

STATEMENT OF PRINCIPLES AND ETHICAL FOUNDATIONS

FRAMEWORK FOR THE APPRAISAL OF
THE VALUE OF INTERVENTIONS IN HEALTH
AND SOCIAL SERVICES – JUNE 2021

Produced by the Institut national d'excellence
en santé et en services sociaux (INESSS)

This document has been approved by the Board of Directors of the Institut national d'excellence en santé et en services sociaux (INESSS) at its meeting held on June 16, 2021.

The content of this document was written and edited by INESSS.

The Institute is thankful to all members of its staff who contributed to preparing this document.

Legal deposit

Bibliothèque et Archives nationales du Québec, 2021

ISBN 978-2-550-89650-0 (format PDF)

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INTRODUCTION

The *Statement of principles for a framework for the appraisal of the value of interventions in health and social services* of the *Institut national d'excellence en santé et en services sociaux* (INESSS) is the first step of a broad process of practice evolution and continuous institutional improvement. It seeks an approach to evaluate, on the same ethical and methodological foundations, the diversity of interventions,¹ in physical health, mental health and social services, that are subject to appraisal by the institution, and to elaborate fair and reasonable recommendations aiming at creating value for Quebec's society. This framework is based upon shared principles within INESSS and a concern for the common good.

By stating these principles, INESSS:

- 1. adopts a position in favour of collective choices that are focused on creating value in health care and social services for the benefit of users,² patients and their families, and for Quebec's population as a whole;**
- 2. participates in the development of evaluation practices;**
- 3. supports responsible innovation³ for a sustainable development of the health and social services system, and this in response to decision needs at all levels.**

INESSS developed its statement of principles by mobilising a committee that included members with diverse practical and theoretical expertise from each of its units.

The work of this committee was based on a review of the practices of INESSS units and exploration of new approaches, a survey of the literature and of innovative practices, consideration of the evolution of the relevant theoretical concepts, and a consultation process that involved the different bodies of INESSS as well as its partners and the community.

This statement aims to clarify, on the one hand, the general approach to the overall appraisal of the value created by the introduction, the improved use or the withdrawal of interventions and by the transformation of practices in physical health, mental health and social services, and, on the other hand, the operational principles on which the evaluation processes of INESSS are based.

Five major fundamental principles were first submitted for deliberation to the Scientific Council and the Ethics and Governance Committee of the Board of Directors and then adopted by the Board of Directors. The implementation of the institutional framework will be evolutive, and this statement of principles is part of this progressive implementation process.

1. The term "intervention" used here in its broad sense and includes modes of intervention (cognitive, psychosocial, sensory, physical, physiological or relating to a living or care environment), technologies (bio-medical tests and procedures, drugs, cell and gene therapies, medical devices, medical equipment, blood products, digital technologies), modes of care and service organisation and modes of governance.

2. The term "user" refers to the people who use or benefit from the intervention.

3. The term "innovation" refers to innovations in any form, ranging from improving the governance or organisational practices of existing interventions to disruptive technologies that have a major impact on current practices.

PREAMBLE AND GENERAL APPROACH

INESSS was created in 2011 through the merging of the Drug Council and the Agency for the Evaluation of Technologies and Interventions in Health and expanded by the creation of the Directorate for Social Services in 2015. Its mission is to promote clinical excellence and efficient use of resources in health and social services. It aims to be an essential reference for informing decisions and practices regarding care and services offered by Quebec's health and social services system.

INESSS exercises its mission in accordance with the values of excellence, independence, openness, scientific rigour, transparency, probity, and fairness towards those who use health and social services, whilst taking account of its resources.

The present framework relates to evaluations conducted by INESSS that involve recommendations about the introduction and public coverage, and the optimal use or withdrawal of interventions in physical and mental health and in social services. The guidelines and some of the principles that are described herein are also applicable to knowledge products developed by INESSS that do not contain recommendations.

The accelerated development of interventions in physical and mental health and in social services has led INESSS to seek a harmonisation of its evaluation practices to develop fair and reasonable recommendations across the spectrum of interventions offered in Quebec's health and social services system. To reach this objective, evaluation practices and continuous improvement efforts at INESSS need to promote appropriateness and methodological coherence across diverse interventions.

