HEALTH TECHNOLOGY ASSESSMENT AND THE REGULATION OF MEDICAL DEVICES AND PROCEDURES IN QUEBEC

Synergy, Collusion, or Collision?

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Abstract

In this paper, we discuss the complex relationship between health technology assessment (HTA) and the regulation of medical devices and procedures. The relationship is first examined through a conceptual framework describing the itinerary from research to three levels of policy making: micro (standards of medical practice), meso (institutional rules), and macro (health policies). Four reports from the Quebec Health Technology Assessment Council (CÉTS) are used to illustrate how HTA activities can influence the regulatory mechanisms operating at each decision-making level. We then discuss the skillful balancing act required from HTA agencies to constantly negotiate the right distance from the regulatory process at which to operate. We propose that HTA agencies should not be incorporated into any regulatory, auditing, or monitoring process. Finally, the relationship between health technology assessment and health care reform is discussed. It is suggested that HTA activities will contribute most during the data-driven preparation and consolidation phases of a reform process. The fast pace of events and the political turmoil characteristic of the implementation phase provide a less receptive environment for HTA contributions.

Keywords: Health technology assessment, Quality of health care, Policymaking, Health care reform

The Quebec Health Technology Assessment Council (CÉTS) was founded in 1988 by a provincial government decree. Its mandate is to produce technology assessment reports, disseminate assessment results and information, and to promote an assessment culture within the health care system (14).

In this paper, we explore the relationship between CÉTS and the regulatory process for medical devices and procedures through four examples of work done in the past years. We then examine the evolving relationship between CÉTS and regulatory organizations using examples that illustrate the necessity for a technology

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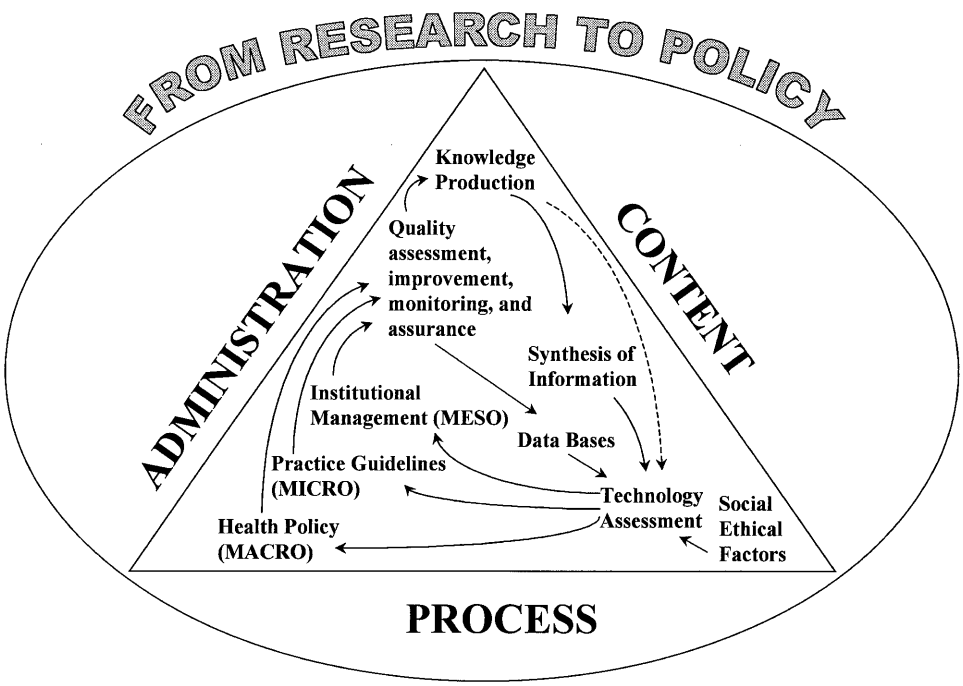

Figure 1. A conceptual framework summarizing the steps involved in translating technical and scientific information into decision making.

assessment organization to negotiate constantly the right distance from the regulatory processes at which to operate. Finally, the complex relationship between health technology assessment and health care reform is discussed.

