Review

Liability issues for the use of artificial intelligence in health care in Canada: AI and medical decision-making

Mélanie Bourassa Forcier,[1] Lara Khoury, AdE,[2] Nathalie Vézina, AdE[1]

1. Faculty of Law, University of Sherbrooke, Sherbrooke, Quebec, Canada

2. Faculty of Law, McGill University, Montreal, Quebec, Canada

Abstract

This paper explores Canadian liability concerns flowing from the integration of artificial intelligence (AI) as a tool assisting physicians in their medical decision-making. It argues that the current Canadian legal framework is sufficient, in most cases, to allow developers and users of AI technology to assess each stakeholder's responsibility should the technology cause harm.

I believe this artificial intelligence is going to be our partner. If we misuse it, it will be a risk. If we use it right, it can be our partner.

Masayoshi Son, Founder of SoftBank

Introduction

Artificial intelligence (AI) is gaining traction in a variety of industries, including the financial, legal, and health care (HC) sectors. Within HC delivery, AI offers a plethora of benefits. In particular, it helps HC professionals in making decisions in a more timely fashion and even in performing their work. AI technologies are increasingly being developed as tools to assist physicians in diagnosing diseases and identifying appropriate treatments for their patients' condition. For instance, using AI may allow a physician to assess whether his or her patient will respond to chemotherapy. Imaging, combined with deep learning, may also speed up the diagnosis of some cancers, such as those of the lung and skin. AI apps are also increasingly appealing to clinical care users as it has been demonstrated that they may decrease human fatalities and hospitalizations due to human error[1]. The integration of AI in HC attracts attention not only due to its potential to improve the quality and efficiency of HC in Canada in terms of hospitalization and fatality rates, but also because it can significantly reduce labour costs[2,3].

Nonetheless, despite its potential, the integration of AI in HC is still limited in Canada. There is reluctance to embrace AI technologies, particularly within the medical community, due to uncertainties regarding the potential liability attached to the use of AI. The ongoing legal dispute in Great Britain over investment losses allegedly caused by AI is one of the first lawsuits in the field[4]. As case law evolves, more light will be shed on the risks of developing and using such technologies. For now, however, legal uncertainty seems to have a chilling effect on the further integration of AI in HC. The purpose of this paper is to provide the medical community with a better understanding of the liability risks surrounding the integration of AI in medical decision-making.

AI as a tool for medical decision-making refers to technologies that help physicians in their decision-making process, through the use of apps or other devices. For instance, IBM's supercomputer, "Watson", can scan genetic data from the tumours of patients with brain cancer in only a few minutes[5]. Researchers in Canada are currently developing AI technology aimed at informing surgeons of imminent cardiac arrests while patients are undergoing surgery. If successfully launched, this new technology will enable physicians to react promptly in order to prevent the cardiac arrest and avoid its adverse side effects, such as cognitive impairment[6]. Other AI tools assist physicians in identifying the most suitable drug for their patient according to that patient's genetic profile[7]. The margin of error associated with AI-assisted HC decision-making is seen as relatively low compared to the risk associated with decisions made by humans alone[2]. And while AI-assisted decision-making still carries a risk of misdiagnosis, so does the failure to use a technology that is increasingly available to HC professionals.

Who Should Be Held Liable for a Mistaken Diagnosis Made While Using AI as a Tool for Medical Decisions? The Hypothetical Case of Ms. Lafrance

Below is a fictional case highlighting the liability issues that may arise when misdiagnosis occurs while using AI as a decision-making tool.

Ms. Lafrance

Ms. Lafrance, aged 70, consults her physician, Dr. Knapp. It has been a few months since her last appointment and she has recently had a bad cough. Dr. Knapp orders a CT scan that shows a four-millimetre nodule in her left lung. Let us assume that the accepted

medical standard of care for nodules under five millimetres is to order follow-up scans every three months until the nodule reaches ten millimetres. In light of the costs associated with this protocol, and his duty to control HC expenditures, Dr. Knapp decides to rely on a new AI technology that combines deep learning and radiomics. Deep learning is a subset of AI . As for radiomics, this technology allows mineable high-dimensional data to be extracted from clinical images[8]. This new technology allows Dr. Knapp to inform Ms. Lafrance immediately after the first scan that she does not have cancer. Six months later, Ms. Lafrance goes back to her doctor as she is not feeling well. Dr. Knapp orders another CT scan which shows that the nodule has now reached fifteen millimetres. A subsequent biopsy reveals that Ms. Lafrance has a malignant tumour. By the time treatment is initiated, her prognosis has become bleak.

