INESSS
LE SAVOIR PREND FORME

APPLICATION OF THE INESSS FRAMEWORK

ASSESSING THE VALUE OF **DIGITAL TECHNOLOGIES** IN HEALTH AND SOCIAL SERVICES

JUNE 2026

Québec

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Legal deposit

Bibliothèque et Archives nationales du Québec, 2026
ISBN 978-2-555-04285-8 (PDF)

To cite this document: Institut national d'excellence en santé et en services sociaux (INESSS). *Assessing the Value of Digital Technologies in Health and Social Services: Application of the INESSS Framework.* Document written by Benoit Mailhot and Geneviève Plamondon. Québec, Qc: INESSS; 2026. 21 p.

The Institute would like to thank the members of its staff who contributed to the development of this document.

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- Réjean Junior Fortin, Senior Advisor, Project Manager – Innovation at the Direction du Développement professionnel continu of the Fédération des médecins spécialistes du Québec.
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Declaration of interests

All INESSS staff members who have contributed to this document have declared their interests and roles in full compliance with the Policy on the Prevention, Identification, Assessment and Management of Conflicts of Interest and Roles applicable to INESSS staff and contract employees.

Responsibility

The Institute takes full responsibility for the final form and content of this document. The conclusions and recommendations do not necessarily reflect the opinions of external readers or others consulted in its preparation.

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BACKGROUND

In 2021, INESSS adopted a framework for assessing the value of health and social services interventions based on its Statement of Principles and Ethical Foundations. Since then, INESSS has published a Guide to Support Value Assessment and an Innovation Lexicon. This document describes the application of the approach to value assessment for digital technologies in health and social services.

Digital technologies comprise a broad and diverse range of devices and infrastructure. These technologies can be used to meet a variety of health and social services needs. They can be defined as electronic systems, incorporating software or hardware components, that generate, store or process data, often automatically or by using artificial intelligence (AI)[1].

Assessment of the potential value of digital technologies is based on the same principles as other health and social services interventions. However, certain characteristics specific to digital technologies mean there are particularities in how these principles are applied.

Purpose and target audience

This document aims to support stakeholders by providing guidance on the issues and considerations associated with assessing the value of digital technologies in health and social services. It is intended for assessors, innovators, facilitators and decision-makers in health and social services. It may serve as a reference tool to support the various steps of assessing the value of digital technologies.

Methodology

The content of this document is based on the value assessment framework found in the INESSS *Statement of Principles and Ethical Foundations*. A summary of scientific and grey literature and consultations helped contextualize and enhance the content of this document. The methodology is presented in the Appendix.

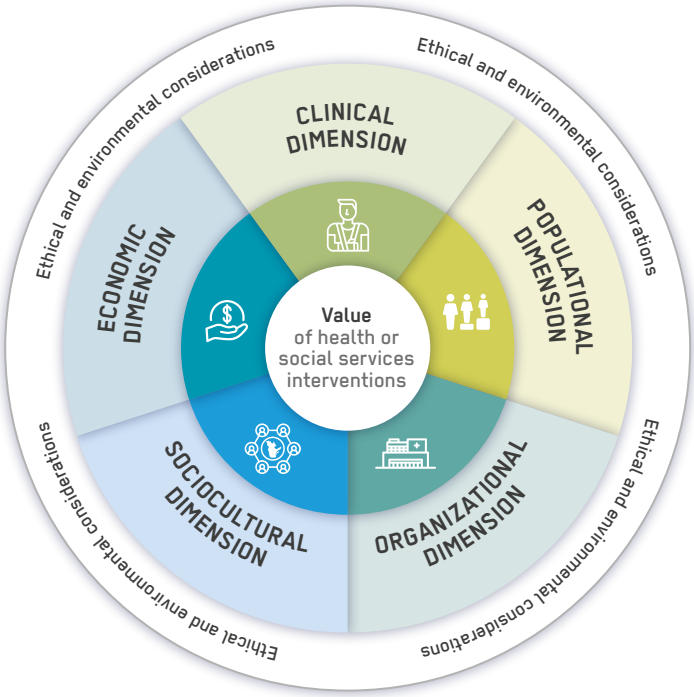
INESSS may update this document as digital technologies, evaluation processes and applicable regulatory frameworks evolve.