AN APPROACH BASED ON OVERALL VALUE APPRAISAL

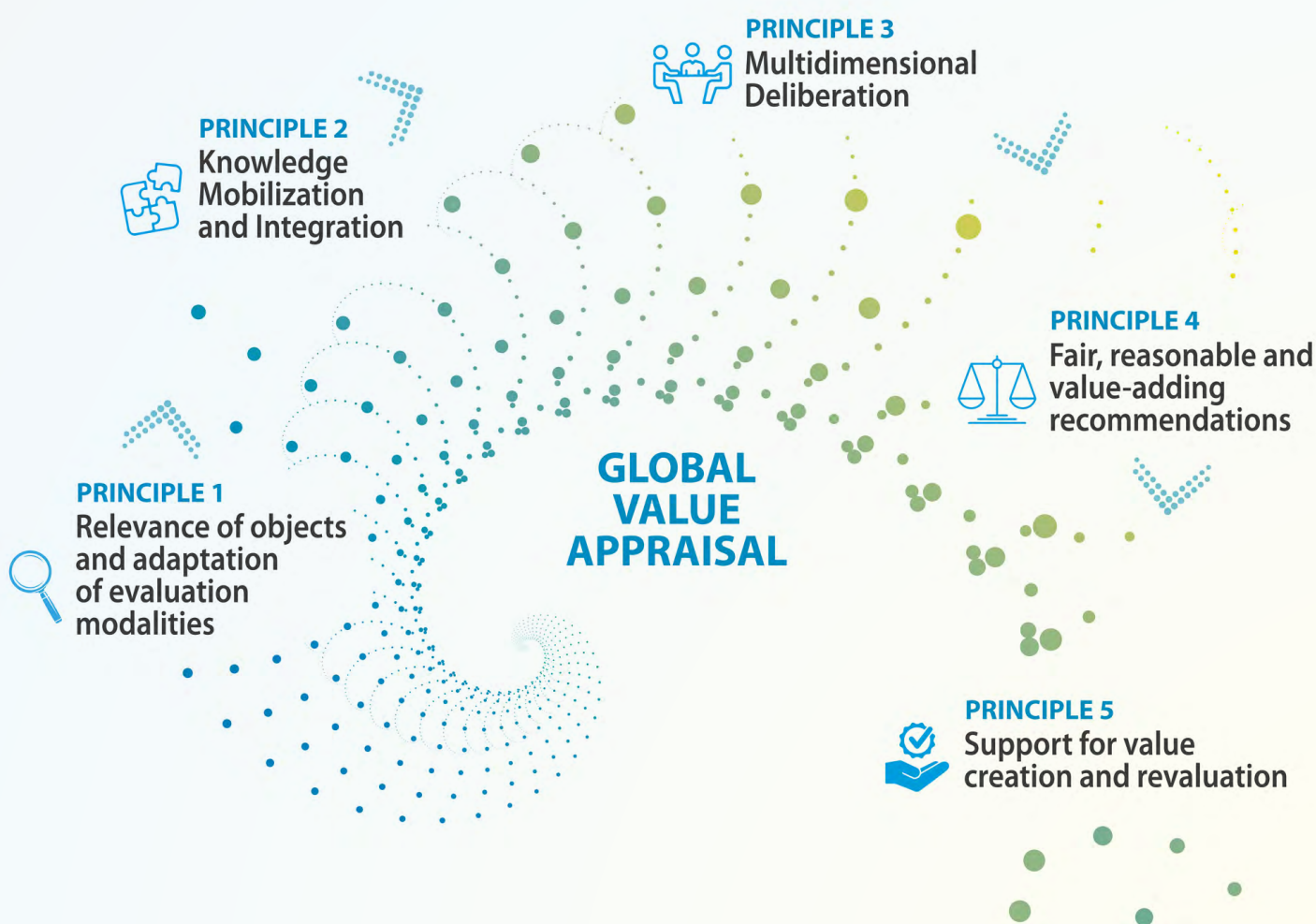
To evaluate means to make a judgement on value. An intervention provides value to the extent its use or its implementation contribute to the Triple Aim of the health and social services system (clinical, populational and economic dimensions) in a given context (organisational and sociocultural dimensions), meaning that, as much as possible, it:

