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Could New Regulatory Mechanisms Be Designed after a Critical Assessment of the Value of Health Innovations?

by

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Highlights

- The last 20 years have seen numerous clinical and organizational innovations in the health sector.
- These innovations are transforming not only the nature of care and the way it is dispensed, but also the expectations of the population.
- While there have been efforts to impose a rational approach by means of health technology assessment, that approach nonetheless leads to some difficult choices. What proportion of our collective resources are we prepared to invest in increasingly specialized and costly services? How can we ensure that access to these services remains equitable and fair?
- This paper develops the idea that a new way of regulating the design, management and use of technology has to be adopted, and proposes a new role for the federal government.
- It is not only relevant but necessary for the state to contribute more actively to the development of new technologies that can help reduce cost pressures and meet health needs.
- The main objective of this study is therefore to reformulate the issue of technology costs so as to identify some new regulatory solutions.
- The objective of the first part of the study is to analyse the tensions between the market value of technologies (i.e. their return once they are introduced on the market), their clinical value (what they allow clinicians to know and do) and their social value (the positive and negative changes they can bring).
- The second part stresses the importance, for the federal government, of creating “upstream” regulatory instruments that can influence R&D processes and the adoption of innovations, in order to promote the marketing and utilization of technologies that more clearly contribute to the collective well-being.
- The paper closes with three series of recommendations aimed at: (1) promoting innovation; (2) managing better the complexity of technologies; and (3) consolidating technology assessment.

Executive Summary

Introduction

Researchers who have attempted to address the issue of the cost impact of technologies have encountered some formidable conceptual and empirical difficulties. Because the nature, role, operation and effects differ greatly from one technology to another, it is impossible to measure their overall present or future impact on costs. This paper attempts instead to develop a rigorous and useful analysis by responding to the following question: Could the design of new regulatory instruments benefit from a critical assessment of the value of innovative technologies and processes? The study is supported by a body of multidisciplinary literature, and emphasizes the importance of R&D activities that take place “upstream” from clinical adoption of technologies.

This particular approach is based on three observations: (1) the value of technology is often defined from a narrow perspective which measures costs and clinical outcomes only; (2) while there have been efforts to impose a rational approach to the adoption of technologies, including by means of health technology assessment (HTA), that approach nonetheless leads to some difficult choices; and (3) it seems necessary to renew our regulatory instruments by expanding the structures for public deliberation, as the issue of the proper use of technology has to be discussed in the public arena and not just within expert groups.

Part 1: Redefining the Value of Technology

From a commercial standpoint, technologies generate revenues for professionals, manufacturers and distributors. From a clinical standpoint, they give physicians greater capacity for action by generating knowledge and making treatment of the human body possible. From a societal standpoint, technology affects the redistribution of costs and benefits among social groups and transforms expectations about health care systems.

The tensions observed between “innovation” and “regulation” seem significant enough for us to take a very close look at how consistent the economic and clinical contributions of technologies are with their social value. Do technological developments that are increasing the diagnostic and therapeutic capacities of clinicians correspond to specific health needs? Do we know exactly what the population and patients want? Are those desires reasonable and legitimate in light of the distribution of collective resources and the social transformations that they imply? In the years to come, the role of HTA will be increasingly important. It will not be possible to fully execute that role unless analysts can succeed in estimating the “real cost” of technologies and unless they can clarify the social debate while including the notions of ethics and fairness.

Part 2: Rethinking the Instruments of Technology Regulation

At the federal level, three types of policies influence technologies: (1) commercial policies affect the funding and establishment of companies primarily involved in the medical equipment field; (2) R&D policies can promote the development of specific technology niches that transform health care services; (3) health policies have a more direct impact on the supply of

health care, especially those regulating the entry on the Canadian market of equipment and drugs.

To date, however, there seems to have been relatively little effort toward harmonizing these policies. There is even reason to ask whether they are not “schizophrenic”. Since the processes for designing and marketing medical innovations directly affect the nature, cost, usefulness and relevance of these technologies, it seems increasingly urgent to co-ordinate provincial and federal technology development policies with those aimed at rationalizing health services. The federal government has to revise (if not reinvent) its role in technology regulation. It would seem not only relevant but necessary for the government to be able to help define the “concrete problems” of our health care systems. A greater contribution to the piloting of R&D projects should encourage the development and distribution of technologies that reduce cost pressures and respond to health needs.

Recommendations

Recommendation 1: Encourage innovation where it matters for the Canadian population. National and provincial departments of health can play a greater role in R&D activities in order to target sectors where there are few or no therapeutic options and where more cost-effective technologies could be developed.

Recommendation 2: Manage the complexity of technological systems. The technological developments we are witnessing are of unprecedented nature and scope. We must review the ways in which we acquire, finance, manage and use health technologies. It is important to define an organizational framework encompassing all of the elements for offering safe, effective and quality care.

