INESSS - A key player in the regulation of Québec's health and social services system

INESSS – um ator fundamental na regulação do Sistema de Saúde e Serviços Sociais do Québec

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Resumo

Um dos aspetos fundamentais da regulação dos sistemas de saúde modernos é a forma como a inovação tecnológica e terapêutica é introduzida e monitorizada nesses mesmos sistemas. O Canadá não é imune à complexidade destes sistemas, o que este artigo tenta clarificar apresentabndo o caso da província do Quebec, onde, em 2011, foi criado o Instituto Nacional para Excelência Clínica na Saúde e Serviços Sociais (INESSS). No contexto da regulação em saúde do Quebec, o INESSS contribui para essa regulação ao analisar a mais valia das inovações de forma a otimizar os seus benefícios económicos e em saúde.

Palavras Chave:
INESSS, regulação da saúde, sistema de saúde público, Quebec.

Abstract

One of the dominant features of the regulation of modern health systems is the way in which technological and medicinal innovations are introduced and monitored. Canada is not immune to the complexity of this systems, which this article tries to clarify by presenting the case of the province of Quebec where, in 2011, the National Institute for Clinical Excellence in Health and Social Services (INESSS) was established. In the regulation of the Québec health system context, INESSS contributes to regulation by assessing the added value of innovations in order to optimize their health and economic benefits.

Key Words:
INESSS, health regulation, public health system, Quebec.

Introduction

Regulation is defined as: any intervention carried out within the framework of an appropriate action and measured in order to maintain or restore the deemed desirable or acceptable state of a system, such as the health system.

The modernization of health systems imposes a complex regulation, often carried out by several organizations or systems, unfortunately not always convergent, which are ultimately under the authority of a higher and political governance.

One of the dominant features of the regulation of modern health systems is the way in which technological, medicinal and even intervention innovations in service delivery systems are introduced and monitored.

Canada, as well as its ten provinces and three territories, is not immune to this complexity, which we will try to clarify by presenting the case of the province of Quebec. In 2011 the National Institute for Clinical Excellence in Health and Social Services (INESSS) was established. Its mandate is to assess the relevance of introducing innovations in the service offerings of health and social services to the population. In order to better understand the scope of this technostructure, it is important to describe the general framework for the functioning of the Canadian health care system, as well as the main regulatory levers in place.

The Canadian and Quebec Health Systems at a glance

Canada is celebrating 150 years of history this year, with its constitution signed in 1867. From its inception Canada provided for provincial responsibilities for health care. This vast country, the second largest in the world with a population close to 35 million, is a federation of ten provinces and three territories.

The federal government is primarily responsible for providing health services to Aboriginal and military populations. Provinces like Quebec, for their part, have full responsibility for the organization, administration and funding of health and social services systems as well as professional legislation. Quebec itself has more than 8 million inhabitants, mostly French-speaking, and has an integrated, universal public health and social services system to which the population can contribute, have rights and can complain, based on legislative frameworks. 7% of Québec's workforce is within the health and social services system, which globally accounts for more than half of the total program expenditure of the Government of Québec, an indication of its social and political importance.

Not surprisingly, in both Quebec and Canada, life expectancy at birth is among the best in the world. Over the past 50 years, it has increased by almost five hours per day, mainly due to the improvement of several health determinants, including the organization of the health care system, which is not the main determining factor of growth. Canada, as well as Quebec, invests over 10 per cent of its GDP, being the top-most per capita spending in OECD countries, though it is lower than their US neighbor, which now exceeds 16 per cent.

Public health systems in Canada are relatively new. At the turn of the 1960s after seeing the development of universal health insurance systems in some provinces, the federal government voted a law governing its financial transfers to the provincial health systems (Canadian Health Act (R.S.C., 1985, c. C-6). After a major public reflection (Royal Commission on Health Services, 1961-1964), the country agreed that it would financially support half of all annual provincial health expenses provided the systems in place met five essential requirements:

1. a public administration;
2. universality: coverage of services for all citizens;
3. financial accessibility: essentially ensuring that citizens have nothing to pay directly;
4. integrity: all the necessary medical services had to be provided by these systems;
5. transferability: allowing Canadian citizens, regardless of their engagement from one province to another, to be under constant coverage of their original provincial public system.

