Regulatory challenges of AI products
A pre-market perspective

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Agenda

1. Digital Health
2. Health Canada Readiness for AI
3. Challenges
Digital Health
Digital Health Division - Objectives

Digital Health is intended to:

- Make health information more accessible
- Improve and facilitate more timely diagnosis
- Provide access to care for patients at home, at other health care facilities, and in rural and remote communities

**OBJECTIVE:** To advance and adapt regulatory approach to respond to system needs by:

- Building expert review capacity in Digital Health
- Developing a targeted review process for large volumes of digital health products (e.g., wireless medical devices, mobile medical apps, telemedicine, software as a medical device, etc.)
- Being better positioned for regulating innovative technologies (e.g. AI)
- Engaging with internal and external stakeholders to map challenges and opportunities
- Continue to be a key international player in regulating digital health devices
Newly Created Digital Health Division
Established on March 28, 2018

Priorities

- Build a workforce of reviewers (pre-market) in the digital health field, including engineers
- Develop work tools and guidance documents
- Engage with stakeholders to better understand trends and needs, and identify areas for collaboration
Current Activities

• In addition to > 250 Class III and Class IV applications…

Cybersecurity
- Guidance Finalization
- Co-chair IMDRF WG with FDA
- Collaboration with NRC and Canadian Centre for Cybersecurity
- Participation in cybersecurity standards development

AI / Machine Learning
- Training
- Scientific Advisory Committee: May 9
- Best Brains Exchange on AI
- Continue to review devices that employ machine learning

Software
- Guidance Finalization
- Continued classification on SaMD
- Continue to develop a targeted review process

3D Printing
- Guidance Finalization
- Participating in regulatory review activities on point-of-care manufacturing
- Participating in policy development on software for 3D printing
Health Canada Readiness for AI
Emergence of Machine Learning in Devices

• Health Canada is seeing the emergence of machine learning predominantly in image-based healthcare applications (e.g. diagnostic imaging/radiology)
• Several licences already issued that employ machine learning

Readiness for AI
Health Canada is well-positioned to deepen its support of AI advancements in digital health by:

1. **Building in-house Expertise**
   - Digital Health Division with a specialized training plan for AI for existing staff.

2. **Deepening Dialogue with Industry & Key External Experts**
   - HC stakeholder engagement (national/international government, industry, etc.)
   - Canadian Institutes of Health Research / Health Canada co-hosted BBE (*Best Brains Exchange*) on AI and Machine Learning in Medical Devices.
   - A *Scientific Advisory Committee on Digital Health Technologies (SAC-DHT)* has been convened. Future meeting to seek input on the regulatory approach to AI and Machine Learning (May 9, 2019)

3. **Modernizing Medical Device Software Authorizations**
   - Software as a Medical Device Guidance Document
   - Considering drafting Guidance Document for medical devices that use AI
   - The inclusion of web-based/cloud-based software products under the term “sale”.
   - The potential for new regulatory models (new classification rules, establishment oversight vs product oversight) that are more conducive to software products and their lifecycle.

4. **Continue to Review Devices that use AI to get more experience**
Regulatory Challenges with Artificial Intelligence and Machine Learning
Challenges - Introduction

• Artificial intelligence has the potential to revolutionize the health care sector, including advancements in diagnosis, disease onset prediction, prognosis, and more

• There is currently no established regulatory framework for AI in medical devices
  – Require further experience to develop manageable framework
  – Currently managing AI submissions on a case-by-case basis

• Health Canada is faced with several challenges for developing a regulatory framework to regulate AI devices
Challenges

FOSTERING INNOVATION
• How do we balance safety and effectiveness while facilitating market access to innovative products?

EFFECTIVE REGULATION
• What are the requirements for the manufacturer to get pre-market authorization?
• Do we regulate manufacturer’s process instead of the product itself?

TRAINING DATA
• How reliable and representative is the training data?
  - Representative patient population, multi-centre, disease prevalence, accuracy, data curation, simulated data, data imputation, etc.
Challenges

VERIFICATION AND VALIDATION

• How can the AI algorithms be assured to be generalizable and transferable?
• What are the best verification/validation approaches to ensure algorithms generate correct and predictable results?
• Do we recommend third-party verification/validation?

PERFORMANCE METRICS

• What are the ideal performance metrics to assess performance of an AI algorithm?
  - Receiver operator characteristics may not be accurate predictors of algorithm performance

INTEROPERABILITY

• How can we ensure that AI is integrated appropriately into the end user environment without any unintended consequences?
Challenges

CONTINUOUS/ACTIVE LEARNING

• How do we approach continuous learning algorithms where results can vary in time and between institutions?

POST-MARKET

• How can we develop an effective post-market regulation framework?
• What are the key elements for post-market?

RESPONSIBILITY

• Who is accountable for mistakes made by the software?
Challenges

STANDARDS

• No current standards for regulation of medical devices that use AI algorithms. How do we proceed without standards?

ETHICS

• Do underlying ethics concerns impact the effective regulation of medical devices in terms of safety and effectiveness?
Conclusion
Conclusion

- AI will likely become a standard technology in medical devices in the future
  - There are already some licensed products in Canada that use AI
- Health Canada is well-situated to deal with the emerging technology
- Health Canada has several planned activities to address the new technology to overcome the potential challenges
  - Engage with stakeholders
  - Develop more in-house expertise through training and experience
  - Consider developing a guidance document for industry to help communicate our expectations for pre-market submissions of devices that employ AI
  - Consider adapting our regulatory framework for the regulation of AI-enabled medical devices