Ms. Lafrance v. Dr. Knapp

In the common law provinces—all Canadian provinces except Quebec—Ms. Lafrance would have to first demonstrate a physician-patient relationship between herself and Dr. Knapp in order to establish that her physician owes her a duty of care under the tort of negligence. A doctor-patient relationship giving rise to a common law duty of care normally arises as soon as a physician attends to a patient. Therefore, it is clear that Dr Knapp owes Ms. Lafrance such a duty as he is her regular physician. She would then have to prove a breach of this duty, in that the physician failed to meet the required medical standard of care and was therefore negligent.

Meanwhile, in Quebec, where civil law governs liability principles, Ms. Lafrance would typically have to show that her physician failed in his contractual obligation of means, in that he did not use reasonable means to establish a proper diagnosis, thereby committing a fault (art. 1458)[9]. If the misdiagnosis does not result from the physician's lack of prudence and diligence in providing medical services, but results instead from a malfunctioning of the AI device used to provide such services, the physician is bound by the same warranties as the seller of that device (art. 2103)[9].

Whether Ms. Lafrance attempts to demonstrate a departure from the common law standard of care or a breach of the civil law obligation of means, her burden of proof is similar. She must show that Dr. Knapp did not exercise the level of skill, diligence, and judgment that would be expected from a reasonable physician in the same circumstances, in accordance with accepted medical practice[10-11]. In both legal traditions, it is common for expert opinion to be used to establish the accepted standard of medical practice in the circumstances.

Assuming that standard consists in the above-mentioned protocol of ordering a scan every three months for a nodule under five millimetres until it reaches ten millimetres, it is arguable that, by delegating his duty to diagnose to the AI technology rather than following this accepted standard, Dr. Knapp was negligent (in common law terms) or did not comply with his obligation of means (in civil law terms). Indeed, it could be asserted that he should only have used the AI as a tool to assist him in his decision-making process, just as he would ask a colleague for advice[12,13]. Following this line of argument, reliance on these new technologies could be treated similarly to a pharmacist's use of software to flag incompatible drug treatments in a patient's file. It has long been recognized in Quebec that pharmacists can be held liable if they rely solely on the software and do not fulfill their duty to duly read the patient's file[14].

In both legal systems, Ms. Lafrance would also need to prove that the physician's fault or negligence caused her alleged injury. In other words, proving Dr. Knapp's negligence is insufficient. The common law requires the patient to show that the type of injury she sustained resulted, in fact, from the physician's negligence, and was reasonably foreseeable[4,15]. The civil law requires the patient to prove that her injury was the direct and immediate result of the fault (art. 1607)[9]. In order to fulfill her burden in both legal traditions, Ms. Lafrance must demonstrate that it is more likely than not (balance of probabilities standard) that a proper diagnosis would have prevented her injury. For instance, she would have to prove that a proper diagnosis and prompter treatment would have led to a favourable prognosis (e.g., a greater than 50% chance of survival). While the demonstration of a causal relationship between the misdiagnosis and the ensuing injury will be fairly straightforward in a number of cases, it may sometimes be more difficult, as it is not always possible to assess whether the patient's condition was treatable, and the outcome likely to be good, at the time of the misdiagnosis. This is especially so in cancer cases where the stage of the patient's cancer at the time of the misdiagnosis may be unknown.

The integration of AI in HC has the potential of involving a new party in liability claims, namely the AI company. Could the AI company be held liable toward Dr. Knapp for contractual breach or to Ms. Lafrance for the injury she suffered? These two questions raise distinct considerations and shall therefore be analyzed separately.

Dr. Knapp (or the hospital) v. the AI Company

If held liable to his patient, can Dr. Knapp (or the

hospital, should it be the purchaser of the technology) sue the AI company ? In answering this question, one needs to take into consideration the terms of the contract between Dr. Knapp (or the hospital) and the AI company. The company's responsibility toward its clients is contingent on the terms of the contract and, in particular, on the scope of the obligations outlined therein.