1. Adapted definition from In Fieri for Responsible Innovation in Health.

VALUE CRITERIA TO CONSIDER FOR DIGITAL TECHNOLOGIES

The overall assessment of the value assessment of health and social services interventions aims to take into account and balance population-based, clinical, organizational, economic, and sociocultural dimensions. Ethical issues and environmental considerations complement these dimensions in a transversal manner (Figure 1). The assessment of the value of digital technologies is aligned with the approach described in the Guide to Support Value Assessment. This general approach applies to all health and social services interventions and can be adapted based on the specific characteristics of the technologies being assessed.

Figure 1. Dimensions and cross-cutting aspects of the value assessment framework



How to use the digital technology assessment framework

This methodological document can be used as a **reference tool** throughout the various steps of INESSS's value assessment process for digital technologies.

The following tables present the **criteria associated with each value dimension**, along with examples of the data that may be gathered to support their assessment. All value criteria are, in principle, relevant for the evaluation of digital technologies. Criteria that include digital-specific considerations are marked with an "**N**" Examples of data **specific to the assessment of digital technologies** are highlighted in **bold** in the tables. The order in which the dimensions are presented, as well as the amount of information gathered for each criterion, may vary from one assessment project to another. In some cases, the data used may be limited or descriptive, while in others it may be extensive and quantitative. Finally, integrating the gathered data used allows to formulate findings, uncertainties and issues for each dimension. For more information on these stages of value assessment, please refer to the Guide to Support Value Assessment.

Ethical and environmental considerations are presented following the tables.

POPULATION DIMENSION
Providing better health and well-being for the population as a whole, with a focus on equity

Value criteria	Examples of data to be gathered (data specific to digital technologies are shown in bold)
Populational morbidity and mortality burden	• Vital prognosis and mortality • Morbidity (e.g., clinical changes, health events, disability, pain levels, physical functions, emotional impact) • Impact on quality of life and autonomy • Epidemiological prevalence and incidence data
Magnitude of unmet needs	• Description of current practices and their limits (e.g., in terms of efficacy, safety, effects on quality of life, acceptability and accessibility)
Accessibility N	• Impact of technology on the accessibility of care and services • **Factors that may influence equitable access to technology across population groups*** (e.g., levels of digital literacy, ability to use technology [digital self-efficacy], operational and technical requirements for users, or digital divide [e.g., access to a mobile device or other accessory, network coverage, availability of adequate Internet service], traditional literacy levels, geographic regions and socioeconomic status)
Ability to act on social health determinants N	• Targets factors that affect the health and well-being of a population with a view to reducing disparities related to social, economic and environmental conditions (e.g., ethnicity, religion, socioeconomic status, gender, sexual orientation, age, geographic region and disability) • **Digital determinants of health*** involving digital technology access, skills and confidence levels at the individual, interpersonal, community and societal levels

*For more information, see veille stratégique N° 14, which describes the digital determinants of health (French only).

Legend: **N** Criterion with elements specific to digital technologies.

CLINICAL DIMENSION Improving user health and well-being	
Value criteria	**Examples of data to be gathered (data specific to digital technologies are shown in bold)**
Clinical efficacy • Clinical benefits	• Nature and extent of clinical benefits (e.g., improved health status, shorter disease duration, impact on survival, clinical validity and utility)
• Utility and algorithm validity **N**	• **Software performance** (e.g., specificity, sensitivity, accuracy and precision of algorithm results, calculation speed, error rates, presence and frequency of hallucinations in AI responses, clinical consistency of results) • **Reliability** (e.g., stability of AI algorithms over time despite updates, machine learning, or changes in input data, fault-free operation). • **Robustness** (e.g., the system works in a variety of situations, maintains performance and is reproducible despite variations, ability to handle execution errors and incomplete or poorly formatted data)
Adverse effects **N**	• Harmful and unexpected reaction to a technology • **Direct risks to the user or beneficiary** (e.g., impact of device or service failure, malfunction, misuse or hardware failure) • **Risks related to software operations** (e.g., effects of incorrect information or suggestions, errors associated with false positives or false negatives, incidental discovery, secondary results)
Care and services experience • User acceptability **N**	• User attitudes toward technology (e.g., trust, perceived intrusiveness) • User adherence to technology, persistence and compliance with use. • **User perceptions** of the increased use of technologies in care and services (e.g., effect on user-professional relationship, impact on social relationships
• Usability **N**	• **Ease of appropriation and use by users** (e.g., ergonomics, user-friendliness, clear and understandable information, ease of use, learning curve, component customization, adequate IT support for users)
• User autonomy **N**	• **User's ability to use technology without third-party assistance**, ability to contribute to their own care. • **Ability to make a personal choice**, without undue pressure, regarding its use; to exercise personal judgment about the digital technology-based services, and to override a technology's recommendation.
Effects on quality of life and health as perceived by users **N**	• Effects of the intervention on physical, mental (psychological) and social well-being as perceived by the user (e.g., results from questionnaires such as EQ-5D and SF-36) • Impacts on the performance of daily living and domestic activities • Impacts on managing one's own condition (e.g., impact on the time, quantity and length of trips, on the time spent on professional follow-up and on health condition management)