THE RELATIONSHIP BETWEEN CÉTS AND THE REGULATORY PROCESS FOR THE USE OF MEDICAL DEVICES AND PROCEDURES

Figure 1, an expansion of a diagram published previously (2), presents a useful conceptual framework summarizing the different steps involved in translating technical and scientific information into decision making. This framework is also pragmatic in that it captures the modus operandi of CÉTS. The point of departure of any translational exercise is research or knowledge production. Synthesizing the many products of research has become an activity in and of itself, with its variety of available instruments such as task forces (18), consensus conferences (17), meta-analysis (16), and meta-modeling (12). Major efforts at synthesizing information have been made through the Cochrane Collaboration Centers around the world (3). These syntheses, along with primary data at times and information from databases, constitute an important input in the more complex technology assessment exercise that will combine this technical and scientific information with a variety of economic, social, ethical, and other context-specific factors in producing reports, the aim of which is to influence decision making by activating regulatory mechanisms.

Mechanisms for regulating the use of devices and procedures include those of a financial, clinical, professional, institutional, and political nature. These mechanisms can operate at the micro level (standards of medical practice), the meso level

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(institutional rules), or the macro level (health policies). CÉTS disseminates its reports to audiences at these three levels. Following the implementation of regulatory decisions, a variety of quality assessment, improvement, monitoring, and assurance activities can be triggered, allowing for the creation of databases and the identification of further research priorities. The content of these activities can be defined differently across jurisdictions (1). Likewise, the administrative infrastructure necessary to carry out these activities varies. However, the ultimate success of this complex itinerary, moving from research to policy, depends on how these activities are linked, a matter of process.

Four examples, chosen for didactic purposes, illustrate the relationship between CÉTS and the various levels of regulation for the use of medical devices and procedures: a) screening for prostate cancer; b) contrast media; c) reuse of hemodialyzers; and d) laparoscopic cholecystectomy. Indeed, while the sale of devices in Canada is regulated by the federal government, their use is subject to provincial regulations. Hence, provincial technology assessment agencies such as CÉTS can have a notable impact on regulatory mechanisms affecting use of technology. A more comprehensive evaluation of the impact of CÉTS on the Quebec health care system is provided elsewhere (14;15).

Screening for Prostate Cancer

This report, published in 1994, following a request from the Minister of Health and Social Services, examines the benefits, risks, and costs of prostate cancer screening (10). It documents the accuracy of the prostate-specific antigen (PSA) test in over- and underdetecting fatal prostate cancers. It then looks at the evidence of effectiveness of treatment (mainly surgical) of prostate cancer, quantifies the side effects of treatment, and presents data on the costs of a screening program. Additional information on the prevalence and incidence of the disease, as well as the state of diffusion of this screening practice in Quebec, is also presented. The report established that a provincewide prostate cancer screening program would not be useful. It also indicated that patients should be informed of the risks and benefits of screening before undergoing the test.

This technical document led to the development of clinical practice guidelines on prostate cancer screening. Indeed, a special Task Force on Clinical Practice Guidelines was established three years ago with the participation of the College of Physicians of Quebec, CÉTS, the General Practitioners and Specialists Unions, the Medical Council of Quebec, the Association of Public Health Physicians, the Association of Hospital-based Physicians, and the Deans of Medicine. A subcommittee of this task force formed of family physicians, urologists, public health specialists, and lay persons produced guidelines on prostate cancer screening released by the College of Physicians in the spring of 1998 (4). An evaluation of the impact of these guidelines on practice is ongoing.

This example illustrates the impact of the CÉTS document on three levels of regulation. At the health policy or macro level, the document has enabled the Ministry of Health and Social Services to decide not to launch a provincewide screening program. At the micro level, clinical practice guidelines have been developed and widely disseminated to physicians and patients. Although to a lesser extent, the document has also been used in at least one institution (meso level) to design a laboratory protocol for the use of PSA testing.