Most contracts are likely to provide a warranty against a technology's defects, either through the terms of the contract itself or through the legal provisions governing the contract. If no such conventional or legal warranty is applicable, finding a breach of contract is likely to be more complex. The physician (or the hospital) will have to prove that the technology was defective and that this defect was in breach of a contractual undertaking.

Regardless of the existence of a warranty, the misdiagnosis in our example is probably not due to a defect in the technology, but is instead the result of a foreseeable risk of misdiagnosis due to the inherent limitations of such technology. These limitations do not, in and of themselves, qualify as a defect. However low their rate of error may be, no AI technology can ever be 100% reliable—just as no human can ever be. One could argue that the risk of misdiagnosis is "reasonable" given that the AI is meant "to be more accurate on average than a physician" and that such accuracy is intended to improve a physician's knowledge, not to replace it[2]. Therefore, any liability on the part of the AI company would require proof of an actual defect, such as a malfunction which distorts or omits essential data, or proof of a failure on the part of the AI company to warn users about the inherent limitations of the technology.

Ms. Lafrance v. the AI company

The absence of a contract between Ms. Lafrance and the AI company does not prevent her from claiming damages against the company under the rules of extra-contractual liability (Quebec) or the tort of negligence (common law provinces). The common law tort requires that the patient prove negligence on the part of the company. The product safety rules in civil law are more favourable to her. The AI company's liability can flow from a mere safety defect (art. 1468)[9], i.e., where the technology does not afford "the safety which a person is normally entitled to expect" (art. 1469)[9]. This regime imposes strict liability (i.e., "no-fault" liability) on the manufacturer, the provider, and some of the intermediaries in the chain of distribution, which eliminates the need to demonstrate negligence in the manufacturing process.

In fact, the civil law concept of safety defect is highly dependent , on users' expectations regarding the technology[16]. As AI decision-making tools becomes more widespread and understood, their low risk of inaccuracy will necessarily increase patients' expectations as to the reliability of the AI tools. However, to the extent that the technology cannot be entirely accurate, a manufacturer would then benefit from a defense based on normal expectations regarding the product's safety, rather than the actual expectations on the part of the patients – provided that the manufacturer properly disclosed the inherent risks and dangers that the technology involves and the means to avoid them. This information would normally be disclosed to the competent intermediary, the HC professional, who uses the AI technology and is in a better position to lower the patients' expectations to a realistic level as to the technology's accuracy. Therefore, it is unlikely that Ms. Lafrance would be successful, unless she can prove that the tool was actually defective in its functioning (in civil law terms) or negligently manufactured (according to common law rules), causing it to mislead her doctor, which would generally be rare. The same observation goes for the application of the warranty against latent defects: a mere demonstration of the inherent limitations of the technology in terms of its reliability as a tool for assisting HC professionals would be insufficient to bring the warranty into play, without evidence of actual malfunctioning of the technology.

Can a manufacturer's general warning as to the imperfect nature of a tool's reliability, in and of itself, actually lower the user's expectations in a legally relevant sense, thereby allowing the manufacturer to avoid strict liability? This is doubtful, in that expectations regarding a product's safety are judged according to an objective standard based on a normal user's reasonable expectations given the type of product, and not on the subjective expectations of a specific user. A general warning to users that the tool may not be entirely reliable may be intended as a waiver of liability, but such waivers are subject to important restrictions, notably where the defendant is a manufacturer or professional seller (art. 1732–1733)[9,17] or where the defect resulted in bodily or moral injury (art. 1474)[9].

Another question is whether the patient is required to choose between claiming against the treating physician or the AI company. If the conditions for liability are met, the victim may have a successful claim against both of them and seek conclusions for joint and several (common law) or solidary (civil law) liability. Going back to the hypothetical case of Ms. Lafrance, had the damage been caused both by Dr. Knapp's failure to follow the usual standards for a treating physician and by a defect of the decision-making AI tool, both the physician and the company could be held liable. If she chooses to sue only one party, that defendant could

bring an action in warranty against the other party to claim its contributive part in the damage suffered by Ms. Lafrance.