Abbreviations: EQ-5D: *EuroQol-5 Dimensions*; SF-36: *Short Form-36 Health Survey.*

Legend: **N** Criterion with elements specific to digital technologies.

ORGANIZATIONAL DIMENSION
Strengthening the health and social services system

Value criteria	Examples of data to be gathered (data specific to digital technologies are shown in bold)
Alignment of intervention with health and social services system goals	• Consistency with the mission and mandate of the system or institutions concerned • Alignment with the strategic priorities of the Ministère de la Santé et des Services sociaux, Santé Québec or other relevant institutions • Technology's ability to adapt to current and future challenges (e.g., demographic changes, epidemiological changes, changing practices, human resources and service delivery challenges)
Organizational requirements and intervention impacts • Interoperability and compatibility with existing information systems **N**	• **Requirements and impacts of integrating and maintaining the use of technology** in existing systems (e.g., need to upgrade infrastructure, facilities and equipment) • **Compatibility of software and data** (e.g., format, version, quality) with existing systems and devices (e.g., compatibility with provincial assets or assets of common interest [EHR, QHR, HUB-RDV, PACS, EMR], operating system, software backward compatibility, printer, fax machine)
• Digital data management **N**	• **Data quality management** (e.g., quality assurance procedures for software operations and databases, processes allowing access to data relevant to AI software) • **Requirements and impacts of measures to adequately protect information and mitigate risks associated with data use and sharing** (e.g., mechanisms for accessing and sharing personal information and data, respect for individual consent, rules on data confidentiality or anonymization of user data) • **Digital autonomy** (e.g., local or non-local management of data and data hosting, user participation in hosting and data-sharing choices) • **Data and version traceability** (e.g., availability of information on data sources used to design the technology's algorithms and operational functions, and the version and update log)
• Professional appropriation and supervision **N**	• Ease of appropriation and learning curve, training, expertise and impact on knowledge retention • **Level of professional oversight of technology utilization** that corresponds to the level of risk associated with a technology failure (e.g., a high level of professional supervision may be necessary when the consequences of technology failure are serious or critical)
• Organization of care and services	• Impacts on resource organization (e.g., workflow, time and/or number of steps to complete a task, frequency or time dedicated to user follow-up, time dedicated to administrative tasks) • Impacts on the use of other care and services (e.g., additional tests required) • Implementation requirements (e.g., change management, human resources required for management and technological support, development of digital component contingency plans in the event of breakdowns, failures or technology errors) • Impact on care and service continuity (e.g., information sharing and collaboration between different settings and stakeholders, follow-up on users across various care settings)

Abbreviations: EMR: Electronic Medical Record; EHR: Electronic Health Record; QHR: Québec Health Record; HUB-RDV: Québec health appointment system; PACS: Picture Archiving and Communication System.

Legend: **N** Criterion with elements specific to digital technologies.

ORGANIZATIONAL DIMENSION (CONTINUED) Strengthening the health and social services system	
Value criteria	**Examples of data to be gathered (data specific to digital technologies are shown in bold)**
Experience and well-being of human resources • Acceptability by human resources **N**	• **Impacts on cognitive load** (e.g., alarms, data overload, information overload) • **Perceptions of professionals and stakeholders** regarding the use of technology in care and services (e.g., impact on relationships with users, impact on interactions between health and social service professionals) • **Attitudes of professionals toward technology** (e.g., confidence in technology, acceptance) • **Ability to explain results clearly and unambiguously** (e.g., information on how AI predictions are generated, analysis of the impact and presence of bias in algorithms and databases)
• Professional autonomy **N**	• **Ability to make a personal choice,** without undue pressure, regarding the use of digital technology, the exercise of one's own judgment, and the possibility to override a technology's recommendation

Abbreviations: EMR: Electronic Medical Record; EHR: Electronic Health Record; QHR: Québec Health Record; HUB-RDV: Québec health appointment system; PACS: Picture Archiving and Communication System

Legend: **N** Criterion with elements specific to digital technologies.