- 1. Improves the health and well-being of its users (clinical dimension);** *i.e., produces desired outcomes in health and well-being in terms of efficacy, safety, quality of life and care experience for its users and their caregivers, while respecting their individual contexts and values.*
- 2. Contributes to a better state of health and well-being for the population in keeping with equity considerations (populational dimension);** *i.e., targets important needs of health and well-being of the population and is accessible to all who need it.*
- 3. Optimises the use of resources to support their responsible and sustainable management (economic dimension);** *i.e., contributes to using the full potential of the financial resources by attenuating costs, both in the long- and the short-term perspectives. This includes also the preservation of environmental resources.*
- 4. Fits into the organisational context of care and service delivery in a manner that contributes to strengthening the health and social services system (organisational dimension);** *i.e., contributes to reinforcing quality of care and optimising care pathways as well as the organisation and the governance of the system.*
- 5. Fits into the societal context in such a way that it promotes its evolution towards the common good (sociocultural dimension).** *i.e., contributes to a sociocultural evolution for the common good and aiming at the promotion of the values of Quebec's society.*

Note: The considerations under point 4 and 5 refer to feasibility and social acceptability of the intervention in the context of Quebec's health and social services system as well as their impacts on these contexts.

The general approach based on overall value appraisal seeks to consider and balance these five dimensions. It draws on a methodology that combines different types of data from diverse sectors and knowledge domains, decision ethics and the principles of a reflective, multidimensional approach. The latter takes into account the multiple dimensions that are relevant to the evaluation and seeks a comprehensive understanding of the intervention.

Overall value appraisal using a harmonised and operationalizable methodology provides a common basis to evaluate the potential for value creation across multiple, diverse interventions, i.e., their actual or potential clinical, economic, populational, organisational or sociocultural impacts. This approach is, in practical terms, structured around five principles that frame the evaluation process, as illustrated below.



PRINCIPLE 1

RELEVANCE OF OBJECTS AND ADAPTATION OF EVALUATION MODALITIES

DEFINITIONS

The relevance of the objects of evaluation depends on their potential of value creation. Relevant and appropriate evaluation modalities are those that adapt methods to the intervention in a way that allows developing recommendations aiming at value creation in a timely and efficient manner.

APPROACH

INESSS welcomes evaluation requests from a variety of sources (network of health and social services, ministry, manufacturers, developers, patients, or citizens) and processes them by first determining the admissibility and evaluability of the object by INESSS in agreement with its mission. Additionally, the Institute identifies objects to evaluate, in concertation with actors of the sector of health and social services, including the research and development community. In certain cases, INESSS conducts an analysis of their potential of value creation to enable a reasoned prioritization as a function of its evaluation capacities.

Once an object enters the evaluation process, evaluation challenges are systematically analyzed in relation to the decision question (e.g., little known disease, phenomenon or intervention; limited evidence; benefits dependent on the organizational context of care and services; uncertainties about costs; large gaps between clinical practice and expected standards). It is on this basis that appropriate, necessary and sufficient evaluation modalities are put in place, in retroaction with the requesting party as appropriate, and according to a principle of proportionality of effort, including, among others:

- A project team that mobilizes the required expertise (including patients, users or caregivers, if applicable) depending on the challenges raised by the evaluation;
- Appropriate timelines to enable high-quality recommendations to be issued in a timely fashion for decision-making whilst respecting commitments made in this regard;
- Methods and processes to mobilize relevant knowledge;
- A deliberative process that is adapted to the object of the evaluation and considers the identified challenges.

Although, for the sake of effective project management, these modalities are established at the beginning of the evaluation project, they should be adapted, if new challenges arise during the project.

4. See note 1 for more detail.

BASIC PRINCIPLES

The principle on the relevance of the objects of evaluation seeks to focus evaluation efforts on interventions that have the greatest potential of value creation, notably, by: improving the health and well-being of users in an equitable way; attenuating costs; reinforcing the health and social services system; and by promoting Quebec's values. Value creation can be brought about by the transformation of practices, by the introduction or the improved use of an intervention that is largely aligned with these value objectives, or by the withdrawal or the refusal to introduce an intervention that, on the whole, not aligned with them.

To this end, the selection of evaluation objects must consider the diversity of interventions in terms of their purpose (e.g., prevention, treatment/intervention, palliative care), their type (e.g., medicine, psychosocial intervention), and the environment in which they were developed (e.g., health industry, network of health and social services). This diversification also needs to consider the type of decision-making question, i.e., introduction, public funding, improved use, or withdrawal.