It must be understood that this legislation, which was still in force and strengthened by adjustments made in the mid-1980s to prevent over-billing among physicians, essentially set the spending power of the federal government in the health sector. In the early years, the federal government effectively supported half of the total costs incurred by the provinces and territories until all provinces and territories set up systems that met these criteria. Subsequently in the mid-1970s, the country gradually decreased its transfers, which were reduced, in all proportion, by one-half, with one-quarter of the expenses of public health care systems in Canada being covered by the federal government, the majority being by the provinces themselves.

The implementation of these public systems has meant that essentially, in Canada and of course in each of its provinces and territories, there are no private health systems, no user fees, no overbilling of physicians, in contrast to all OECD countries. Canada is a country with fourteen different health systems: ten of the provinces, three of the territories and one for the populations served by the federal government, all of which are related in

their very foundations by this Canadian law introduced 50 years ago.

Physicians have remained liberal professionals who are not employed by public health systems but enjoy exercise privileges by charging all their contributions, generally paid under a fee-for-service plan, to the various public plans in place in the provinces and territories.

The Canadian and Quebec situations, despite the presence of a strong and well-established public system, show shortcomings when compared to other OECD countries, particularly in terms of accessibility. Citizens all have access to the health system, but waiting times do not stand out to the advantage of the leading OECD countries showing underperformance in this area despite the fact that public funding for systems of health care almost doubled from 2003 to 2015 on the Canadian scene as a whole. More specifically in Quebec, studies by the Health and Welfare Commissioner (CSBE) persistently show the delays experienced by this province in terms of improving access to primary and specialized health services, not to mention hospital emergency services (La performance du système de santé et de services sociaux québécois 2010 à 2017, CSBE et Apprendre des meilleurs: étude comparative des urgences du Québec – CSBE 2016).

In 2015 the Government of Quebec underwent a major transformation in the governance of the health care system by giving the Minister more direct powers in the administration of health and social services reconstructed on a regional basis and by promulgating laws that have resulted in adjustments in the service offerings of general practitioners and specialists (Acts 10 and Act 20, Éditeur officiel du Québec, 2015). This, two years later, will have markedly improved the situation in terms of access to all medical services.

The Canadian and Quebec regulation

If we go back to the definition of regulation, there are actually several institutions or components of the system that regulate health systems in Canada and Quebec as well.

The Canadian government, under the responsibility of its Department of Health, houses a portfolio that includes the Canadian Institutes of Health Research (CIHR), the Public Health Agency of Canada (PHAC), and Health Canada (HC). Each of these major subsystems performs regulatory functions, whether they are in the areas of protecting the health of populations through monitoring of the evolution of infectious diseases and environmental hazards (PHAC), of structured efforts in fundamental, clinical and organizational research to enable systemic improvements and innovations (CIHR) and of Health Canada (HC), which more accurately monitors the use of drugs and technologies, as well as their registration through very high-level scientific processes.

Other Canadian agencies, primarily benefiting Canadian health systems as a whole, have regulatory responsibilities such as the Canadian Agency for Drugs and Technologies in Health (CADTH), the Patented Medicine Prices Review Board (PMPRB), Infoway Canada, the Canadian Food Inspection Agency (CFIA), the Canadian Foundation for Healthcare Improvement (CFHI), the Canadian Institute for Health Information (CIHI), the Radiation Safety Institute of Canada (RSIA), etc., and other publicly funded, non-profit, well-established and regulated organizations such as the Health Standard Organization (HSO), the Canadian Association for Health Services and Policity Research (CAHSPR) and several others such as universities, research centers, councils of advocacy platforms, etc.

As in other provinces the regulatory levers of the health care system in Quebec are contextualized according to their specific mode of global organization. Administrative systems are well-organized, exploiting the levers of ministerial action plans, from specifications to the various regional health and social service system managers, and rigorous follow-up based on departmental governance that puts forward specific projects and proposes public policies to the government.