Recommendation 3: Enhance the process of rational assessment by organizing structures for public deliberation. A culture that adopts a critical stance toward technology can contribute to better use of technologies by clinicians and patients and to better public policies. The social and ethical issues surrounding new technologies require that structures for public deliberation be put in place.

Conclusion

The issue of the cost impact of technologies may well remain on the agenda of provincial and federal governments for decades to come. Nothing indicates that our health care systems have reached a state of balance with respect to structural and technological change. One is even tempted to venture the opposite. This paper proposes a new role for the federal government, that being to pilot the development of technologies that are more efficient and more socially legitimate. It seems useful to pay closer attention to the financial, legal and commercial instruments that would allow manufacturers and distributors to benefit from producing technologies that, instead of magnifying the negative effects of budget constraints, could more clearly contribute to the collective well-being.

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Biographical Note

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Pascale Lehoux takes theoretical models from the social sciences and uses them to analyse the organizational, professional and social dimensions of health technologies. She has published on information technologies (automated medical records, telemedicine) and technologies used at home (oxygen therapy, IV antibiotic therapy, parenteral feeding, etc.). She helped design and is co-ordinating the implementation of an International Master's Program in Health Technology Assessment, a joint project of five Canadian and European universities (University of Montreal, McGill University, Ottawa University, Catholic University of Rome, and University of Barcelona) and five technology assessment agencies.

Introduction

This paper was prepared at the request of the Commission on the Future of Health Care in Canada. The following question was submitted to the author: How will diagnostic and therapeutic technologies and procedures drive costs in the foreseeable future? The Commission also submitted a series of specific questions aimed at identifying technologies that may have an influence on health care and costs, the extent to which the cost of these technologies would be offset by a reduction in required services, and how expenditures could be controlled (see the Appendix).

The Question Addressed in this Paper

Researchers who have attempted to address the issues raised by the Commission have encountered daunting conceptual and empirical difficulties (Chernew, Hirth, Sonnad et al. 1998; Ahrens 1998; Boldy and Lewis 2000; Bryan, Buxton and Brenna 2000; Rettig 1994). First, the word “technology” refers to many very different things, from implants to medical imaging to surgical technology. Next, while it is possible to demonstrate that a particular technology can, under specific conditions, generate cost savings, it is still extremely risky to generalize from such conclusions to other organizational contexts and other technologies. Finally, the time frame in which the costs and benefits of a technology are measured has a considerable impact on the findings. In other words, because the nature, role, operation and effects differ greatly from one technology to another, it is impossible to measure their overall impact on costs. Only a comparative empirical approach could identify relatively robust dynamics, analysing them within a typology of economic impacts. To our knowledge, this exercise has been attempted at least twice (Mohr, Mueller, Neumann et al. 2001; AHQ 1989). Such an exercise can give us a better understanding of the ways in which technologies reduce or increase certain costs (days of hospitalization, emergency visits, etc.), but does not allow us to propose new ways of regulating access to these technologies. Furthermore, it was not possible to conduct empirical analyses in the context of this study.

Therefore, in order to develop a rigorous and useful analysis of the issues raised by the Commission’s questions, we first decided to reformulate them from a broader perspective: Could the design of new regulatory instruments benefit from a critical assessment of the value of innovative technologies and processes? Then, to enrich the discussion, we chose to tap a body of multidisciplinary literature, including the analytical frameworks from the field of sociology of innovation (Akrich 1994), and emphasize the importance of R&D activities that generally take place “upstream” from clinical adoption of technologies. Our decisions are supported by three observations that are both personal and empirical.

Three Aspects of the Technology Issue

First, in the course of our research projects, it has become clear that the value of technology is often defined from a narrow utilitarian perspective that measures costs and clinical outcomes only (survival, objective measurement of functional capacities, diagnostic precision), assuming in principle that those outcomes are beneficial or desirable. Such a perspective is in contradiction

with sociological analyses which indicate that the population as well as affected patient groups are more interested in the practical consequences of treatments (quality of life, autonomy, after-effects) and their ethical significance (e.g. why screen or diagnose if treatment is not possible?) (Blume 1997; St-Arnaud 1996, 1999; Heitman 1998). Hence the importance of expanding the discussion on the value of technologies beyond their clinical and economic outcomes (Giacomini, Cook, Streiner et al. 2000).

Second, the growing complexity of “technological systems” is very often underestimated, causing us to ignore their “real cost”, to mismanage their use and replacement, and to not exploit their full potential (Casey 1998; Patton 2001). This latter observation is closely related to our training in industrial design, which prompts us to take a closer look at how technologies are understood, managed and used in the real world. It is critical that we rid ourselves of an idealized conception of technologies which holds that acquiring them is all that is necessary to be able to benefit from them. Technology historians insist on the major changes that have occurred over the last 20 years (Tenner 1996; Rip, Schot and Misa 1995). They say that we are no longer mere manipulators of tools whose immediate results can be observed and controlled, but managers of “portions” of technological networks whose ramifications and scope far exceed the skills of a single occupation or profession. The result is a situation of great interdependence where a series of distinct, specialized skills are required to introduce, maintain and utilize technologies (Casey 1998). The latest report of the Auditor General of Quebec (2001) refers to this systemic complexity when it confirms that existing radiology equipment has not been appropriately managed, that many pieces of equipment are obsolete or not used for lack of human or financial resources to operate them, and that public health is being compromised as a result.

