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Conditional implementation of innovative technologies

English summary

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SUMMARY

Conditional implementation of innovative technologies

Context

Bringing hope to many Quebecers, innovative health technologies offer new diagnostic and treatment options and are characterized by the potential advantages they offer over current practices. Assessing these technologies, however, poses a challenge, since their novelty means that the knowledge about the benefits and consequences of introducing them into the health and social services system is often limited. On the one hand, speedy access to potentially effective technologies is sought for the patients who might benefit from them, but on the other, the available data do not always provide a sufficient level of confidence to make widespread use of these technologies.

In this context, health-care systems are looking at optimal mechanisms that would enable patients to benefit from innovative technologies in a timely manner while at the same time managing the risks associated with the limited evidence. Non-pharmaceutical technologies pose a special challenge because of their nature and the often-limited evidence - in terms of quantity and quality - prior to their adoption. There is also little international experience with conditional implementation of non-pharmaceutical technologies.

Methods

To support this reflection, the Institut national d'excellence en santé et en services sociaux (INESSS) conducted a review of the literature on the mechanisms for the assessment and the conditional implementation of innovative technologies. The objectives were as follows: 1) to describe, in conceptual and operational terms, the various mechanisms proposed; 2) to identify the main circumstances that are and are not conducive to their implementation; and 3) to identify the experiences of other authorities and the lessons learned. Although this state-of-knowledge report specifically concerns non-pharmaceutical technologies, the literature pertaining to the pharmaceutical domain was examined as well. Indeed, there is a wealth of international experience on the pharmaceutical side, and the underlying principles are potentially applicable to the different types of technology. Moreover, this report is informative in nature, is not a position paper and does not offer recommendations.

Results

General points

There is extensive literature on the mechanisms for accessing innovative health technologies in a context of uncertainty, and different terms are used to refer to this concept: *managed-entry agreements, risk-sharing agreements, market access*

agreements, performance-based schemes, filed evaluation, coverage with evidence development, access with evidence development, patient access schemes, and *conditional reimbursement*. Numerous definitions and taxonomies have been proposed, but all of these classifications make a distinction, at different levels, between agreements depending on the type of uncertainty they are intended to manage or resolve: clinical vs. economic. The taxonomy adopted for the purposes of this report places mechanisms into two main categories: coverage with evidence development and performance-linked reimbursement. The first category is aimed at providing access to a technology while evidence is being developed, whereas the second is aimed at managing the use of the technology in order to control its cost-effectiveness in real-world conditions.

Relevance of establishing agreements

Different criteria or frameworks for guiding the decision to establish conditional technology implementation mechanisms have been developed. The recurring elements used to guide coverage with evidence development decisions can be grouped into five points: 1) The assessment of the technology's expected value from the available evidence, which is generally the starting point. It is used to make a judgement about the magnitude of the expected benefits for patients and the health-care system; 2) With this information, the gaps in the available evidence can be established, along with the corresponding uncertainty, which has an impact on coverage decision-making; 3) The other elements often considered are aimed at estimating the value of reducing this uncertainty by generating additional evidence, including the use of value-of-information methods. In other words, they seek to weigh the potential benefits of new data (e.g., the extent to which it will contribute to more-informed decision-making) against the associated costs, whether in terms of resources allocated to conduct a study or the imposition of a delay before the widespread adoption of a technology; 4) Investment costs and unrecoverable costs can be considered when making a coverage with evidence development decision, since they are "lost" resources if conditional implementation ends with a refusal after the data collection process; 5) Lastly, in certain situations, the possibility of obtaining a price reduction on the technology is examined, since it can have an impact on the assessment of the technology's expected value and the uncertainty.

Guiding principles for implementing agreements

Guiding principles at three levels have been proposed to guide the application of conditional innovative technology implementation agreements. First, the characteristics of the system-wide agreement need to be spelled out, including the decision problem, the underlying uncertainty, the objectives of an assessment project, the stakeholders' engagement, and planning a subsequent assessment. Second, the agreement's organizational characteristics, primarily in terms of funding and governance, need to be formalized. They have a major impact on the agreement's actual or perceived credibility. Lastly, the operational characteristics of

each agreement need to be determined regarding the design, the scope of the assessment, and the subsequent actions (impact on decision-making).

Experiences in other countries

Several Canadian and international experiences were identified, showing the perceived large potential of conditional implementation mechanisms for innovative technologies. In Canada, previous and ongoing work in Alberta, Ontario and Québec is discussed. At the international level, the formal programs that have been implemented are presented in a more standardized manner. Evidence generation programs aimed at reducing uncertainty in decision-making were first analyzed and can be divided into two main categories. One is embedded in technology assessment processes, and studies in real-world settings are undertaken because of the uncertainty observed during the assessment. Examples from France, the United States, Australia and Switzerland are presented. The other category includes programs that can be described as parallel to conventional assessment processes. In these situations, the premise is that the available data are not sufficient to support decision-making using traditional mechanisms, but that, given the promise held by the technologies, an early assessment in real-world settings is warranted and should be supported in part by public funds. The programs in France, England and Germany are presented. In addition, no exercise in managing technology utilization in real-world conditions were found for non-pharmaceutical technologies, but many countries have established such structures on the pharmaceutical side. Examples from England, Belgium and Italy are presented.

