

POLICY

NHMSFAP New Technology Policy (Including Artificial Intelligence)

Purpose

This policy outlines the Non-Hospital Medical and Surgical Facilities Accreditation Program's (NHMSFAP) position on the introduction of new technology (including clinically relevant artificial intelligence) in accredited facilities.

Policy

New technology

The NHMSFAP Committee has directed that prior to use in a non-hospital facility, any new technology must first

- have a Health Canada licence,
- have demonstrated clinical safety and efficacy by a health technology assessment (i.e. BC HTAP, CDA, NICE or other), and
- be granted approval by the NHMSFAP Committee following review of an application for expansion of services,

or

- be approved for use in a health authority, and
- be granted approval by the NHMSFAP Committee following review of an application for expansion of services.

Note: It is the direction of the NHMSFAP Committee that any new technology must have strong evidence of clinical safety and efficacy, in addition to a Health Canada licence. This is in part due to the limitations of the Health Canada medical device regulation process. The Canadian Medical Devices Regulations utilizes a risk-based approach to regulating products within its scope. This approach reviews evidence of safety and effectiveness proportional to the risk of the device, which is determined by applying the Classification Rules for Medical Devices.

For lower risk devices (class II), the manufacturer must make a declaration that they have the necessary evidence to support the safety and effectiveness of the medical device, but this is not necessarily reviewed by Health Canada, unless there is a specific cause to do so.

For moderate and high-risk medical devices (class III/IV), Health Canada reviews evidence of safety and effectiveness, including the clinical effectiveness of new technologies.

Note: If there is any uncertainty whether a new device or equipment would be considered new technology under NHMSFAP criteria, contact nhmsfap@cpsbc.ca for clarification.

Note: Approval to introduce new technology does not include an accredited expansion of a facility's scope of services. Once determined that a new technology is approved for use, an application for expansion of services is submitted to the NHMSFAP to initiate a focused assessment, if deemed necessary.

Artificial Intelligence

Artificial intelligence (AI) is rapidly growing in all aspects of health care. This policy includes medical devices and systems that use AI as well as tools such as ChatGPT and AI scribes. The NHMSFAP does not validate the efficacy or quality of AI tools.

To ensure the deployment of any AI tool is appropriate, it is the position of the NHMSFAP Committee that:

- Facility medical directors are responsible for acceptance testing, approval and quality assurance processes of AI tools deployed.
- Facility medical directors are responsible for ensuring applicable federal and provincial legislation are met.
- Medical staff maintain direct responsibility for clinical care.
- AI is a supplementary tool, and does not replace clinical judgement.
- Medical staff clinical judgement must be evident and must be used as the final step when there is a decision-making algorithm used.
- It is recommended that medicolegal advice is gained in each planned AI implementation.

References

College of Physicians and Surgeons of BC, Interim Guidance, Ethical Principles for Artificial Intelligence in Medicine, 2024. Retrieved from: [IG-Artificial-Intelligence-in-Medicine.pdf](#)

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Definitions

artificial intelligence (AI)	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.
NHMSFAP	Non-Hospital Medical and Surgical Facilities Accreditation Program
new technology	Any equipment, method or system not previously accredited by the accreditation programs.

Responsibility

Role	Responsibility
Medical director	<ul style="list-style-type: none"> Ensure new technology has approval for use in their facility Ensure proper acceptance testing, approval and quality assurance of AI tools Ensure appropriate federal and provincial legislation is met
NHMSFAP	<ul style="list-style-type: none"> Periodic review of policy
NHMSFAP Committee	<ul style="list-style-type: none"> Review of new technology applications prior to use in non-hospital facilities

Contact

NHMSFAP-accredited facilities must contact the NHMSFAP at nhmsfap@cpsbc.ca to request use of new technology.