Third, while efforts have been made toward a more rational adoption of technologies, including by means of health technology assessment, that approach nonetheless leads to some difficult choices. What proportion of our collective resources are we prepared to invest in increasingly specialized and costly services? Is judicious funding and regulation of technology use possible? How can we ensure that access to these services remains equitable and fair? These questions cannot be resolved solely by evaluating the effectiveness, safety and cost of technologies; they also require an examination of the ethical and socio-political aspects that accompany technological change (Cookson and Maynard 2000; Lehoux and Blume 2000). In this paper, we therefore stress the need to renew regulatory mechanisms by expanding forums for public deliberation, since the issue of the proper use of technology has to be discussed in the public arena and not just within expert groups – which are and will be increasingly subject to pressure from such stakeholders as medical professional bodies and the biomedical equipment industry (Jasanoff 1990; Cozzens and Woodhouse 1995; Giacomini 1999; Faulkner 1997).

Study Design

In attempting to clarify and articulate these three observations, the study develops the idea that a new way of regulating the design, management and use of technologies must be adopted, and proposes a new role for the federal government. The objective of the first part of the study is to analyse the tensions between the market value of technologies (i.e. their return once they are introduced on the market), their clinical value (what they allow clinicians to know and do) and

their social value (the positive and negative changes they can bring). The second part stresses the importance, for the federal government, of creating new “upstream” regulatory instruments that can influence R&D processes and the adoption of innovations, in order to promote the marketing and utilization of technologies that more clearly contribute to the collective well-being. The paper concludes with a series of recommendations aimed at promoting innovative activities within a joint cross-sectoral approach, with the objective of reconciling the market, clinical and social values of technology.

Part 1: Redefining the Value of Technology

From a commercial standpoint, technologies generate revenue for professionals, manufacturers and distributors. This largely explains the pressure exerted for their adoption and utilization (Gelijns and Rosenberg 1994; Cookson and Maynard 2000). From a clinical standpoint, they give physicians greater capacity for action by generating knowledge (diagnostic capacity) and permitting intervention on the human body and its physiological functions (therapeutic capacity) which influences the health or quality of life of patients. It is relatively rare for a new technology to produce clinical outcomes that are not considered “promising” by the clinicians concerned (McKinley 1981; Goodman and Gelijns 1996; Rothman 1997). From a societal standpoint, technology affects the redistribution of costs and benefits among various social groups and transforms expectations about health care systems.

It is argued in the following pages that, while assessment allows to determine more precisely the clinical value of innovations, it very often obscures their market value and hardly provides an analysis of their social value. It is important to better define these last two aspects in order to consolidate the role of assessment in decision making and develop effective regulatory instruments.

Technologies as Means of Transforming the Human Body and the Health Care System

Health technologies are attracting media attention and prompting numerous controversies. There have been major breakthroughs in many fields, transforming the relationship with the human body and the health care system. Imaging technologies now make it possible to intervene at earlier stages. Genetic testing can predict disease development at the foetal stage. Tissue engineering can reconstruct the human body from hybrid materials (half -human/animal and half-artificial) (Hogle 2000). Some of these innovations make certain practices technically possible although they remain socially questionable (cloning, “patenting life forms”, use of stem cells in research, heterografts, etc.). Indeed, the turn of the millennium has very clearly been characterized by major technological developments concurrent with the need to introduce ethical guidelines and legal rules to prevent things from getting out of hand (Daniels 1993; Callahan 1990). It is in a context of tension between “innovation” and “regulation” (Rip, Schot and Misa 1995) that most medical technologies are being developed and adopted.

In more concrete terms, there are six major sectors where rapid and important developments are noted in the literature. (1) With the advent of informatics and the development of by-products from defence technologies (such as ultrasonography), there has been an increase in medical imaging possibilities (Blume 1992). Because they use different imaging processes, magnetic resonance, positron-emission tomography and axial tomography yield different information. As a result, they cannot easily be substituted for one another. (2) More and more telehealth projects using videoconferencing or digital data transmission by Internet, telephone line, optical cable or satellite are being introduced in different health care sectors, including home care. In addition, information systems are transforming the management and storage of administrative clinical data and information sharing among facilities. (3) The biotechnology sector, which encompasses

various classes of innovations, is in full expansion. The best-known applications are: Apligraf™, an artificial skin cultivated from the patient's cells, whose uses include the treatment of major burn victims and was authorized in 1999 by the FDA; and Carcitel™, a cartilage which prevents or reduces the effects of bone ageing and improves the healing of fractures (Hogle 2000).

