COLLEGE OF PHYSICIANS AND SURGEONS OF BRITISH COLUMBIA

INTERIM GUIDANCE

Ethical Principles for Artificial Intelligence in Medicine

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Interim guidance from CPSBC provides information to express or clarify CPSBC's view on a particular matter. It is intended as guidance for registrants in areas where research and current practice are evolving or changing rapidly, the implementation of processes and procedures may be premature, or it is timely to communicate CPSBC's stance on an issue before a practice standard or professional guideline is developed.

Preamble

As defined by Health Canada, artificial intelligence (AI) is a broad term for a category of algorithms and models that perform tasks and exhibit behaviours such as learning, making decisions and predictions. Machine learning (ML) is the subset of AI that allows ML training algorithms to establish ML models when applied to data, rather than models that are explicitly programmed. Reference to AI within this document encompasses ML.

Currently, Health Canada acts as the oversight body for medical devices and systems that use AI. In June 2022, the Government of Canada tabled the *Artificial Intelligence and Data Act* (AIDA) as part of Bill C-27, the *Digital Charter Implementation Act*, 2022, as one of the first national regulatory frameworks for AI. In 2023, Health Canada published *Draft guidance: Pre-market guidance for machine learning-enabled medical devices*, to provide guidance to manufacturers who are submitting a new or amendment application for Class II, III and IV machine learning-enabled medical devices (MLMD) under the regulations. Registrants must only use Health Canada approved MLMDs and when doing so, understand the device classification, the level of evidence supporting the use of the device in clinical practice and the limitations of the device.

Though Health Canada's legislation focuses on directing the development and commercialization of AI devices (including MLMD devices) in Canada, it does not regulate the application of publicly available AI-enabled tools, including large language models (LLMs) like ChatGPT and Bard AI, or AI scribes, by individual health care providers. This document seeks to fill current regulatory gaps and provide guidance for the safe and appropriate application of AI in medicine.

The impact of AI on the quality of medical care and services is rapidly evolving and because of the speed of change, there is currently limited research-based evidence to guide regulatory policy. CPSBC does not endorse any specific AI tool, including AI scribes, but will continue to monitor developments in this field and make every effort to communicate them to registrants and update its guidance as more information becomes available.

CPSBC's position

AI has demonstrated the capability to assist health care providers with multiple elements of care such as diagnosis, creating treatment plans and writing patient communications. However, AI must be used with caution to ensure patient safety and wellbeing. Registrants are expected to always act in the best interest of the patient and ensure that the use of AI in medical care meets professional standards of practice, ethical codes of conduct, and privacy obligations.

When using AI in medical care, registrants are expected to adhere to the following principles:

- **Privacy, confidentiality, and consent**: Registrants are expected to ensure that patient privacy and confidentiality is maintained when using AI. If using personal patient data, the data must be securely stored, accessed, and transmitted and the AI tool must comply with applicable privacy and security laws and regulations.

Personal patient data must not be transferred from the clinical environment at which care is provided without patient consent or where required or permitted by law. Registrants are advised to contact the Office of the Information and Privacy Commissioner (OIPC) to understand *Personal Information Protection Act* (PIPA) regulations regarding AI.

When seeking patient consent to transfer personal patient data, registrants must explain the nature of the AI being used, potential benefits and limitations, and risks associated with its use.

Many AI tools, such as ChatGPT, do not currently comply with privacy and security regulations. As such, personal patient data or identifying data must never be used; data must be de-identified such that the patient's identity cannot be reconstructed.

- **Accuracy and reliability**: Responsibility for decisions made about patient care rests principally with the registrant. Although AI is proficient in generating responses that appear to be accurate and reliable, they can be partially or completely wrong, leading to erroneous decision-making if relied upon without critical thinking. Registrants must always use critical thinking and clinical expertise when applying AI to patient care.
- **Transparency**: Registrants using AI must be transparent about the extent to which they are relying on such tools to make clinical decisions and must be able to explain to patients how these tools work and what their limitations are.
- **Interpretability**: AI tools can produce results which are difficult to interpret or replicate. When used in medicine, registrants must be capable of interpreting the clinical appropriateness of a result reached and exercising clinical judgement regarding findings.
- **Bias**: Registrants must be mindful of the inherent bias and critically analyze all AI-driven results or recommendations through an equity, diversity, and inclusion (EDI) lens. An EDI lens considers an individual's unique needs, circumstances and lived experiences and may require alternate approaches for interpreting or delivering information.
- **Monitoring and oversight**: Registrants must monitor the use of AI in patient care to ensure that it is used appropriately and effectively. This includes critically reviewing and assessing whether the AI tool is suited for its intended use and the nature of practice it is being applied to. Registrants must also ensure that there is proper oversight of the AI tool that they or their employees are using, including regular updates and maintenance.

Note: The above principles also apply to the use of AI scribes. Informed consent must be obtained from the patient, before using an AI scribe. Registrants must be aware if the software stores audio recordings and, if so, must follow the principles in the *Photographic, Video and Audio Recording of Patients* practice standard. Registrants are responsible for reviewing documentation produced by the AI scribe prior to its entry into the medical record.

Registrants are accountable for ensuring the note is a correct representation of the patient encounter. AI scribes do not replace clinical judgment for proper medical record keeping. Registrants are liable for errors made by the AI scribe.

CPSBC does not endorse any specific AI scribes.

Conclusion

AI holds great potential for optimizing resource allocation and improving health outcomes. However, this potential is accompanied by significant concern related to its misuse. Registrants are expected to use AI in a safe and responsible manner that respects patient privacy and confidentiality, promotes transparency, and meets professional standards of practice. Registrants are expected to provide medical care based on objective evidence and sound medical judgment, using AI to complement – and not replace – their own expertise.

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