Contrast Media

In the early 1990s, CÉTS produced three documents on contrast media used for radiologic examinations. The first document examined the existing evidence on the benefits and risks of low- and high-osmolar media (5). The second report presented the legal and ethical implications of restricting the use of the more costly low-osmolar media to high-risk patients (6). The third document presented the results of a cost-effectiveness analysis of the issue (8). On the whole, the reports supported a selective-use policy for low-osmolar contrast media. These reports were useful to the Ministry of Health and Social Services in endorsing a selective-use policy for low-osmolar contrast media (macro), to hospitals in adopting utilization rules for contrast media (meso), and to the College of Physicians in developing clinical guidelines (micro) (14). This example illustrates the links between technology assessment and the three levels of regulation when the evidence is convincing, while the context of cost constraints in hospitals creates a receptive environment for the information.

Reuse of Hemodialyzers

CÉTS' report on the reuse of hemodialyzers demonstrated that under the strict observance of a reutilization protocol (sterilization procedures, labeling procedures, and appropriate number of reuses), the reuse of hemodialyzers was safe and efficient (7). After diffusion of this report, practitioners (micro) and hospitals (meso) developed and implemented reuse protocols in their hemodialysis units to varying degrees (15). Furthermore, reusing the hemodialyzers for the same patient reduces clinical uncertainty by eliminating some allergic reactions, referred to as "first-use syndrome." This example illustrates links with two levels of regulation. In this case, although the scientific evidence is reasonably convincing, it is not devoid of controversy. Hence, the adoption of the recommendations varied according to the existing institutional and professional cultures and practices of hemodialysis.

Laparoscopic Cholecystectomy

The first CÉTS report on laparoscopic cholecystectomy concluded that the procedure was safe and efficient (9). However, there was a large increase in the procedure rate (24%) a few years later as clinical indications for the procedure appeared to be widening. A second report was published and raised the question of the observed increase in health care spending attributable to a total increase in the number of procedures, even though the procedure itself was more efficient (11). This document alerted decision makers (macro) to the necessity of encouraging clinicians to further refine utilization guidelines for this procedure (micro) (15). However, in this case, easy access to the procedure, increased convenience for the patients, and newly found interest for the operators outstripped the boundaries of scientific evidence and accelerated the diffusion of this technology.

Figure 2 summarizes the four examples. In all four examples, we clearly see that the roles of CÉTS and regulatory entities are distinct. While the input for regulatory actions was produced and disseminated by CÉTS, the actions themselves did not emanate from CÉTS.

THE EVOLVING RELATIONSHIP BETWEEN CÉTS AND THE REGULATORY PROCESS FOR MEDICAL DEVICES AND PROCEDURES

The operational distance between CÉTS and the regulatory actors has been put to a test in the past year. In effect, the information produced by CÉTS is increasingly

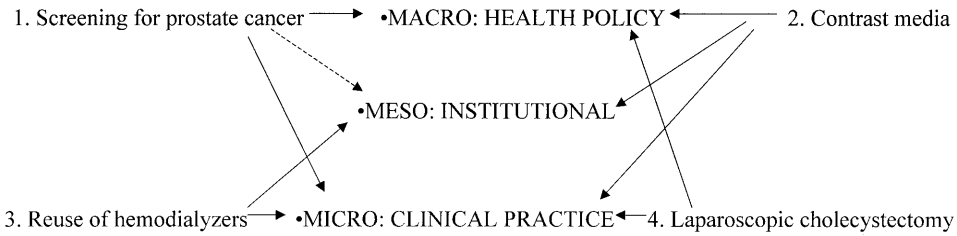

Figure 2. Four case studies and the three levels of regulation.

sought after. In a certain sense, CÉTS is victim of its own success. The following examples of CÉTS' increasing collaboration with regulatory bodies illustrate why and how this collaboration can be risky or could even result in collision.