Evaluation modalities are adapted according to the intervention by considering decision-making needs, the diversity of evaluation challenges and the levels of uncertainty. This adaptation must also be guided by the principle of proportionality of effort, i.e., ensuring that the effort invested in an evaluation corresponds to the degree of complexity and the challenges encountered.

PRINCIPLE 2

KNOWLEDGE MOBILIZATION AND INTEGRATION

DEFINITIONS

The term "knowledge" generally refers to the body of knowledge gained through study, observation, learning, or experience.⁵ For evaluations, this includes published data; unpublished data submitted by the applicant or from the health care and services milieu and other relevant sources; and the knowledge and experience of those concerned by the intervention. This knowledge is mobilized through a diversity of sources using appropriate methods, followed by analysis and synthesis. Knowledge integration involves organizing the data from these different sources for each evaluation dimension.

APPROACH

Data mobilization seeks to collect complementary data (scientific, experiential, contextual) from different sources.⁶ It is based on a scientific approach with valid and rigorous methods and processes for each source, respecting the principle of proportionality of effort. Data sources can include:

- scientific literature, including grey literature
- unpublished data submitted by the applicant (e.g., manufacturer, developer)
- care and service settings (clinical-administrative databases, medical records, registries, etc.), other settings when required (e.g., education, justice, economic development), or other relevant sources (e.g., regulatory agency)
- consultation with the people concerned (e.g., patients, users, family members, clinicians, managers, citizens, researchers) to capture the diversity of perspectives.

Different domains or fields of knowledge are explored (clinical, economic, epidemiological, management, ethics, etc.) and different types of studies and analyses are employed (e.g., experimental, observational, qualitative, and real-life studies; economic, statistical, and other models; ethical analyses, analyses of organizational processes).

The data collected are analyzed and synthesized, using quantitative, qualitative or mixed methods of synthesis. They are then organized by dimension to inform the deliberation about what is known and the associated limitations, uncertainties and ethical issues.

This is done in respect of the values of INESSS, seeking:

- Scientific rigor in line with the best methodological standards;
- Quality assessment and critical analysis of the data;
- Identification of uncertainties, due to the limits of the available data, and assessment of the level of uncertainty and likelihood;
- Clear and transparent description of the contents and the methods used, in compliance with applicable laws;
- Independence of the processes and the people involved;
- Methodological consistency across different data sources;
- Proportionality of effort and agility to optimize the Institute's resources.

5. Trésor de la Langue Française informatisé (<http://atilf.atilf.fr/>)

6. This corresponds in social sciences to the principle of data triangulation.

BASIC PRINCIPLES

The objective is to shed as much light as possible on the object of the evaluation to enable its adequate understanding at the deliberation. To shed light on the clinical, population, economic, organizational, and sociocultural dimensions of the intervention, appropriate and complementary data sources must be mobilized. To fully leverage these data, they need to be integrated to support deliberation and the clear transmission of knowledge to the applicant, decision makers, and others.

The work of mobilizing and integrating knowledge is guided by the values of INESSS, including independence, openness, scientific rigour and transparency.

PRINCIPLE 3

MULTIDIMENSIONAL DELIBERATION

DEFINITIONS

Deliberation is when a group of diversified individuals aiming for the common good come together to appraise and weigh the arguments for and against introducing an intervention or changing existing practices. Multidimensional deliberation is organized around the dimensions of evaluation (clinical, population, economic, organizational and sociocultural).

APPROACH

Multidimensional deliberation is carried out by a deliberative body that brings together relevant perspectives adapted to the intervention and its specific challenges (notably those of citizens, clinicians, managers, ethicists and scientists). It aims to establish a group dynamic that is conducive to individual and collective understanding of the meaning of the available pieces of knowledge integrated for each evaluation dimension, as well as the uncertainties and ethical issues that surround them, while respecting individual perspectives.

Based on the knowledge mobilised for each dimension and taking into account the associated uncertainties, the deliberative body considers how the introduction, use or withdrawal of the intervention being evaluated contributes to creating, or not, value in each of these dimensions.

The strength of the resulting arguments and their relative importance are discussed, keeping in mind the collective well-being of the population, and to establish orientations for the recommendations, including, as needed, the appropriate modalities and conditions for their implementation.

BASIC PRINCIPLES

By reconciling necessary perspectives, brought together through a structured deliberative group exercise, the deliberative body reflects on the contributions of the intervention being evaluated towards the achievement of the Tripe Aim of the health and social services system, as well as on its feasibility and its impacts on the care system and, more broadly, on society.

