

VOLUME 12, NUMBER 4

Cited as (2022-23), 12 Electronic Healthcare Law Review

MAY 2023

THINKING OF USING AI IN A MEDICAL CONTEXT? KEY ISSUES TO CONSIDER¹

Alice Tseng, Principal, Graham Hood, Principal and Patrick Roszell, Principal, Smart & Biggar LLP © Smart & Biggar, Toronto





Graham Hood



Alice Tseng

Patrick Roszell

"Artificial intelligence" (AI) is a broad term that encompasses a variety of computing techniques with many different views and approaches. This article sets out a potential use case for AI in the healthcare space and outlines some key considerations that Canadian companies should be aware of before embarking on such projects.

HOW CAN AI BE USED IN THE HEALTHCARE SPACE?

An example of AI in the healthcare space would be a company creating an AI tool to detect lung cancer by building a training data set from digital images of x-rays sourced from various hospitals in Ontario. Once the AI model has been developed, radiologists can upload new x-ray images into the AI tool to get diagnostic results in near real time. The purpose of such an AI tool would be to:

- detect lung cancer;
- classify lung cancer (*i.e.*, from stages 1-4); or
- segment images (*i.e.*, draw borders around areas of interest on the image, such as tumours, to make further processing and analysis by clinicians easier).

Such an AI tool include would:

- be automated images would take seconds to be uploaded. Faster results would lead to cost savings in the long term as fewer radiologists would be required;
- be more consistent and accurate given that radiologists have error rates of between approximately 3% and 5% in image interpretations,

AI may play an important role in preventing medical errors. AI applications can process large amounts of data without being affected by radiologists' lapses in memory, fatigue, illness or other human factors;

- provide an objective output there would potentially be less bias since the training data set could be based on multiple sources (*e.g.*, multiple hospitals and healthcare professionals, not just one person); and
- generate fact-specific benefits it could result in less radiation exposure for patients. If it was very accurate, it could enable a patient to be assessed using an x-ray only and not require additional screening after the x-ray (*e.g.*, through a computerised tomography or magnetic resonance imaging scan) to be certain of diagnosis

In Canada, an AI tool to detect lung cancer would likely be used as a "secondary diagnostic tool" in the short term — that is, it would support a radiologist's decision-making process.

DATA CONSIDERATIONS

When using an AI system to solve a business problem, it will likely involve machine learning and require a training data set. The data set would be used to "train" a machine learning model that the AI system would then employ to generate results or solutions.

In the context of the example mentioned above, the input data set would consist of individual images such as x-rays and the output data would be known as "corresponding diagnoses". The x-rays might be characterised by specific features (*i.e.*, not just the image), such as the relative proportion of light and dark greys as well as shapes in an x-ray image.

That data set would be input to an algorithm to generate a model that links the characteristics of input images to one or more possible diagnoses. Later x-rays characterized by the same features could then be inputted into the model to get a predicted diagnosis. The data input from the training set is critical for the machine to do its job properly and generate useful results and solutions. The following considerations must be kept in mind when using data to train an AI model for healthcare purposes:

- personal health information legislation under current Canadian privacy laws, organizations can typically only use personal information for the purposes for which the individual consented, unless otherwise permitted;
- data ownership issues some of the imaging databases may come from Canadian hospitals that have contracts with a particular supplier of imaging machines and associated software; and
- data bias a goal of AI in healthcare is to ensure medical treatment is as objective and accurate as possible. The proposed *AI and Data Act* states that organizations which are responsible for an AI system are required to determine whether it is a "high-impact system" and, if so, must establish measures to identify, assess and mitigate the risk of harm and biased output.

LIABILITY CONSIDERATIONS

Canadian companies that wish to embark on a project involving AI in healthcare must also be aware of the following potential sources of liability:

- transparency currently, there is no law in Canada requiring transparency of when an AI system is being used, but there are proposed laws to change that;
- misdiagnosis or delayed diagnosis (*e.g.*, through poor triaging of patients); and
- prioritization of patients in a discriminatory manner.

Legal liability will be influenced by best practices and industry standards. Key questions to consider include the following:

- Was there informed consent by patients for use of the AI?
- If the use of AI is standard of care, is the standard to use AI to assist doctors with their medical diagnosis or to replace doctors? Ironically, liability

can be greater for a doctor if they maintain some discretion in the decision-making process.

• Can or should a doctor not accept an AI recommendation, including ignoring a recommendation that a patient has lung cancer and should be treated? If the use of AI in the practice of medicine becomes a standard of care, doctors could be liable if they fail to use AI.

[Alice Tseng is a Principal and Patent Agent at Smart & Biggar in Toronto. She is recognized as one of Canada's leading regulatory lawyers with more than two decades of experience adeptly counselling clients in highly regulated industries such as pharmaceutical, cannabis, food, medical devices and cosmetics. Ms. Tseng can be reached at ATseng@ smartbiggar.ca. **Graham Hood** is a Principal and Trademark Agent at Smart & Biggar in Toronto. As a highly experienced trademark lawyer, his practice spans all aspects of trademark counselling, prosecution and litigation. He helps brand owners protect, manage and monetize trademark portfolios. Mr. Hood can be reached at GHood@smartbiggar.ca.

Patrick Roszell is a Principal and Patent Agent at Smart & Biggar in Toronto. With over a decade of experience counselling clients, his practice focuses on patent prosecution and strategy, including drafting patent applications and providing patentability, infringement, and freedom to operate opinions. Mr. Roszell can be reached at PMRoszell@smartbiggar.ca.]

A version of this article was originally published in Lexology on February 8, 2023.