Nurse Practitioners Association of Canada

Association des infirmières et infirmiers praticiens du Canada

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The Honourable Mark Holland, P.C., M.P.
Minister of Health
House of Commons
Ottawa, ON K1A 0A6

October 29, 2024

Subject: Regulation & Validation of Artificial Intelligence in Health Care

Minister Holland,

We are writing to you today on behalf of all medical professionals to express our profound concern that little progress has been made to protect both Canadians and Health Care Professionals from new risks associated with artificial intelligence in health care, and in tandem, little has been done to capitalize on the opportunity that could improve both the efficiency and outcomes of care.

Today, Health Canada's regulatory approval does not assess or reassess the changing state of AI products to the extent AI systems require. As compared to AI, the regulatory approval process is a point-in-time process. This does not give Health Canada the needed assurances that a product continues to be safe, and more broadly, it does not inspire needed confidence for these products to be deployed within the health care system by health professionals. The lack of a post-market certification system for AI in health care could lead to the deployment of unvalidated technologies, increasing the risk of patient harm and inefficacies. Or worse, the lack of adoption of these new technologies exacerbating all issues in health care, further disenfranchising health care professionals.

In 2017, the European Union established post-market surveillance regulations that require manufacturers to put consistent systems in place to proactively collect and review experience gained from devices they place or make available on the market in order to identify any new needs, or any necessary or corrective actions related to their products. The EU is going even further by proposing an AI Act which envisions that "once an AI system is on the market, authorities are in charge of market surveillance, users ensure human oversight and monitoring, and providers have a post-market monitoring system in place. Providers and users will also report serious incidents and malfunctioning."

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Health Canada needs to move expeditiously not only to keep pace with other international regulators, but to protect patients and health professionals and – overall – maintain confidence in our health product regulatory system. Further, without a national post-market surveillance system, provinces and territories may develop disjointed standards, leading to market fragmentation and inconsistent standards for the health care system.

As a result, we are calling on Health Canada to revise its regulatory approvals process to establish a post-market surveillance network focused on AI powered Software as Medical Devices (SaMD). This would require manufacturers to establish a Health Canada directed standard for post-market analysis, recouping any costs associated with this activity through medical device approval fees placed on manufacturers.

To implement an effective system, we are further r**ecommending the creation of an independent not-for-profit network** with broad governance and specialized capabilities to develop and implement this post-market surveillance system. This network would be responsible for feedback from vendors, health care professionals (users), and patients. We further believe that this structure needs to be led by Health Canada with a cost-neutral-to-government approach as any efforts by manufacturers directly to invest and manage a process would not relay the same confidence in the regulatory system. Further, due to the complex nature of this work, it's unlikely Health Canada – in the immediate future – will have the capabilities internally to develop and deploy a post-market surveillance system. As a result, this network needs the capabilities of those who work in the health care sector to appropriately create the structures that would assess the ongoing safety of AI health products. Given the novelty of AI, we need regulatory leadership from Health Canada to first build trust with the public and health care system by developing this approach and protect patients and staff while delivering their mission, further enabled by AI.

The Health Artificial Intelligence Network – or HAIVN for short – could involve a phased approach to validate and monitor AI technologies in health care.

We have developed an initial approach that could inform Health Canada's thinking by leveraging such network that could:

- Set safety performance baselines and define key performance metrics.
- Undertake continuous monitoring, assess performance drift, collect data, integrate user feedback, and report any adverse events.
- Define data collection efforts for longitudinal assessment and value.

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- Audit AI deployments to ensure alignment with approved protocols and standards.
- Undertake periodic ethical and privacy audits to ensure compliance.
- Produce an annual review evaluating if AI continues to meet safety and
- performance standards, with technology updates and re-certification as needed.
- Provide feedback to health care societies to guide ongoing education, guideline developments, scope of practice and changing standards.

We know that AI will play a crucial role in health care by complementing and perhaps at times replacing individual tasks or even individuals. Today, there are already hundreds of AI based solutions focused on supporting radiology. How health professionals work with AI is just as important as which solution for a patient they choose to use. The decision of what is complemented or replaced must be made according to benchmarks set by experts in the field with appropriate oversight given the complex interplay between health care professionals This cannot be done without a rigorous post-market surveillance network in place, leveraging a process like HAIVN. It is imperative that Health Canada make progress towards this objective for the sake of Canadians' confidence in our regulatory systems, to support health care professionals, maintain safety and keep up with our international regulatory peers.

Furthermore, it is vital that there is collaboration across government departments, specifically, between Health Canada and Innovation, Science and Economic Development, leveraging the intent of the Biomanufacturing & Life Sciences Strategy to align the opportunity for AI in health care with the necessary regulatory approach that both protects patients and harnesses the economic potential of artificial intelligence in health care.

We look forward to meeting with you to discuss this vital initiative.

Sincerely,

Dr. Laura Housden, PhD, MN-NP(F)
President

Dr. Stan Marchuk, DNP, MN-NP(F), FAANP
Chief Executive Officer