(4) Vaccines have helped to eradicate many infectious diseases, but research in the field is continuing, aimed at diseases thus far considered chronic (such as Parkinson's). (5) Research on new materials and micro-electronics has made it possible to design implants such as ventricular aids for heart disease patients, or cochlear implants which restores certain auditory functions in deaf persons. (6) Finally, medications are administered by increasingly varied and enhanced devices, such as patches, programmable pumps and inhalators, with more refined pharmacological action.

All of these innovations are being used in an organizational context that is becoming ever more diverse. Hence the necessity, in the assessment field, of introducing the concept of modes of intervention or treatment. Not only are the new technologies means of treatment, but they lead to new care delivery models, as in the case with non-intrusive surgical techniques. Some of these enable surgeons to operate using local anaesthetics in out-patient clinics, while others reduce patient convalescence time. The home care sector is booming thanks to devices that are lighter, more compact and more mobile, not to mention easier to use, to the point that patients are becoming their primary users (mechanical infusion devices to administer antibiotics, oxygen concentrators, remote monitoring systems for diabetes, heart disease or high-risk pregnancies). For a growing number of congenital diseases or defects, several prenatal tests are available, including genetic screening. This is a controversial service offering, since the "treatment" generally proposed to pregnant women is abortion. A great future is being predicted for gene therapy, which is said to make possible early intervention *in utero*, although significant results have yet to be seen. Finally, while organ grafts have been a reality for some time now, there is controversy over the possibility of procuring organs in economically disadvantaged countries and of using animals for this purpose.

In summary, the last 20 years have seen numerous clinical and organizational innovations in the health care sector. They are transforming not only the nature of care, the ways it is provided and the flows of private and public spending, but also the expectations of the population (Bastian 1998).

Can We Put a Figure on the Impact of Technology on Health Spending?

Since the late 1970s, the impact of technologies on health expenditures has generated a fair amount of literature (Chernew, Hirth, Sonnad et al. 1998; Ahrens 1998; Boldy and Lewis 2000; Bryan, Buxton and Brenna 2000; Rettig 1994). It is difficult to quickly summarize this material since authors adopt different analytical perspectives and do not measure economic impacts in the same way. Should we focus solely on the cost of new technology and assume *substitution* effects? In other words, should we postulate that use of this technology renders previous forms of patient management obsolete? Should we include the cost of *complementary* services generated by the use of technology? This applies particularly to the medical follow-up, testing and treatment required by patients who have been *treated* by means of new technology but not

necessarily *cured*. What about technologies used in the context of a new *model* of service organization? For example, the measurement of costs associated with technologies used in out-patient and/or home care services raises certain methodological challenges: (1) we must ensure that the costs of all components of the intervention are captured (pre- and post-operative, telephone follow-up, information management, costs borne by patients, etc.); and (2) to be able to generalize from the outcomes, we must next ensure that these models are fully implemented (personnel training, monitoring tools, care protocols, patient selection, etc.) (Coyle, Davies and Drummond 1998; Jonsson and Husberg 2000; Arno, Bonuck and Padgug 1995). Furthermore, it is often found that increasing recourse to the out-patient method, while potentially reducing the unit cost of interventions, increases the intensity and volume of hospital services, and consequently total expenditures (Chernew 1998). Gelijns and Rosenberg (1994, p.42) identify three main mechanisms by which costs are affected by technology use: (1) increased intensity of interventions (the “technological imperative”); (2) introduction of new technologies and adaptation of existing technologies for other purposes; and (3) expansion of therapeutic and diagnostic information.

Generally speaking, the literature supports the idea that technology is one of the main factors behind rising health expenditures. Chernew et al. (1998) recently reviewed this literature as well as studies of the impact of managed care on the adoption of new technologies in the United States. Each of the 11 studies they identified pertaining to the cost impacts of technology concludes that technology has contributed to a substantial increase in expenditures. For example, Newhouse (1992, 1993), adopting a “residual” approach which determines the total increase in health spending while neutralizing the effects of non-technological factors such as inflation, the ageing of the population and increases in personal income, has concluded that technology was the main growth factor in the period following World War II. Peden and Freeland (1995) have estimated that, since the 1960s, 70% of the increase in spending has been attributable to the development and distribution of medical technologies, which they claim were largely induced by the deployment of health insurance (on this subject, see Danzon and Pauly 2001). The studies listed by Chernew et al. that have adopted an “affirmative” approach – focussing on the economic impact of a technology used for a specific health problem – have come to similar conclusions (Legorretta, Silber, Constantino et al. 1993; Cutler and McLellan 1996, Lu-Yao, McLerran, Wasson et al. 1993).