Moving on with regulation, the overall framework for the functioning of the Québec health system provides for citizen participation on the boards of directors of service organizations as well as citizen forums to participate in the deliberation surrounding the issues of well-targeted systems. Service users' involvement is carried out by committees in each of the institutions responsible for informing, promoting and defending users' rights, in conjunction with the setting up of a protector of citizen-user for all government services. Moreover, citizens can complain to established bodies such as the Complaints and Quality Commissioners, which are concerned with respect of rights and with the analysis of complaints situations coupled with recommendations.

Québec also has a health and welfare commissioner whose role is to assess the results of the health care system, by consulting citizens and stakeholders. Finally, the professional orders established by legislation, for each of the health and social services professions, regulate professional practices and protect the public.

In the current exercise of regulation, several statutory reports are anchored in the exercise of the health system and are subject to monitoring, recommendations and follow-up on safety and quality of care as well as user satisfaction and the evolution of health profiles specific to groups of patients or more broadly for the entire population and groups at risk.

INESSS: the key actor in the regulation of innovations

In the exercise of its governance and management the regulation of Québec's health system, which is instrumented by Canadian components, allows moving towards a system that values access, quality, safety and equity, including the effectiveness, relevance and efficiency to ensure a fairness in the allocation of resources and a balance in the actions on the different determinants of the social and economic development of Quebec.

Nevertheless one of the key perspectives of regulation remains the way in which innovations are evaluated and introduced. INESSS is essentially the key player in this field.

The National Institute for Clinical Excellence in Health and Social Services has been legally created in 2011 from the merge of a precedent council on the evaluation of medication and a public agency of technology evaluation as mode of intervention in health. Its vision is to promote clinical excellence and the efficient use of resources in health and social services sector. Its vision is to be the reference to inform decision and practices and it values excellence, independence, openness, scientific rigour, transparency, integrity and equity (INESSS mission). Its main mandate is to assess, in particular, the clinical advantages and the cost of technologies, medications and interventions used in healthcare and social services. It issues recommendations concerning their adoption, use and coverage by the public plan. It develops guides to clinical practice in order to ensure their optimal use in the Québec healthcare system. The institute is composed of over 160 people, essentially high-level scientific professionals mobilizing expertise across the province of Québec and other jurisdictions. Through its recommendations about adoption, use and coverage by the public plan of the technologies, medications and interventions, the Institute contributes to improving the performance and sustainability of the public healthcare system of the province of Quebec.

INESSS is supporting practices' continuous improvement effectively by identifying priorities aiming to inform the choice of priorities to the sectors where potential practice optimization gains are highest; by developing knowledge products, which is the art of its activities leading to the production of assessments, reviews, and guides based on the best available knowledge; by implementing its recommendations aiming to provide tools for the Ministry as well as for the clinicians and the managers, to accelerate the implementation of the recommendations; and by measuring and evaluating, aiming to instrument key players in Quebec's healthcare. In fact, as others, INESSS considers that probably around 10 to 15 percent of current health and social service interventions may not be beneficial to target groups.

More specifically INESSS is responsible in assisting the Minister in the updated of the drug list, promoting its optimal use and making recommendations to the Minister on all and any questions regarding drugs. In relation with the Public Prescription Drug Entrance Plan (PPDEP) which was launched 20 years ago in 1997, the Institute evaluates the "therapeutic value" of a medication and recommends to the Minister its usage after assessing:

1) the reasonableness of the price charged;
2) the cost-effectiveness ratio of the medication;
3) the impact that entering the medication on the list will have on the health of the general public and on the other components of the health and social services system; and
4) the advisability of entering the medication on the list, given the purpose of the basic prescription drug insurance plan of Quebec.