Can a Hospital or Physician be Held Liable for an Omission to Use AI as a Tool for Medical Decisions? The Obligation or Duty to Use AI Technology

The preceding analysis addresses potential liability issues flowing from reliance on AI technology in making medical decisions. However, it is equally conceivable that an omission to use such technology could lead to malpractice claims. This is especially so if AI offers physicians the opportunity to considerably reduce death and hospitalization rates attributable to human error.

In 2015, the University Health Network (UHN), a research organization, released an analysis of the costs associated with medical errors. According to UHN, "in 2013, inappropriate prescriptions written to older patients cost the Canadian health care system $419 million, […] and the costs to Canadians for preventable adverse events in acute care [amounted] to over $396 million every year"[3]. Moreover, "research suggests that about 70,000 patients a year experience preventable, serious injury as a result of treatments […]. More shocking, a landmark study published a decade ago estimated that as many as 23,000 Canadian adults die annually because of preventable 'adverse events' in acute-care hospitals"[18]. These statistics show the grim reality of errors in HC systems, but also lay bare the opportunity for positive changes through the use of AI.

Conclusion

Our analysis demonstrates that the current legal framework in Canada allows for clear identification of the liability risks surrounding the use of AI as a medical decision-making tool. Nevertheless, until the case law confirms how the Canadian common law and civil law frameworks regarding liability will apply to AI technology, measures seeking to reduce AI-related legal risks must be implemented in accordance with the precautionary principle. More precisely, promoters of AI technology in health care should ensure the best information possible is provided to users as to the limitations of AI tools, rather than relying on marketing strategies designed to attract users on the basis of unrealistic promises and expectations regarding the reliability of these tools. The drafting of good and detailed contracts may also help in the allocation of risks, although contractual technique alone cannot serve as a panacea because the scope of such clauses are narrowly construed by the legislator or the courts. In this unchartered territory, also in the spirit of the precautionary principle, it might be worth considering international guidelines on Good AI Design/Manufacturing Practice, similar to the Good Manufacturing Practice Guideline and the Good Clinical Practice Guideline developed by the International Council for Harmonization (ICH)[19,20].

Finally, one might wonder if, in the near future, both hospitals and doctors could have an obligation to integrate AI technology into their practice. If good medical practice evolves in such a way that the use of AI becomes the norm, a failure to take advantage of this technology, such as when reviewing test results, could eventually trigger liability if the patient can demonstrate a causal connection between the damage suffered and the omission to use the technology. To date, however, the case law suggests that a hospital's liability is likely to be limited if this omission is due to a lack of financial resources[21] .

Acknowledgements

Mélanie Bourassa Forcier worked in collaboration with Siobhan Mullan, and Dary-Anne Tourangeau, and research assistants. We wish to express our gratitude to Adam Allouba, from Dentons, for the time he has taken to review this article and provide his very helpful comments. Lara Khoury wishes to thank Pierre William Gaudry BCL/JD candidate (McGill) and Rebecca Schur BCL/JD (McGill) for their assistance. Nathalie Vézina wishes to thank Richard Silver for his assistance regarding an earlier version of the text.

References

1. Standing Senate Committee on Social Affairs, Science and Technology. Challenge ahead: Integrating Robotics, Artificial Intelligence and 3D Printing Technologies into Canada's Healthcare Systems. Ottawa (ON): Senate; 2017 October. 48p.
2. Greenberg A. Artificial intelligence in health care: Are the legal algorithms ready for the future? [Internet]. 2017 Oct 06 [cited 2020 Apr 02]. In: McGill Journal of Law and Health. McGill Journal of Law and Health . Montreal: MJLH. 2017 -. [about 2 screens]. Available from: https://mjlh.mcgill.ca/tag/dr-anastasia-greenberg/.
3. Bogoroch RM. The frightening reality of medical error [Internet]. 2016 Sep 12 [cited 2020 Apr 02]. In: Bogoroch Associates LLP. Bogoroch Associates LLP. Toronto: Bogoroch Associates LLP. 2016 - [about 4 screens]. Available from: https://www.bogoroch.com/the-frightening-reality-of-medical-error/.
4. Thompson K, Allouba A. Use of AI Algorithm Triggers Lawsuit and Countersuit [Internet]. 2019 Aug 14 [cited 2020 Apr 02]. In: Dentons Data. Dentons . Toronto: Dentons. 2019 - [about 4 screens]. Available from: http://www.dentonsdata.com/use-of-ai-algorithm-triggers-lawsuit-and-countersuit/.
5. Tsang L, Kracov DA, Mulryne J, Strom L, Perkins N, Dickinson R. The Impact of Artificial Intelligence on Medical Innovation in the European Union and United States. Intellectual Property & Technology Law Journal. 2017 August;29(8):3-11.
6. Goldenberg A. Research Project presented at the Parliamentary Health Caucus. Communication au: Artificial Intelligence and