Since they associate technology with increased spending, these studies tend to support the view that tighter control over the adoption and use of technology is necessary. However, the review by Chernew et al. (1998) indicates that, even though managed care seems to succeed in containing spending increases, the effects observed may only be transitional, in that the adoption of new technologies has been delayed but not avoided. It is also clear that the choice of technology in an “affirmative” study will have a determining effect on its results. Weisbrod (1991) suggests that, for some pathologies, technology has been able to reduce costs substantially (e.g. the polio vaccine). In a recent issue of *Health Affairs* (September/October 2001), a number of authors go so far as to say that the overall cost of technology development yields health gains that are significant enough to justify an increase in spending. For example, Cutler and McClellan (2001) have observed that in four out of five clinical cases, interventions have yielded benefits outweighing their costs (heart attacks, treatment of underweight babies, depression, and cataracts); only one showed costs equivalent to the benefits generated

(breast cancer). To calculate these benefits, the authors estimate that a year of good health is valued at US\$100,000 (so if expenditures do not exceed that figure, the intervention is considered “cost-effective”). They also argue that people whose lives have been saved or whose health has been restored will make an economic contribution to society by (re-)entering the labour market and spending income. While they recognize the importance of reducing the use of technologies that yield marginal benefits, the authors fear that policies of technology cost containment, including managed care, will be detrimental to the productivity of health care systems over the long term by limiting innovation.

However, nothing indicates that the main issue for health policy is to determine the degree to which technology is responsible for increased spending. The solution probably does not lie in adopting fewer new technologies. It is more important to get a better understanding of the relationship between the nature of the technologies and expenditures, as well as the incentives for the development and use of innovations. Gelijns and Rosenberg (1994) emphasize the need to take a critical look at technological development: “Empirical analyses that *unpack* the forces underlying technological change and its relationship to health care costs are urgently needed to strengthen the basis for future policy making.” Some authors say that the current context is driving manufacturers to develop technologies that help reduce costs (Goodman and Gelijns 1996; Gelijns and Rosenberg 1994; Arno, Bonuck and Padgug 1995). However, if such technologies are deployed in an environment where physicians are given financial incentives to use them, not only is it possible that total expenditures may rise, but there may also be unnecessary and potentially risky treatments. Table 1 below summarizes the impacts that broad technology categories are likely to have on health care spending.

In summary, the clinical value of medical innovations is often difficult to determine, and their contribution to society remains open to debate. On one side, sceptics underscore how much innovations cost. On the other, enthusiasts emphasize their intrinsic value in pushing back the frontiers of medicine. Health technology assessment (HTA) has been a product of this type of confrontation in virtually all industrialized countries.

The Challenge of Assessment: Estimating the Value of Technologies

Since the late 1980s, Canada has enjoyed an excellent international reputation in the field of HTA. Directly contributing to this reputation has been the work of agencies established since the end of that decade in various provinces (BCOHTA, HSURC, AHFMR-HTA Unit, ICES, AETMIS) and at the national level (CCOHTA). HTA is a field of applied, interdisciplinary research oriented toward policy development. It examines the clinical, economic, ethical, legal and social dimensions of the introduction, use and dissemination of technologies and new methods of providing health care (Banta and Perry 1997; Battista, Banta, Jonsson et al. 1994). HTA aims to encourage clinicians, managers and planners to become more rational in their decisions, practices and policies.

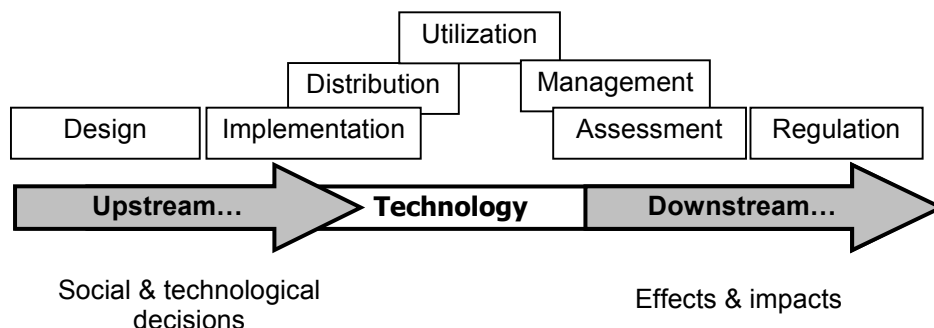
Table 1 Potential Effects of Broad Categories of Technologies on Expenditures and Health			
Categories	Effects on health	Increased expenditures	Expenditures avoided
Prevention (healthy workplaces and neighbourhoods)	Reduction of risk factors / trauma Quality of life	Costs of establishing and monitoring a program	Reduction of mortality/morbidity
Screening	Less uncertainty Timely management	Acquisition costs Costs of establishing and monitoring a program False positives, false negatives	Early treatment likely to reduce mortality/morbidity
Diagnosis	Less uncertainty Timely management	Acquisition costs Low substitution	Timely treatment likely to reduce mortality/morbidity
Non-intrusive surgery	Faster healing/ convalescence Quality of life	Acquisition costs Increased volume of services Complications	Reduction of mortality/morbidity Reduced lengths of stay
Chronic treatment	Reduction of pain, symptoms and disability Quality of life	Recurring costs	Control of mortality/morbidity
Palliative treatment	Reduced suffering	Increased intensity of services	Less aggressive therapy
Technical aids	Minimization of disability status	Recurring costs	Social integration
Drugs (for preventive, curative or palliative purposes)	Healing/control of pain and symptoms Quality of life	Recurring costs if problem is chronic	Control of mortality/morbidity
Home/community care (for preventive, curative or palliative purposes)	Non-institutionalized convalescence Reduction of pain, symptoms Quality of life	Private expenses Recurring costs if problem is chronic	Reduced lengths of stay Institutionalization deferred

