RISK NOTE



Artificial Intelligence in Health Care Authority Settings

The purpose of this Risk Note is to: define Artificial Intelligence (AI), identify some of the principal risks / considerations and related risk management strategies, and, to confirm the information that HCPP will require in order to consider individual risk exposures and indemnity approval requests in a timely manner. This Risk Note is not intended as an exhaustive document concerning the subject matter as this is emergent technology that is rapidly evolving and must be evaluated on an individual risk basis.

1. What is Artificial Intelligence (AI)?

o There are many and varied definitions of Artificial Intelligence (AI), but at its core, AI refers to technology that enables machines such as computer systems to simulate human intelligence, learning, understanding, perception, reasoning, problem solving and decision making.

2. AI use in health care

- AI technology is rapidly evolving and integrating into all facets of society.
 Some of the most common types of AI use in health care are:
 - Chatbots: AI systems engaging in conversation with users
 - e.g. Navigational assistants for initial client contact / inquiries
 - Documentation: Listening / recording / transcribing:
 - e.g. AI scribes: Transcription of healthcare provider-client interactions and chart summaries
 - Clinical Care Delivery
 - e.g. Reviewing symptoms, test results etc. and suggesting diagnosis and treatment options
 - Computer Vision: AI interpreting images
 - e.g. Reviewing ultrasounds, x-rays, MRIs and other diagnostic imagery

- Client Monitoring Systems: notifications, alerts and alarms
 - e.g. Automated monitoring systems, drug dispensation

3. Risks and considerations

- o Safety Creating unintended harm as a result of AI implementation
 - Erroneous diagnosis
 - Incorrect treatment suggestions
 - Errors in image analysis
- Privacy & security
 - Cyber security and private health information breaches
- Reputational risk
 - Undermining of public trust
- Equity
 - Bias in algorithm, data and system that amplifies over time
- IP & Copyright
 - Who owns the data, who owns the IP rights, copyright
- Financial Risk
 - Losses not covered by insurance, for example:
 - Losses purely economic in nature
 - IP infringement
 - Privacy breaches
 - Losses from unapproved indemnities
- Ethical
 - Flawed or incomplete data sets resulting in bias or discrimination against a specific group
- Performance bias
- Governance / legal / regulatory
 - Compliance with privacy laws
 - e.g. FOIPPA
 - Compliance with professional standards and guidelines
 - e.g. BCCNM, CPSBC etc.
 - Compliance with HA policies and procedures
- Communication
 - Assumptions regarding how we interact or communicate
 - Informed consent vs. Notice

- Misdirection
 - Error leading to misdirection in services
- Misinformation
 - Errors in input resulting in flawed output and delays
- AI hallucinations
 - AI generated output containing incorrect or misleading information presented as fact
- Incorrect transcription by AI scribes
- Data sovereignty
 - Foreign (U.S.) information exposure
- Secondary use of data by service providers

4. Mitigation strategies

- Pre-release testing
- Learned Intermediary
 - Fully understanding the AI tool in question
- o Critical 'Human-in-the-loop' and 'Human Interaction Endpoint' reviews
- o Deidentified / anonymized data
- Use of Canadian providers / servers whenever possible
- Allowing data use to train own model only, not to train service provider system
- Implement safeguards
 - Fail-safes / alerts in case AI behaves unexpectedly
- o Appropriate risk allocation and indemnity language in related agreements
- o Resisting supplier Limitations of Liability whenever possible / reasonable
- Resiliency safety testing
- Continuous monitoring of outputs
- Transparency

- Disclose AI involvement to health care recipient
 - Obtain client consent or provide Notice where appropriate

5. What information does HCPP need to assess AI risk?

- Fulsome description of how the AI will be used
 - Including purpose, inputs and outputs
- o Where / in what contexts will it be used?
 - Type of care: virtual, telephone, emergency, urgent, palliative, mental health ...
- Flow chart / schematic visual representation of flow / process including an example application scenario
- o Confirmation of Knowledge Bank from which the AI draws information
- Details of any continuing internal oversight / review / monitoring
- Has an equivalent Canadian AI provider been considered?
- Location of information storage / servers: Canada or foreign (U.S.)
- Who is the 'Human-in-the-loop'? HCA employee or contracted party?
- o Is the AI component being integrated into existing HCA systems?
- o Is there a Generative AI component?
 - Generative AI occurs when the AI creates new information / content based on the inputs or prompts
 - What are the inputs for the Generative AI
 - What is the output being generated and which parties will it be provided to
- Is personal health information released / exchanged?
 - With whom
 - Foreign exposure
 - Client consent
 - Deidentified / anonymized data
- o Who owns the data, IP rights?
- Confirmation of undertaking of:

- Privacy Impact Assessment (PIA)
- Security Threat and Risk Assessment (STRA)
- Legal Assessment
- Ethical Assessment
- AI Risk Impact Assessment (ARIA)

*Note: The extent and detail of the above required information will be dependent on the individual AI application and related risks. It is always recommended that you consult with your internal privacy / security /IMIT support. Please contact HCPP to discuss.

6. Timeline for AI indemnity reviews and approvals

 10 business days or greater depending on the complexity involved, the completeness of the information provided, and, submission volumes

7. Additional information resources

- Government of BC; AI 101: https://digital.gov.bc.ca/policies-standards/ai/learn-the-basics/
- Government of BC; Information Security Quick Links: https://www2.gov.bc.ca/gov/content/governments/services-for-government/information-management-technology/information-security/information-security-quick-links
- HIROC; AI Risk Management in Healthcare:
 https://www.hiroc.com/resources/risk-resource-guides/artificial-intelligence-risk-management-healthcare
- Government of Canada: https://www.canada.ca/en/government/system/digital-government/digital-government-innovations/responsible-use-ai/guide-use-generative-ai.html.html
- Health Canada, Draft guidance: Pre-market guidance for machine learning-enabled medical devices. September 18, 2023:
 https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/pre-market-guidance-machine-learning-enabled-medical-devices.html.html
- World Health Organization, WHO issues first global report on Artificial Intelligence (AI) in health and six guiding principles for its design and use. June 2021: https://www.who.int/news/item/28-06-2021-who-issues-first-global-report-on-ai-in-health-and-six-guiding-principles-for-its-design-and-use.
- College of Physicians and Surgeons of Alberta, Artificial Intelligence in Generated Patient Record Content, 2023: https://cpsa.ca/wp-content/uploads/2023/08/AP Artificial-Intelligence.pdf.pdf

- Canadian Medical Protective Association. The emergence of AI in healthcare,
 2019 (revised 2023): https://www.cmpa-acpm.ca/en/advice-publications/browse-articles/2019/the-emergence-of-ai-in-healthcare.
- Personal Information Protection Act (PIPA):
 https://www.bclaws.gov.bc.ca/civix/document/id/complete/statreg/03063_0
 1.
- Office of the Chief Information Officer, BC: https://www2.gov.bc.ca/gov/content/governments/organizational-structure/ministries-organizations/central-government-agencies/office-of-the-chief-information-officer
- Practical Considerations For Using AI Scribes:
 Practical Considerations For Using AI Scribes | Doctors of BC
- Al Scribes: Answers To Frequently Asked Questions:
 CMPA AI Scribes: Answers to frequently asked questions

Published by the Health Care Protection Program: June 2025

It should be clearly understood that this document and the information contained within is not legal advice and is provided for guidance from a risk management perspective only. It is not intended as a comprehensive or exhaustive review of the subject matter and readers are advised to seek independent legal advice where appropriate. If you have any questions about the content of this Risk Note, please contact your organization's risk manager or chief risk officer to discuss.