ECONOMIC DIMENSION
Optimizing use of resources for their responsible and sustainable management

Value criteria	Examples of data to be gathered (data specific to digital technologies are shown in bold)
Cost to the health and social services system, and budgetary impact • Fee model **N**	• **Pay-per-use model, temporary, single or multiple licence, open-source licence** (e.g., Québec LiLiQ open-source licences) • Hybrid or freemium model (e.g., fee-based advanced features, periodic subscription) • Contractual agreement (e.g., Software as a Service (SaaS), included or optional service or maintenance agreements, performance, early termination and risk-sharing clauses, contract term, development, testing and deployment schedule, intellectual property)
• Costs associated with acquisition, operation and maintenance **N**	• **Digital infrastructure costs** (e.g., upgrading digital infrastructure or cloud services, data hosting costs, costs associated with replacement or integration with existing systems) • **Costs associated with cybersecurity and compliance** (e.g., costs related to data protection, audits, certification and regulatory compliance) • **Costs associated with technical support and user training** (e.g., costs related to maintenance, updates and technical interruptions or incidents [outages, security breaches]) • **Costs related to the technology lifecycle** (e.g., obsolescence or depreciation of a device or software version, replacement or migration costs, anticipated device lifespan)
• Human resource costs **N**	• Human resources required for technology management, training costs • Impact on the remuneration of professionals and practitioners
Cost to users and families **N**	• Costs related to training and education for users and caregivers • Costs related to travel and time (e.g., opportunity costs, travel expenses, absenteeism from school or work) • **Costs associated with required hardware** (e.g., smartphone, tablet, connected devices) **and accessories** (e.g., cables, stands, compatible medical devices) • **Costs associated with software components and digital services** (e.g., subscription to an application or platform, user licence [temporary or permanent], Internet or cell phone plans required for use) • Costs related to energy consumption (e.g., device charging, batteries, higher electricity bills)
Cost to society	• Costs to society measured in terms of positive externalities (e.g., productivity gains, reduced travel, knowledge spillovers) and negative externalities (e.g., carbon footprint, impacts on waste management costs) • Opportunity costs related to resource allocation choices in a context of scarcity (e.g., labour allocation, kilowatt-hour allocation, and cost interdependence between different sectors of society, such as harm reduction)
Efficiency	• Efficiency analysis that captures non-health-related effects (e.g., cost-consequence analysis when the outcome cannot be expressed using quality-adjusted life years (QALYs))

Note: For more information on economic evaluation methods, consult the guidelines on the economic evaluation Évaluation économique des interventions en santé et en services sociaux à l'Institut national d'excellence en santé et en services sociaux (INESSS) (French only).

Legend: **N** Criterion with elements specific to digital technologies.

SOCIOCULTURAL DIMENSION
Promoting the common good within Quebec society while respecting the principles of solidarity, autonomy and inclusion

Value criteria	Examples of data to be gathered (data specific to digital technologies are shown in bold)
Integration into the social and political context N	• Regulatory decisions and those of other agencies or associations • Provincial priorities (e.g., sustainable development, provincial strategy on AI in healthcare) • **Compliance with national and international standards, measures, requirements and norms in cybersecurity and data management** (e.g., compliance with TGV certification, international standards [ISO/IEC 27001, ISO 42001, ISO/TS 82304 21]*, *Personal Information Protection and Electronic Documents Act* [PIPEDA/LPRPDE], Laws 5 and 25 concerning the protection of personal information and health and social services information of Québec citizens) • Factors influencing technology's social acceptability • Recognition and protection of intellectual property • **Organizations' ability to maintain freedom of choice regarding technology and data usage** (e.g., the software is not tied to a specific technology or vendor, the technology can be used independently of the underlying hardware or software infrastructure) • Risks related to the innovator's viability and track record (e.g., financial viability, possibility of company being sold, product sustainability, data or personal information breaches)
Alignment of intervention interests and practices with the common good	• Inclusion of stakeholders in technology development (e.g., co-creation, focus groups, pilot tests; user evaluation and feedback) • Research, development and experimentation practices supporting the common good (do not favour specific professional or commercial interests) • Position of stakeholders and their interests, roles and potential influence (e.g., pressures or barriers to use or implementation, such as marketing, advertising, promotion, lobbying and media appearances)

*ISO 27001: *Information security, cybersecurity and privacy protection — Information security management systems — Requirements; ISO 42001: Information technology — Artificial intelligence — Management system*; ISO/TS 82304-2: *Health and wellness apps — Quality and reliability*.