Nonetheless, the challenge is a formidable one. On the one hand, the number of technologies that can be submitted for assessment far outstrips the current capacity of these agencies (Battista, Lance, Lehoux et al. 1999; Goodman 1992). On the other, the receptivity of health care decision makers to using this evidence has to be increased and supported by appropriate structures and incentives (Garber 1994; Roberts 1999; Lehoux, Battista and Lance 2000). In other words, there are now tangible achievements in HTA, but they have to be consolidated. That consolidation should rest on two main initiatives.

First, a better conceptualization of health technologies is required (Giacomini 1999; Lehoux and Blume 2000). Figure 1 illustrates a linear model where a technology is developed through successive, incremental phases. Within this model, the assessment cannot really generate rigorous data unless it focuses on the clinical use of the technology, because that is when its effects can best be measured in random clinical trials (Goodman 1992). However, major works in the sociology of technology have clearly demonstrated that formative decisions are made well upstream from this clinical phase (Koch 1995; Rip, Schot and Misa 1995; Latour 1989). The cost of technologies is largely determined by decisions that involve both technical choices (material, functionalities, energy, performance, etc.) and social choices (level of competencies required, clinical information, context of use, etc.) (Callon 1989; Williams and Edge 1996). A more elaborate conceptualization of health technologies should recognize that assessment of R&D activities is just as important, since the time has come to make changes and encourage the development of less expensive technologies (this idea is developed in Part 2: see Shine 1997; Coile 2000). A more elaborate conceptualization should also encourage the use of qualitative HTA research, including case studies that offer more refined organizational analyses and interviews or focus groups that clarify the views of users of technologies (professionals and patients) (Giacomini, Cook, Streiner et al. 2000).

Second, dissemination of HTA projects has to be improved and should target broader groups (Cookson and Maynard 2000; Koch 1995). Patient groups and the general population in particular are still poorly informed about the effectiveness, safety and cost of technologies. The public's main sources of information are the health columns in the popular press, which usually vaunt the promises of medical research or doggedly pursue the funding problems of public health care systems (Rabeharisoa and Callon 1998). The result is an ambiguous situation where the argument of the "demand" for new technologies is used by promoters of technology and clinicians to justify higher spending – and even recourse to private funding – when the distribution of more balanced information on technology might strengthen the role of patients in clinical decisions (Domenighetti, Grilli and Liberatti 1998; Bastian 1998). What do we mean by more balanced information? For instance, when AETMIS assessed the benefits and risks of using antigens to screen for prostate cancer, at a time when this practice was spreading rapidly, a special section was developed to clarify the potential effects on men (impotence, incontinence)

Figure 1
Traditional Conception of Technology Development



and the likelihood of their occurrence (CETS 1995). In addition, the report clearly explained the important epidemiological concept of overscreening to make clear to readers that instead of dying *of* this cancer, the large majority of men afflicted by it will die *with* this condition. This sort of knowledge allows for a more critical estimate of the social value of a technology.

In short, HTA can play an important role in rationalizing the use of technology. However, it will be necessary both to refine its analytical framework and to increase the dissemination of its results. The objective is to develop a general culture that is more critical of technology promises.

Wanting Innovation, Underestimating the Risks and Demanding Perfection

Why should we adopt such a critical attitude? Is it not a disguised way of supporting certain forms of rationing? Even of trying to curb innovation? A review of the initial objectives of HTA and a brief analysis of the current situation should clarify this call for a culture of questioning.

When the Office of Technology Assessment (OTA) was created in the United States in the early 70s, technology assessment was deemed relevant because of the need to know the risks for patients of certain forms of treatments (also for healthy individuals, for screening tests). It must be remembered that the introduction of X-rays in the early 20th century – before the risks of radiation exposure were known – generated rather high mortality and morbidity (Blume 1992). Not until the 1980s did the notion of effectiveness truly begin to take shape and the methodology of randomized clinical trials became grounded in medical research (Koch 1995). During this period, studies on regional variations in practices fuelled the idea that clinical decisions were not based on explicit effectiveness criteria. In the 1990s, the advocates of HTA promoted it as one of the best ways to prevent ineffective, unnecessary and harmful technologies from entering health care systems (Marmor and Blustein 1994; Johri and Lehoux, forthcoming). The cost concept was gradually introduced, along with various tools that were supposed to make it easier to compare different therapeutic options for a given disease (cost-effectiveness) or different health programs (QALY, DALY) (Coyle, Davies and Drummond 1998). Finally, at that time, there was a proliferation of initiatives relating to evidence-based clinical practices.