Political/Health Policy Level (Macro)

Requests by the Health Insurance Board. CÉTS reports can be used for reimbursement decisions. In effect, the Health Insurance Board (RAMQ) is requesting advice from CÉTS more often on the reimbursability of particular devices or procedures. For example, two requests for assessment were made with regard to magnetic resonance spectroscopy and thermography. For both cases, RAMQ wanted to know the technological status of their different diagnostic applications. The defined status, which could be experimental, innovative, or accepted, would directly influence the coverage decision. Although CÉTS will never be directly responsible for coverage decisions and fee setting, an increased activity in response to requests from RAMQ could eventually modify the perception of CÉTS among the other actors in the system, identifying CÉTS as being more closely related to these coverage decisions.

Blood System Monitoring Committee. In the wake of the Canadian blood contamination scandal and the Krever Commission report, a major overhaul of the blood system is under way (13). CÉTS was invited to join a special committee created to monitor the quality and safety of Quebec's blood supply system. The Council decided not to partake in the committee in order to retain its independence and remain in position to offer useful contributions on blood issues in the future.

Institutional/Management Level (Meso)

Evaluating the Performance of Hospital and Ambulatory Services. A lot of attention is presently being focused on the necessity to create a comprehensive system for evaluating the performance of hospital and ambulatory services. At present, such activities are occurring at a variety of levels, including the Ministry of Health and Social Services, the Regional Boards of Health (Quebec has 18 boards), and the Quebec Hospital Association. CÉTS has been asked to consider participating in this evaluation process. This issue, although important, is complex. A distinction must be made between developmental activities leading to the production of performance indicators and/or instruments and the application of these instruments to monitor the performance of institutions. Although CÉTS would consider an involvement in the development of such measurement instruments, their application and the monitoring process should be left to the Ministry and/or the Regional Boards. Nonetheless, the border between instrument development

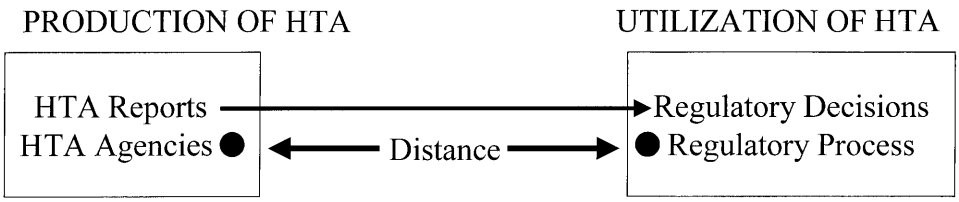

Figure 3. Role of HTA agencies in the regulatory process.

and monitoring can be fuzzy. Any involvement of CÉTS on this terrain will require clarification of its role and its limits.

Links with University Health Centers. CÉTS is engaged in discussion with five major university health centers (UHCs) on how to promote and implement technology assessment within UHCs. Although CÉTS is offering its expertise and participating in the discussions, its intention is to avoid formalizing links with the hospitals. Historically, many UHCs were already assessing technology, especially major equipment, with the main purpose of guiding decisions about their acquisition. However, UHCs may contribute further to the production of assessment information about new technologies as long as this activity remains related to their teaching and research functions. UHCs have to discover their specific niches in HTA, but CÉTS is determined to act as a catalyst in this endeavor. For example, it could provide methodological support, assume a clearing house function, or even develop joint projects.

Clinical Practice Level (Micro)

Links with the College of Physicians and Physicians' Unions. As mentioned earlier, CÉTS collaborates with the College of Physicians and Physicians' Unions through a special Task Force on Clinical Practice Guidelines. However, this precludes a direct involvement of CÉTS in the college's auditing function with regard to the clinical and ethical practices of its physician members.