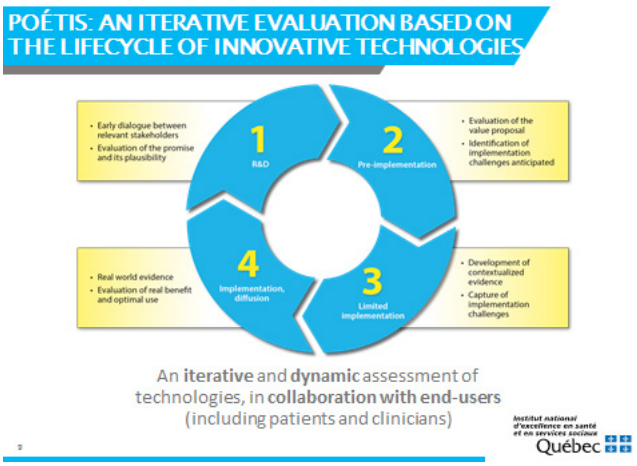
INESSS is not responsible in negotiating the price of the medication, which is the Minister's responsibility, but is the organization that is foreseeing the added value of a new medication, its indication and the perspective of optimal usage of it.

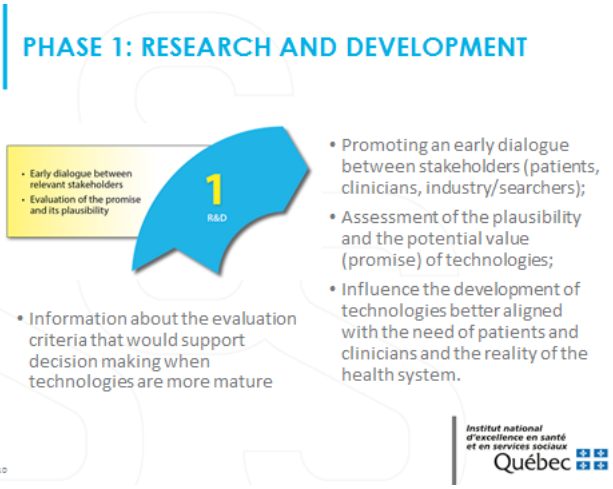
The processes allowing INESSS to do so are of high scientific level, mobilizing clinicians, scientists and benefiting from the perspective of patients, citizens and ethical experts which allow recommendations to be best contextualized in Quebec society and its health system. The Minister receives the recommendations of INESSS and can act according to what appears to him the best. In fact, overall, all of the recommendations sent to the Minister in recent years have been retained in full.

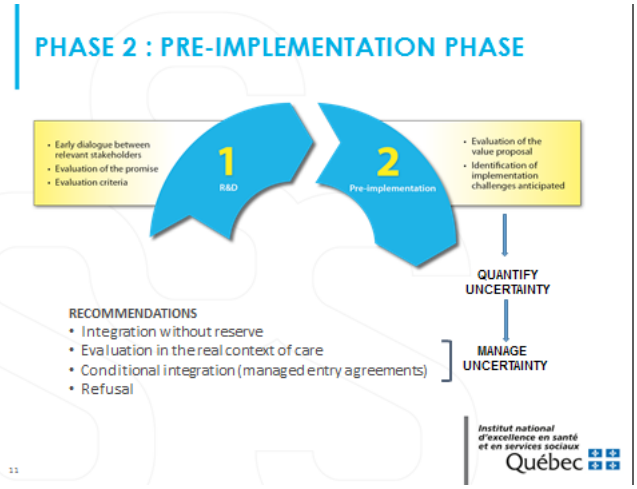
The Government of Quebec recently adopted a new national life sciences strategy covering the next ten years, until 2027. This strategy essentially aims to increase investments in research and innovation in the field of life sciences and to further integrate innovation into the health and social services system. One of the avenues chosen is the implementation of an optimized program for the evaluation of innovative health technologies (POETIS) entrusted to the INESSS.