Machine Learning: Reshaping Health Research and Innovation; 1 May 2028; Ottawa, ON.
7. Khan OF, Bebb G, Alimohamed NA. Artificial intelligence in medicine. What oncologists need to know about its potential—and its limitations. Feature [Internet]. 2017 November 4 [cited 2020 Apr 02];16(4):8-13. Available from: https://pdfs.semanticscholar.org/5379/c5f0dc6a0cd310072cfd5f2c2f1d06a0c8d8.pdf.
8. Rizzo S et al. Radiomics: the facts and the challenges of image analysis. Eur Radiol Exp. 2018 Dec.; 2:36: 1-8.
9. Civil Code of Quebec. CQLR c. CCQ-1991 (1991).
10. Lapointe v. Le Gardeur (1992), 1 SCR 382.
11. ter Neuzen v. Korn (1995), 3 SCR 674.
12. Ashok A. The impact of artificial intelligence in healthcare. 2017 Aug 24 [cited 2020 Apr 02]. In: Unfoldlabs. Medium [Internet]. San Francisco: Medium. 2017 -. [about 10 screens]. Available from: https://medium.com/@Unfoldlabs/the-impact-of-artificial-intelligence-in-healthcare-4bc657f129f5.
13. Allain JS. From Jeopardy! to jaundice: The medical liability implications of Dr. Watson and other artificial intelligence systems [Internet]. La. L. Rev.. 2013 Summer [cited 2020 Apr 02];73(4): 1049-1080. Available from: https://heinonline-org.ezproxy.usherbrooke.ca/HOL/Page?public=true&handle=hein.journals/louilr73&div=36&start_page=1049&collection=journals&set_as_cursor=0&men_tab=srchresults#.
14. Pharmaciens (Ordre professionnel des) v. Bélanger No. 30-14-01785 (2014), Dec 05 (Conseil de discipline, Ordre des pharmaciens du Québec).
15. Overseas Tankship (UK) Ltd v. Morts Dock and Engineering Co Ltd (1961), UKPC 2.
16. Holder C, Khurana V, Harrison F, Jacobs L. Robotics and law: Key legal and regulatory implications of the robotics age (Part I of II). Computer Law & Security Review. 2016 Mar; 32(3). doi:10.106/j.clsr.2016.03.001
17. ABB Inc. v. Domtar Inc. 2007, SCC 50.
18. Blackwell T. Inside Canada's secret world of medical error: 'There is a lot of lying, there's a lot of cover-up' [Internet]. Toronto: National Post; 2015 Jan 16 [updated 2017 Jul 07; cited date – 2020 Apr 02]. Available from: https://nationalpost.com/health/inside-canadas-secret-world-of-medical-errors-there-is-a-lot-of-lying-theres-a-lot-of-cover-up.
19. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Efficacy Guidelines: E6(R2) Good Clinical Practice [Internet]. Geneva (CH): ICH; 2016 Nov 10 [cited 2020 Apr 02]. Available from: https://www.ich.org/page/efficacy-guidelines#6.
20. The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. ICH harmonised Tripartite Guideline: Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients [Internet]. Geneva (CH): ICH; 2000 Nov 10 [cited 2020 Apr 02]. Available from: https://database.ich.org/sites/default/files/Q7_Guideline.pdf.
21. Kouri R, Régis C. Limits to access to care as posed by section 13 of the Act Respecting Health Services and Social Services: a true escape or a simple warning?. R. du B. 2013 Spring;72:177-211.