These examples underscore the fact that the evolving relationship of CÉTS with the regulatory process requires a fine balancing act. Indeed, as CÉTS gains notoriety in the Québec Health System, it is being asked to participate in activities that go beyond its initial narrowly focused mandate, bringing it closer to the decision-making levers in the system. By carefully considering each request and understanding what its contribution could be, CÉTS has expanded its effective influence on decision makers without compromising its overarching objective of providing valid information. Nonetheless, such expansion of the scope of activities to which CÉTS agrees to participate requires a careful management of the evolving perception (and not only content) of its role by all the actors of the health system. Although the information produced by technology assessment can be widely used in regulatory decisions, HTA agencies should not be incorporated into any regulatory, auditing, or monitoring process. As shown in Figure 3, finding the right distance between technology assessment and regulation is the constant challenge for assessors and decision makers. Furthermore, the relationship between health technology assessment and the regulatory process for medical devices and procedures is very dynamic, especially in the context of health care reforms being introduced around the world.

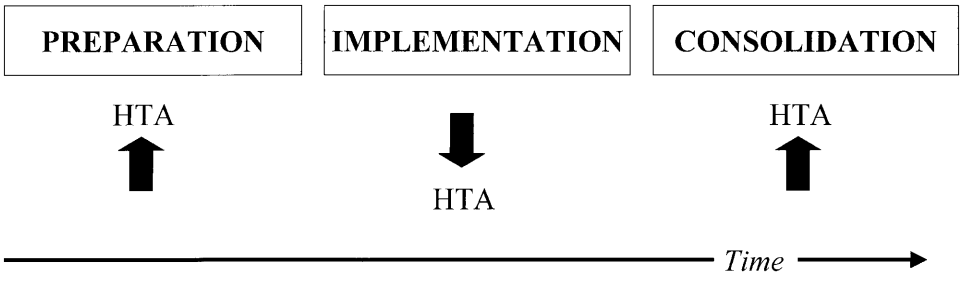

Figure 4. Three stages of health care reform.

TECHNOLOGY ASSESSMENT AND HEALTH CARE REFORM

The role of technology assessment in health system reform must be understood in relation to the three stages of a reform process which are preparation, implementation, and consolidation (Figure 4).

The Stage of Preparation

The incubation period for a health care reform can be long. During that stage, task forces and special commissions are often created with mandates to produce orientation papers and scenarios for change. In this stage, technology assessment organizations can be of great use in contributing technical documents to the overall discussion. An ongoing example is the involvement of CÉTS in helping the health system properly map its future course in the area of genetics. For the past several years CÉTS has supported a specially dedicated research team in producing monographs on the use of genetic tests. In addition, an expert committee created by CÉTS assists the research team and examines a variety of issues related to the offering of genetic services.

The Stage of Implementation

After the preparatory phase, health care reform usually enters an accelerated and politically driven phase of change. Reforms usually occur in a context of political turmoil and chaos, with interest groups being challenged and decisions being made at an accelerated pace. In this environment, technology assessment organizations will find it difficult to follow the pace of events and should remain in the background during this chaotic and politically intense time. For example, during the difficult period in which hospitals were closed in Québec, CÉTS carried on a variety of projects unrelated to this phase of the reform.

The Phase of Consolidation

Health care reform usually puts in place a series of mechanisms that will be very receptive to the type of technical and scientific information produced by technology assessment organizations. In this phase, technology assessment regains its usefulness because decision makers and clinicians will be responsive to HTA information. Several ongoing studies on ambulatory and mental health services illustrate how CÉTS contributes to a reform plan aimed at establishing a better balance between hospital and ambulatory services.

Furthermore, it is important to understand the context in which reform is occurring. Indeed, in a context of rationalization, in which restructuring is occurring but without a sizeable decrease in resources, technology assessment could more

easily contribute useful information to policy decisions. However, a context of severe rationing, in which restructuring is accompanied by massive decrease in resources, might hinder the very usefulness of technology assessment. In the first case, technology assessment can contribute useful input for the fine-tuning of decisions. In the second case, budget cuts can be so drastic that they preclude any useful contribution by technology assessment. The different contexts may determine whether technology assessment will synergize (usually in a context of rationalization), collude, or collide (in a context of rationing) with the regulatory process, depending on whether the information produced will support or run counter to cost-cutting actions taken.