Technological scepticism is thus a feature of a relatively recent historical trend, but one which tends to focus on scientific assessment of the effectiveness, safety and cost of technology. So, during that same period, what was happening on the R&D side? Are ineffective, unnecessary and harmful technologies being put on the market today? A prudent response would be: not many (excluding drugs and medical devices available over the counter). It is probably impossible to provide empirical support for this observation. However, it is becoming increasingly clear from the findings of HTA agencies that current and future medical technology issues cannot be boiled down to a simple, black-and-white choice between adopting and not adopting. The decisions that are required today are much more sophisticated and must be based on varied and ingenious regulatory instruments.

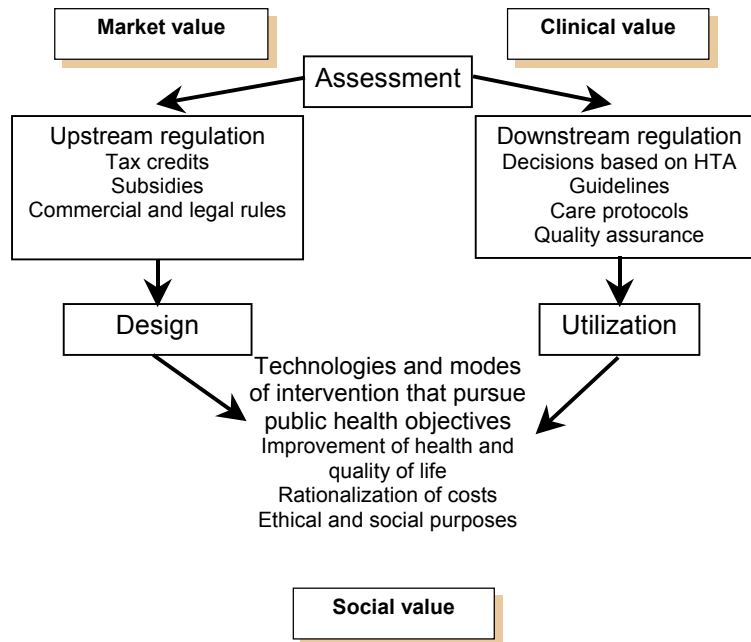
For a growing number of technologies, it is a matter of determining in which clinical and organizational contexts, for which patients and with what level of professional supervision can their use be beneficial. Regulation of this type of practice has to be based on clear guidelines, explicit selection criteria, proven care protocols and appropriate care infrastructures. The complexity of certain technologies demands not only the presence of specialized personnel (such as biomedical engineers, laboratory technicians, genetics consultants or computer specialists), but also adapted infrastructures and effective monitoring programs (for example, a breast cancer screening program requires both equipment that is perfectly maintained, and quality assurance mechanisms). Deployment of specialized technologies in the absence of these types of organizational conditions is tantamount to tacit acceptance of high public health risks.

Furthermore, in many cases, restricting access to patient groups for whom a treatment has been deemed effective raises ethical issues (Nord 1999; Giacomini, Cook, Streiner et al. 2000; St-Arnaud 1999). Can treatment be denied because the health status, age or social environment of the individuals concerned do not meet the ideal conditions for success? How do we respond to patient groups that are demanding faster access to innovations (Barbot 1998)? Finally, some practices, such as assisted reproduction techniques, genetic screening, home telemonitoring and routine testing, seem to be capitalizing on recent social transformations that reveal a close connection between increasing medicalization and the fear of disease together with a quest for the perfect body (Heitman 1998). The more the notion of technological infallibility is reinforced, the higher the expectations of clinical practices. This in a context where the “demand” for technology not only is based on laudatory information sources, but is rather easily manipulated by the proponents of new technologies (Blume 1997).

This brief analysis of the current situation identifies three types of concerns. First, the development of health technologies is greatly encouraged by the fact that they are intrinsically perceived as highly desirable and vehicles of progress. Second, the risks associated with their use are probably more difficult to estimate than was believed at the time that HTA was developed, given that the decision to use them is more complex and requires the establishment of sophisticated regulatory and control structures. Third, it seems paradoxical that public expectations of technology are so high, given the publication of scientific studies and HTA results that show the limits to the effectiveness of technology and that highlight the probabilities of success and side-effects.