The legitimacy and the coherence of deliberative processes depend on the diverse representation of perspectives relevant to the intervention, and consideration of all arguments.

The preservation of the common good in deliberation draws in particular on the prevention, identification, evaluation and systematic management of conflicts of interest and roles to maintain the independence of the process.

PRINCIPLE 4

FAIR, REASONABLE AND VALUE-ADDING RECOMMENDATIONS

DEFINITIONS

For projects of INESSS aimed at developing recommendations, the latter represent the ultimate goal of all the work described above. Recommendations reflect the transformation of knowledge and deliberation into concrete proposals for action. A fair and reasonable recommendation aims to balance diverging views and mitigate ethical tensions in the pursuit of the common good.

APPROACH

The rationale explains how and why the intervention contributes positively or negatively, as the case may be, to the Triple Aim of the health and social services system, as well as its organizational and sociocultural feasibility and impacts, and the level of risk associated with all the uncertainties. This makes it possible to explain whether and to what extent the value of the intervention or change in practices, assessed from an overall point of view, is compatible with the service offer requirements of Quebec's public health and social services system.

In addition, recommendations on the modalities to realise or increase the value of the intervention (in the day-to-day reality of care settings) are developed based on a good understanding of the facilitators and barriers to their implementation to ensure that they indeed add value.

These modalities may include, for example: identification of the users most likely to benefit from the intervention; mitigation of the economic burden; mutual support between people suffering from the same condition (peer support); conditions that promote healthy lifestyle habits; the expertise and skills required; or other measures to ensure or improve the quality of the intervention. This could also include proposals for implementation approaches and indicators.

If the risks regarding the impacts of the intervention (in clinical, economic, population, organizational or socio-cultural terms) are high, clear and specific feasible risk mitigation conditions can be defined. These conditions may include demonstrating a health and well-being outcome in a real-world Quebec context or obtaining stronger clinical, economic, organizational or population data. The administrative burden associated with these conditions must remain acceptable to the health and social services system.

When the rationale on the value of the intervention is negative overall, the recommendation will be to reject or withdraw it (and, if appropriate, to replace it with other interventions) or to refuse its public financing.

BASIC PRINCIPLES

Recommendations are intended to inform decision-makers and others interested parties of the key elements to consider in making fair and reasonable decisions regarding the introduction, optimal use, or withdrawal of the intervention.

Supporting fair and reasonable decisions includes establishing conditions and procedures to promote responsible introduction or optimal use of the intervention allowing value creation in real-world care and service settings.

Communicating a rationale that clearly and transparently articulates the arguments behind the recommendations, including the associated uncertainties, is conducive to reflective practice and greater acceptability of the recommendations by those affected by it.

PRINCIPLE 5

SUPPORT FOR VALUE CREATION AND REASSESSMENT

DEFINITIONS

Value creation refers to the beneficial effects of an intervention in health or social services, in terms of clinical, population and economic aspects, as well as regarding the organization of care and services and socio-cultural dynamics. Support includes all actions that INESSS can take to promote this value creation. Reassessment is the re-evaluation of an intervention.

APPROACH

INESSS is a player in an evolving health and social services system seeking continuous improvement through reflective approaches. As such, it transmits its recommendations and knowledge products in support of clinical and public decision-making with the aim to realize the full value potential of the interventions it has evaluated.

INESSS contributes to stimulating value creation by:

- Making public the results of its evaluations (while respecting confidentiality agreements) as well as its recommendations and their underlying rationale;
- Interacting with stakeholders in governance, care and service settings, professional associations and other relevant areas, including users, patients and citizens;
- Ensuring an optimal transfer of recommendations and knowledge through activities and tools for their dissemination, appropriation and support for implementation;
- Supporting ongoing activities of evaluation and re-evaluation to assess the degree to which the expected value of the evaluation objects is being realized.

BASIC PRINCIPLES

This principle aims to promote the implementation of recommendations and to support the optimal use of interventions for clinical excellence and the efficient use of resources in the health and social services sector.

Measures for evaluating the performance of care and services and, where applicable, implementation and follow-up modalities are specified, in accordance with best clinical governance practices.

INESSS' recommendations are disseminated to stakeholders in the health and social services system and are made public, along with their rationale and the information used to develop them as well as monitoring requirements and implementation issues.

Reassessment is performed in light of new relevant data or new arguments that are deemed admissible.

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