Legend: **N** Criterion with elements specific to digital technologies.

Ethical considerations associated with digital technologies

Taking into account ethical issues and tensions between values (personal, professional or social) is part of assessing the overall value of a health or social services intervention. Ethical considerations are therefore integrated across all five value dimensions. Through this process, ethical considerations that could lead to tensions—within certain dimensions or between them—can be highlighted.

Below are some ethical principles that may help frame the issues associated with the value criteria presented in the previous tables:

Principle of autonomy and individual consent

- Information must be available and clear so that users or their legal representatives can make a free and informed choice about the use of digital technology. User consent may change over time and should be renewable or withdrawable.

Principle of justice and fairness

- Technological accessibility to different segments of the population depends on different characteristics, including ethnic origin, socioeconomic status, literacy level, cognitive or motor skills, age, location and the existence of vulnerabilities or disabilities. These characteristics should be considered to avoid exacerbating or to reduce inequalities in technological access.
- Technologies carry risks of stigmatization or discrimination, particularly because of biases in the algorithms or databases used. Steps must be taken to reduce the impact of these biases in interpreting the decisions made.

Principle of privacy and protection of personal or health information

- The right to privacy is an important societal principle that is governed by laws. The confidentiality of users' personal information must be ensured through measures such as anonymization.
- The use of, access to and sharing of personal and health information are permitted only with the consent of the individuals or with the necessary authorizations.

Principle of human dignity and protection of intimacy

- The technologies used should respect users' physical, psychological and social integrity. It is important to ensure that these technologies do not influence users' judgment or actions in a way that could harm them or have serious consequences. They must also protect users' identity.
- Similarly, the use of digital technologies must respect users' intimacy during both data collection and their use. They should aim to minimize intrusions for users and their caregivers. They must not manipulate users' thoughts or emotions.

Principle of responsibility and competence

- The use of technology by health and social services professionals must be consistent with and comply with all applicable rules of ethics. It engages the professionals' responsibility and requires them to have the necessary skills or that the conditions allow them to acquire such skills.
- The use of technology must be consistent with professional values and the work context. This helps, among other things, reduces the impact on health and social services professionals' sense of competence and increases their ease, comfort and willingness to use these technologies.

Environmental considerations associated with digital technologies

The sustainable development goals encourage reflection on the environmental impacts of technologies and the actions that can be taken to reduce them in light of the 4R's principle (reduce, reuse, recycle and recover). These impacts can be examined at every stage of a technology's life cycle.

Furthermore, since digital technologies rely on an interconnected set of devices and infrastructure, the assessment of a technology's environmental impacts should be limited to digital components that are essential to operation and service delivery[2].

The environmental impacts associated with the use of technologies can be seen through the lens of the dimensions of value. They may involve issues such as greenhouse gas (GHG) emissions in connection with avoided or required travel, for example, or waste management, including the reduced or increased use of perishable or single-use products.

The following sections look at these issues from two complementary angles: material eco-responsibility and software eco-responsibility.

Material eco-responsibility

- **Sustainability:** Assessing the lifespan of devices that support the use of digital solutions, as well as their potential for repair, can help limit the production of electronic waste.
- **Energy consumption:** The energy efficiency of devices is an important factor to consider from an environmental impact reduction perspective.
- **Environmental footprint:**
  - The presence of substances harmful to human health or ecosystems
  - Compliance with national and international environmental regulations (such as the *Canadian Environmental Protection Act and Competition Act*)
  - The environmental impact of transportation
- **Devices end of life:** Consideration of various end-of-life options, such as refurbishment, disassembly, recycling or biodegradation, depending on product characteristics and available resources.
- **Use of resources:** Extraction of raw materials and use of recycled or renewable materials in the manufacture of components.