CONCLUSION

The relationship between health technology assessment and the regulatory process for medical devices and procedures is complex. The potential for synergy, collusion, or collision between technology assessment and regulation will be a function of the context in which decisions are made and the state of progress of health care reform. The art of technology assessment lies in its capacity to establish productive links with researchers on the one hand and consumers of this information or decision makers on the other hand. Finding the right distance between technology assessment activities and regulatory processes is a major challenge that needs to be attended to in each jurisdiction and, within a specific jurisdiction, for every issue being examined by a technology assessment organization. Some of the work of CÉTS illustrates the complexity of these linkages. Ongoing discussions between CÉTS and its partners testify to the creative tensions that must exist between technology assessment organizations and those more directly involved in regulating the system. The consolidation of the role of technology assessment in health systems will depend on our ability to continue walking this tightrope as professional funambulists.

REFERENCES

1. Battista, R. N., Banta, H. D., Jonsson, E., Hodge, M. J., & Gelbland, H. Lessons from eight countries. *Health Policy*, 1994, 30, 397–421.
2. Battista, R. N., & Jacob, R. Evaluation and regulation of the health-care system: The inescapable challenge. *Annals of the Royal College of Physicians and Surgeons of Canada*, 1994, 27, 464–68.
3. Bero, L., & Rennie, D. The Cochrane Collaboration. Preparing, maintaining, and disseminating systematic reviews of the effects of health care. *JAMA*, 1995, 274, 1935–38.
4. Collège des médecins du Québec (CMQ). *A few thoughts before having a prostate cancer screening test*. Montreal: CMQ, 1998.
5. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *Evaluation of low osmolar vs high osmolar contrast media.* Montreal: CÉTS, 1990.
6. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *Access to low osmolar contrast media: Legal and ethical considerations*. Montreal: CÉTS, 1990.
7. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *Hemodialyzer reuse: Considerations of safety and costs.* Montreal: CÉTS, 1991.
8. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *Evaluation of low osmolar vs high osmolar contrast media in general radiology: Update*. Montreal: CÉTS, 1992.
9. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *The cost of conventional cholecystectomy, laparoscopic cholecystectomy and biliary lithotripsy*. Montreal: CÉTS, 1993.

10. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *Screening for cancer of the prostate: An evaluation of benefits, unwanted health effects and costs.* Montreal: CÉTS, 1995.
11. Conseil d'évaluation des technologies de la santé du Québec (CÉTS). *The introduction of laparoscopic cholecystectomy in Quebec: Effects on intervention rates and resource utilization*. Montreal: CÉTS, 1995.
12. Eddy, D. M., Hasselblad, V., & Shachter, R. An introduction to the Bayesian method for meta-analysis: The confidence profile method. In A.C. Gelijns (ed.), *Modern methods of clinical investigation.* Washington, DC: National Academy Press, 1990, 101–16.
13. Health Canada: Report of the Krever Commission. *Commission of inquiry on the blood system in Canada*. Ottawa: Health Canada, 1997.
14. Jacob, R., & Battista, R. N. Assessing technology assessment: Early results of the Quebec experience. *International Journal of Technology Assessment in Health Care*, 1993, 9, 564–72.
15. Jacob, R., & McGregor, M. Assessing the impact of health technology assessment. *International Journal of Technology Assessment in Health Care*, 1997, 13, 68–80.
16. L'Abbé, K. A., Detsky, A. S., & O'Rourke, K. Meta-analysis in clinical research. *Annals of Internal Medicine*, 1987, 107, 224–33.
17. McGlynn, E. A, Kosecoff, J., & Brook, R. H. Format and conduct of consensus development conferences. *International Journal of Technology Assessment in Health Care*, 1985, 11, 1087–89.
18. Woolf, S. H., Battista, R. N., Anderson, G. M., Logan, A.G., Wang, E., & the Canadian Task Force on the Periodic Health Examination. Assessing the clinical effectiveness of preventive maneuvers: Analytic principles and systematic methods in reviewing evidence and developing clinical practice recommendations. *Journal of Clinical Epidemiology*, 1990, 43, 891–905.