Journal of Law-Medicine 65,102; See also Samuel D Hodge Jr, 'The Medical and Legal Implications of Artificial Intelligence in Healthcare - An Area of Unsettled Law' (2022) XXVIII Richmond journal of law & technology 405, 457-458.

74 Frank Griffin, 'Artificial Intelligence and Liability in Health Care' (2021) 31 Health Matrix: The Journal of Law-Medicine 65, 102.

75 Samuel D Hodge Jr, 'The Medical and Legal Implications of Artificial Intelligence in Healthcare - An Area of Unsettled Law' (2022) XXVIII Richmond journal of law & technology 405,457-458 (citing Payas v Adventist Health Sys/Sunbelt Inc 238 So 3d 887, 893 (Fla Dist Ct App 2018).

76 Law no 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of the Patient and Health

obstacle to applying hospitals' direct liability if they refrain from providing AI, but it may also prevent adopting a new standard of care, like using AI. Since the text is permissible, hospitals may or may not use AI. Moreover, although the researcher could not access the relevant requirements and controls issued by the ministry, it is important to include other hospital obligations, like training doctors on the use of AI or exercising maintenance on it.

Conclusion

This research has addressed one of the important and relatively new topics. AI has become an indispensable technology due to its results, which have contributed to the advancement of the medical field. However, AI is not risk-free, as shown in this research, and this emphasizes the importance of the human physicians' role, which has always been the backbone of the medical field. Therefore, AI and human physicians are complementary to each other, and for the best results, the interaction between them is needed. However, doctors may use AI incorrectly, and this would expose them to legal action; hence, applying suitable rules becomes an essential requirement given the complexity of artificial intelligence. This prompted scholars to request changing the medical standard of care by providing some theories such as (adopting AI, using AI, and following either AI or the traditional standard of care), noting that one opinion preserved the idea of applying the traditional standard of care, and this is what the current Kuwaiti and American legislation agrees with, where doctors must apply the traditional standard of care, which does not include AI, to shield themselves from liability. As for Vicarious liability in Kuwaiti and American legislations, it would most probably apply to hospitals due to the doctors' wrongful use of AI. However, wrongful AI outputs themselves may not cause hospitals to be vicariously liable, noting that theories in American legislation, such as respondeat superior or apparent authority, require human physicians' mistakes as a condition to apply, and that does not include the wrongful results of AI because it is not an employee and does not possess the legal personality. Similarly, theories in American legislation, such as negligent selection and retention and negligent supervision, relate to hospital decisions on employees; therefore, they may not apply to hospitals' decisions on whether or not to adopt AI. However, hospitals may be found directly liable when not providing and maintaining AI and when not preparing doctors for the use of AI. On the contrary, the EU has chosen a different path in determining the liability of using AI, where they focused on the characteristics of AI, which led them to adopt a special standard for its users. Despite all that has been said, the researcher believes that to reach suitable rules considering medical liability for the use of AI, it is important that physicians have two standards of care in the EU, Kuwaiti, and American legislation. The first is the medical standard that obligates the use of AI, and the second is the AI user standard. It is also important for Kuwaiti and American legislators to issue legislation similar to the model of the EU AI Act regulation proposal that generally regulates AI, which helps provide safe AI systems, including medical AI. In addition, they need to issue legislation similar to the EU AI Liability directive proposal, which helps extract AI user liability, noting that both legislations strongly relate. In

Facilities, art 24 <https://www.amr.gov.kw/ar/law70-2020.php> accessed 21 September 2024.

addition, the EU AI liability directive proposal needs to indicate the special nature of standards of care when stipulating the AI user standard of care, such as the medical standard of care using AI. Moreover, the researcher should not forget to mention that American law needs to exclude the learned intermediary doctrine in AI products, which may backfire on doctors and make them bear complex dangers that they did not cause, as the Kuwaiti Medical Law needs to exclude the permissible text regarding using AI and replace it with an obligatory one since keeping the permissible text contradicts the necessity of AI existence in hospitals and the idea of adopting its use as the standard of care, as it may shield hospitals from liability in case of not providing AI.

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