Software eco-responsibility

- **Energy consumption:** Software development can aim to minimize energy consumption, by:
  - Optimizing programming, modelling and calculation techniques
  - Using computer components (such as chips) designed to reduce heat dissipation
- **Environmental footprint:** The environmental impact of software can take the following forms:
  - The use of resources by data centres and server farms, particularly with regard to:
    - The energy efficiency of infrastructure (e.g., carbon-neutral systems)
    - The use of clean energy sources (e.g., hydroelectricity)
    - Their geographic location, which can affect water consumption for cooling purposes

2. Component inclusion conditions, as proposed by In Fieri for Responsible Innovation in Health.

THE CONTEXT SURROUNDING THE EVALUATION OF DIGITAL TECHNOLOGIES

The importance of classifying digital technologies for regulation purposes

Digital technologies encompass a range of products including mobile applications, connected objects and software incorporating AI features. The classification of digital technologies in healthcare takes account of the relationship between the technology's intended medical use and its health risks. Among other things, this taxonomy makes it possible to determine whether or not a technology should be evaluated by a health technology assessment agency (see Bulletin de veille stratégique N° 19 on evaluation methods for digital technologies in health and social services [French only]).

In 2025, Health Canada considers technology to be software as a medical device (SaMD) if it has a medical purpose as defined in the *Food and Drugs Act* and is not used exclusively to operate a hardware medical device. By definition, an SaMD is designed to:

- **"Acquire, process, or analyze a medical image, or a signal"** from a device or system that obtains real data from a user, or
- **"Support or provide recommendations"** to professionals, patients or non-healthcare professional caregivers AND has a **"direct impact"** on diagnosis, treatment or management

Based on the level of risk to the user, Health Canada categorizes SaMDs into one of three risk classes (I to III), which determines the level of regulatory oversight required. This classification is based on three main factors:

- The importance of the information provided by the software: treating, diagnosing, driving or informing clinical management
- The severity of the situation or health condition targeted: critical, serious or non-serious situation or condition
- The software's core functionality: how the software processes data, generates recommendations or interacts with other medical devices

Many digital technologies available on the market that promote health and well-being are not subject to regulatory processes. However, validations, evaluations and compliance assurance with quality standards may still be useful. Other processes are presented in Bulletin de veille stratégique No 11 on the oversight of mobile applications (French only).

Variable data and rapid pace of technological change

Although it is best to use data from a variety of sources to assess the value of digital technologies, some of these sources come with limitations. The small number of clinical studies means that few data from the scientific literature are used. In this context, data from consultations with users, potential users and healthcare settings can play a central role in the assessment.

Digital health technologies evolve iteratively as features are added and removed to modify their use and effects. These changes are sometimes so significant that the new versions can be considered distinct from the initial versions. The digital technologies available on the market sometimes differ significantly from those used during the research phases or assessed during an evaluation. These aspects should be considered when assessing the value of digital technologies. In addition, it may be useful to position them in the current landscape using platforms such as clinicaltrials.gov.

USEFUL REFERENCES AND POTENTIAL DATA SOURCES

In Québec

Certification of the trousse globale de vérification (TGV) [comprehensive audit toolkit] from the Ministère de la Santé et des Services sociaux (MSSS) is required for digital technologies considered to be technology products and services. This certification requirement applies when a technology:

- collects, stores, uses, modifies, communicates or destroys health or social services information, or
- is connected or intended to be connected to an information asset that is provincial or of common interest (e.g., Québec health record) and that processes health or social services information, or
- will be deployed at several health and social services institutions in Québec with Web access, for the purpose of providing health or social services

Some Québec **strategic documents and tools** support the framework for digital solutions, including:

- The Plan directeur sur l'intelligence artificielle en santé 2024-2027 du MSSS (French only). Rigorous oversight of AI solutions in healthcare, continuing education for professionals, and awareness of ethical issues.
- The MSSS's Premières réflexions en intelligence artificielle responsable pour les non-spécialistes en intelligence artificielle (French only): Proposes an ethical and inclusive approach to the adoption of AI in Québec's health and social services system, including identifying risks, positions to adopt, and opportunities for action.
- The Ministère de la Cybersécurité et du Numérique (MCN)'s Bonnes pratiques numériques gouvernementales (French only). Standards for ensuring the reliability, efficacy and compliance of public digital services.
- The MCN's Énoncé de principes. 10 principles for the responsible use of AI in public agencies.
- The MSSS's Outil de recommandations et d'évaluation de projets en intelligence artificielle (OREPIA) (French only): Analysis guide on the lifecycle of AI projects and AI solution assessment process for responsible implementation in public organizations.
- The Conseil de l'innovation du Québec: Recommandations pour un développement responsable de l'IA: Legal framework, independent authority, training, responsible R&D and government leadership.