Strengths and challenges

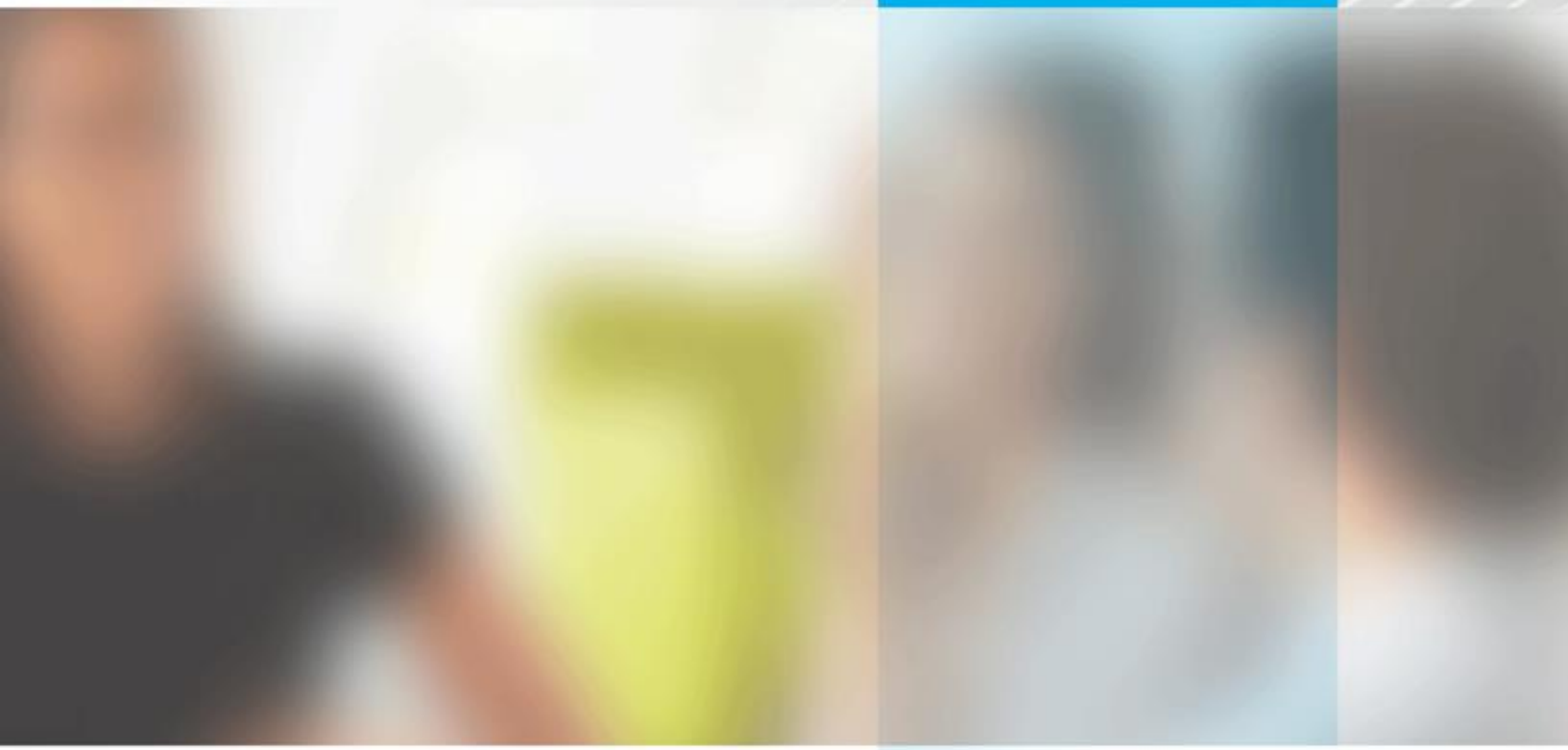
The potential of the various conditional implementation agreements is genuine, but it must be weighed against the different issues and challenges associated with their operationalization. Their strength resides in the fact that they support the implementation of innovative technologies, but in a way that optimizes health-care system resource utilization. These agreements also allow for sharing the risk associated with uncertainty, which traditionally rests with the decision-maker. However, the possibility of adopting a technology that will eventually be deemed inefficient or ineffective remains, and it entails a major difficulty, namely, revoking the decision. In addition, designing and implementing agreements involves varying degrees of administrative and financial burden, both for health-care payers and providers, as well as the manufacturer. There are also significant issues relating to the governance and the funding of agreements, for which there is no systematic approach or framework, and where the issue of leadership remains.

Conclusion

This state-of-knowledge report identifies key elements that need to be considered when developing mechanisms for the assessment and conditional implementation of innovative technologies. First, it is essential that a clear methodology and clear

processes be developed to target the most favorable situations and to put these mechanisms in place, this in light of both the clinical and contextual considerations. It is also important to develop a production framework that will make it possible to design and implement feasible and relevant projects, including, among other things, explicit governance arrangements that would limit the burden and risk placed on the health-care system. Finally, the application of the results should be optimized, on the one hand, to support decision-making and, on the other, to contribute to the advancement of knowledge that is broader than that specific to the needs of conditional innovative technology implementation agreements.

In conclusion, the current context, in Québec and elsewhere, is increasingly conducive to flexible implementation recommendations supported by data generated in real-world settings. Despite the major challenges associated with this type of approach, innovation adoption processes that are realistic, responsible and suited to the reality of non-pharmaceutical technologies can be developed. Ultimately, the necessary precautions could be taken in such processes without impeding innovation.



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