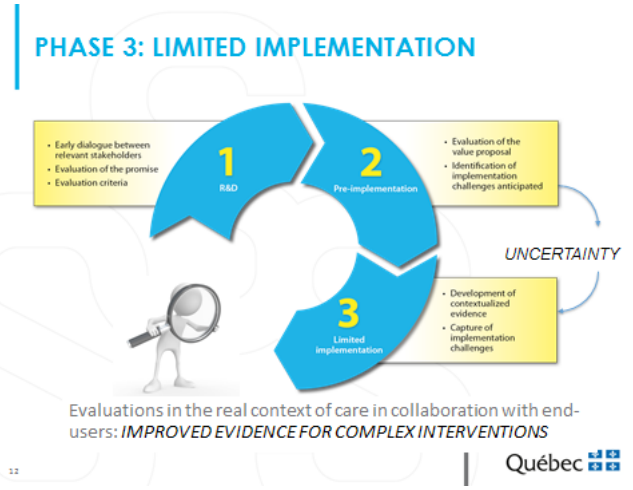
In fact, the new technologies do not come without challenges for policy makers:

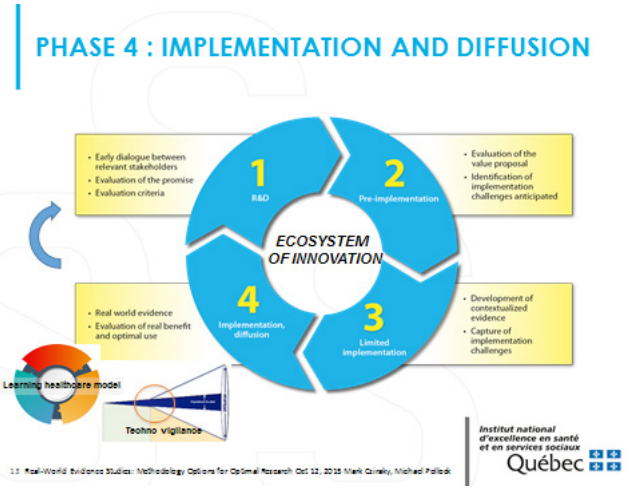
- Technology categories converge in ways that alter the delivery of health care;
- They challenge regulatory systems, which traditionally address a single type of technology;
- New designs need to be tested for evidence development, in addition to the traditional randomized control trial (RCT).











Considering the classical triple "E" of HTA (efficacy: does it work in critical trials – effectiveness: does it work in clinical practice – efficiency: does it contribute to more efficient use of resources), INESSS took the opportunity to develop this specific programme (POETIS) identifying technologies that:

- Are effective and deliver high value;
- Are effective in some indications but prone to expansion of indications and use in a population where the utility diminishes (diluting its effect or value);
- Show weak or non-existent evidence of benefit thus a clinical risk of causing harm.

The challenges and opportunities for INESSS are to contribute to a more rapid and safe integration of these high added value technologies in a responsible, rational and ethical way by skipping the classical HTA model that is often caught in a "too early, too late" syndrome and without enhancing a perception of delayed patient access to promising and effective innovative technologies.

The following illustrations demonstrate the various steps of this model of iterative evaluation based on the life cycles of innovative technologies. This model already implemented and successful in the Quebec experience allows the evaluation of added value to other technologies that is dynamic and iterative along its life cycle.

To achieve this, three elements were found essentials.

1. Stakeholders involvement: clinicians, patients, government, industry, academia, in-hospital units of HTA;
2. Dynamic measurement of health outcomes and costs;
3. Management of uncertainty (limited imple-

mentation, evaluation in real context of care, pragmatic trials…);

Finally decisions need to be re-evaluated as technologies evolve, which is already the case in the implementation of this model in the Quebec environment.

Conclusion

Regulation of the Québec health system is made by using several mechanisms to ensure vigilance and political (public policies), managerial and clinical decision-making in order to maintain, if not improve, the quality of services, their accessibility and safety, particularly in a context of health systems that is exclusively public.

More specifically INESSS contributes to regulation by assessing the added value of innovations in order to optimize their health and economic benefits. This assessment depends on the availability and quality of clinical and administrative information as well as on accessibility (which INESSS has recently obtained in a systematic way) and more particularly in real-world evidence stage of innovation.

Finally to emphasize on the solidity of INESSS analysis and recommendations, collaborations in this field with the other Canadian and international jurisdictions are necessary.