Several **provincial laws** govern digital technologies in healthcare, including:

- The Act respecting health and social services information (AHSSI): Compilation of Québec Laws and Regulations (CQLR), c. R-22.1: Regulates access, use and protection of health information in the public system.
- The Act respecting Access to documents held by public bodies and the Protection of personal information, CQLR, c. A-2.1: Governs the confidentiality of personal information in public bodies.
- For a digital project, a privacy impact assessment (PIA) may be required in accordance with the Act.
- The Act respecting the protection of personal information in the private sector, CQLR, c. P-39.1: Applies if AI is developed or used by a private entity.

Some **professional associations and Québec authorities** have taken position on the integration of artificial intelligence (AI) into clinical practices and set guidelines for the use of digital technologies in healthcare:

- The Collège des médecins du Québec: Pistes de réflexion sur l'intelligence artificielle et page thématique sur l'IA (French only).
- The Fédération des médecins spécialistes du Québec (FMSQ): Communiqué de presse (French only).
- The Ordre des infirmières et infirmiers du Québec (OIIQ): Avis sur l'encadrement de l'IA (French only).
- The Ordre des psychologues du Québec (OPQ): Articles on considered and responsible integration and AI-assisted psychology (French only).
- The Ordre des travailleurs sociaux et des thérapeutes conjugaux et familiaux du Québec (OTSTCFQ): Article sur l'IA (French only).
- A Prototypical Code of Ethics proposed by Université de Montréal researchers in collaboration with various health sector professional orders: A tool to support the regulation of professional practice and the responsible use of AI in healthcare.

In Canada

Several federal initiatives and laws have been introduced to regulate digital technologies:

- Artificial Intelligence and Data Act (AIDA): Bill C-27 proposes specific requirements for AI system governance.
- Personal Information Protection and Electronic Documents Act (PIPEDA): Applies to private businesses that collect, use or disclose personal information.
- Pan-Canadian AI for Health (AI4H) Guiding Principles: An ethical and practical framework for integrating AI into the health sector.
- Good Machine Learning Practice for Medical Device Development: Technical guide for the development and evaluation of AI-based medical devices.
- Directive on Automated Decision-Making: Standards for regulating the use of automated decision-making systems in the public sector.
- Canada School of Public Service AI Project Support Toolkit: A practical four-step guide (discover, define, develop, deliver) to support government AI projects, with success factors touching on objectives, people, policies/processes and partnerships.

EXAMPLE OF A DIGITAL TECHNOLOGY VALUE ASSESSMENT PROCESS

Fictitious example – Assessment of a digital technology incorporating AI (assessor's perspective)

The value of a digital technology incorporating AI, designed to support screening of a common chronic health condition in primary care, is assessed by a team. The aim is to support decision-making for deployment at several institutions within the system.

Value criteria	Data used
POPULATION DIMENSION	
Populational morbidity and mortality burden	• The targeted condition is common among older adults and leads to significant loss of independence. It is often underdiagnosed, delaying access to care and services.
Magnitude of unmet needs	• Current tools are underused due to time and training constraints. Certain vulnerable populations are particularly underserved.
Accessibility to the entire target population	• The technology is designed for primary care dispensed by health and social service professionals but requires a mobile device and a stable Internet connection. Digital equity issues have been identified (digital divide (poor Internet coverage in some institutions), technological literacy (inability to configure the application properly)).
Ability to act on social health determinants	• The algorithm was trained on data from a population with no major disabilities and few comorbidities, raising concerns about representativeness and potential bias.
CLINICAL DIMENSION	
Clinical efficacy	• Available studies indicate superior performance compared to traditional screening tests, but the data comes from controlled settings. Real-world effectiveness is yet to be established. • The tool supports decision-making but does not replace clinical judgment. It is important to preserve users' ability to understand and question the results.
Adverse effects	• Significant risks of false positives have been reported, which may require clinical follow-up and create user anxiety.
Care and services experience	• Some users have expressed concerns about the confidentiality of personal data (voice, image).
ORGANIZATIONAL DIMENSION	
Organizational requirements and intervention impacts	• The technology is compatible with some clinical information systems but requires adjustments for full integration. • Data are hosted in Canada, but reliance on a private provider raises digital sovereignty issues • The technology is usable in its basic form but does not have access to public system databases to refine its predictions. • The tool could improve access to screening but lead to an increase in medical referrals, which entails organizational planning. • Minimal training is required for professionals. The learning curve is considered reasonable.
Experience and well-being of human resources	• The tool is seen as easy to use and has been adopted by most professionals.

Value criteria (cont.)	**Data used** (cont.)
ECONOMIC DIMENSION	
Cost to the system, budgetary impact	• Institutional licence with a low annual cost, but integration and technical support costs are to be expected. • Potential productivity gains for professionals, but also a possible overload if the number of referrals and consultations increases.
Cost to users and their families	• No direct cost. • Some users may have to travel for additional follow-up.
Efficiency	• Preliminary modelling suggests good cost-effectiveness, but there is significant uncertainty due to the lack of real-world data.
SOCIOCULTURAL DIMENSION	
Integration into the social and political context	• The tool is well received by professionals, but raises concerns among some users, particularly in relation to AI.
Alignment of intervention interests and practices with the common good	• The tool fosters prevention and autonomy but raises questions about transparency and accountability. • Few stakeholder consultations were conducted during development.

Ethical considerations:

- The algorithm is trained primarily on data from Caucasian populations. This could introduce discriminatory biases against some populations, leading to less accurate screening for these groups.
- The AI system is being developed by a private company that retains the rights to the data generated. There is a risk of health data commodification, with no clear benefits for users or the public system.
- Social acceptability could be compromised if users do not understand how their data are being used. The technology should respect cultural norms regarding privacy and not be perceived as intrusive.

Environmental considerations:

- Screening is based on audio and image capture, which avoids the use of traditional tests that generate significant waste, particularly in the case of common chronic disorders.
- This approach also reduces travel for users, thereby helping bring down greenhouse gas emissions.
- Data processing and storage consume energy resources, especially in data centres. This environmental footprint should be considered.

GLOSSARY

Information asset
As defined in the Act respecting the sharing of certain health information, an information asset may refer to a database, an information system, a telecommunications system, a technological infrastructure or a combination of such elements, as well as a computer component of specialized or ultraspecialized medical equipment.

Digital self-efficacy
The ability to use digital technologies effectively.

Incidental finding
An unexpected discovery made by chance, often while looking for something else.

Negative externality
An adverse effect of an economic activity that imposes a cost on third parties without compensation

Positive externality
A beneficial effect of an economic activity that benefits third parties without them having to pay the cost.

Digital divide
Disparity in access to digital infrastructure and technologies, such as the availability of digital tools (computers, tablets or smartphones), access to the Internet and telecommunications network coverage.

Freemium
A business model in which a company provides a basic product or service for free while charging for advanced features, additional services or exclusive content.

AI hallucinations
False information produced by generative AI when asked questions.

Secondary outcome
A non-primary effect or consequence of an action, project or research. It may be planned or unplanned, positive or negative, but it is not the activity's initial objective.

APPENDIX

Methodology

This document is based on a review of the scientific and grey literature. The information was collected in February 2025 and updated in August 2025. This document includes elements drawn from assessment methods used in the England, France, Germany, Finland, Belgium, Australia, Spain and Scotland (further details can be found in *Bulletin de veille stratégique No 19* on assessment methods for digital technologies in health and social services).

The INESSS team also consulted key informants in Québec's health and social services system for information and perspectives on their needs related to the evaluation of digital technologies in health and social services as well as their use and integration in their respective settings. The final version of this document reflects the results of this consultative process, but the stakeholders consulted are in no way responsible for its contents.

Inclusion criteria:

- All initiatives to regulate digital technologies in health and social services led by public actors or carried out in collaboration with private actors
- All initiatives to develop methods for evaluating or accrediting digital technologies in health and social services, whether currently in use or in the process of being implemented

Exclusion criteria:

- Evaluation methods and frameworks that apply to specific health conditions
- Publications on specific digital technology assessments
- Case studies, commentaries, editorials and posters

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