Before concluding this first part, it is important to return to our initial question: How can the value of technologies be defined? The links between three dimensions of their contribution seem particularly relevant to this study (see Figure 2). From the federal government’s standpoint, the market value of technologies cannot be concealed. The health technology market has major development potential (Zinner 2001; Quebec, MIC 1987; Canada, CST 1993). It would be naïve to try to regulate access to medical technologies in health care systems (downstream) without examining the incentives for their development (upstream). So there is reason to ask whether medical technology R&D activities supported by the federal government are co-ordinated with the concerns of provincial and territorial health care systems. In other words, is there any coherence between innovative industrial activities and the goals of health care systems?

Figure 2
Reconciling the Three Components of Value of Technologies



Next, the tensions observed between “innovation” and “regulation” seem significant enough to examine, much more closely than has been done thus far, the ways in which the economic and clinical contributions of technologies are consistent with their social value. Do technological developments that are increasing the diagnostic and therapeutic capacities of clinicians correspond to specific health needs? Do we know exactly what the population and patients want? Are those desires reasonable and legitimate in light of the distribution of collective resources and social transformations that they imply? How can these issues be democratically debated? To date, HTA has concentrated on evaluating the clinical effects of technologies and, to some extent, on analysing their costs, but the social, ethical and legal dimensions have received only ad hoc or superficial treatment (Lehoux and Blume 2000). In years to come, the role of HTA will be increasingly important. It will not be possible to fully assume that role unless analysts succeed in estimating the “real cost” of the technologies – including the costs of setting up genuine maintenance and quality assurance programs and systematic strategies for the training and skills maintenance of caregiver teams – and unless they can enrich and clarify a critical social debate, especially about the notions of ethics and fairness (Cookson and Maynard 2000).

Part 2: Rethinking the Instruments of Technology Regulation

Why should we want to link the market, clinical and social values of technologies? First, because the processes for designing and marketing medical innovations have changed dramatically over the years, and directly affect the nature, cost, usefulness and relevance of these technologies. Next, because the issue of containing the costs associated with technology has special significance when formulated so as to grasp the commercial and financial dynamics underlying all the phases of technological development (from upstream to downstream). Finally, because it appears increasingly urgent to co-ordinate federal and provincial technology development policies with those designed to rationalize health services. The second part of the study thus suggests some avenues for the federal government to co-ordinate R&D support activities with technology regulation instruments. The objective is to promote the marketing of technologies that more clearly contribute to the collective well-being.

Are our Technology Policies Schizophrenic?

In Canada, the balance of trade for biomedical equipment is generally negative (Canada, CST 1993). This means that we import more technologies than we export. This “shortfall” has been and remains a recurring argument in federal and provincial science and technology policies for consolidating the industrial fabric and R&D activities of this sector (Canada, CST 1993; Quebec, MIC 1989). More concretely, at the federal level, three types of policies directly affect health technologies. First, commercial policies can influence the financing and creation of firms primarily involved in the medical equipment field (tax credits, entrepreneurship subsidies, international import and export agreements, etc.) (Zinner 2001). Second, policies that aim to support R&D generally can promote the development of specific technology niches that will have the medium- and long-term effect of transforming health care services (biotechnologies, telecommunications, micro-electronics, etc.). Third, health policies have a more direct impact on the supply of health care, particularly those that regulate the entry onto the Canadian market of equipment and drugs (approval, formularies, improvement of technical capacities). To date, however, there seems to be relatively little effort toward harmonizing the effects of these various policies. There is even reason to ask whether some of them are not “schizophrenic”. On the one hand, the government feels obliged to consolidate a profitable and growing industry. On the other, it imposes rigorous measures to control health spending.

How do we go about harmonizing policies that pursue apparently divergent ends (profitability versus efficiency)? Is it possible to promote the development of lucrative firms while limiting their revenues? Does this not amount to squaring the circle (Brown and Brown 2001; Goldstein 2001; Johnson 2000; Levin-Scherz 2001; Smith 2001)? The profit motive is indeed a powerful driver in the design and marketing of medical technologies. The potential number of patients likely to benefit from a technology is naturally an important factor in the decision to innovate in a given technological niche, as is the magnitude of the barriers limiting access to those patients (approvals, patents, competition, reimbursement policies, etc.). We are now seeing developments in the home care sector which, because it is not clearly covered in the *Canada Health Act*, are designed to short-circuit health structures so as to access patients directly. Furthermore, the biomedical equipment industry is clearly more fragmented than the

drug industry (Zinner 2001). It contains big as well as small players. Their medium- and long-term capacity to amortize R&D expenditures, outstrip the competition and win the trust of buyers is highly variable. Equally variable are the human and financial resources they require to bring innovative projects to completion. For this reason, it is conceivable that some firms would be interested in committing to specific R&D projects if the government, in return, would agree to provide them with financial, organizational and commercial support.

The prospect of intervening at the technology design phase is clearly attractive once we accept that it is during that phase that critical decisions to the efficiency of the health care system are made. For example, Christensen et al. (2000) explain why it is helpful to promote the entry on the market of what they call “disruptive technologies”: those that disrupt private preserves in the medical technology market by simplifying both the organizational contexts in which technologies are used and the level of skills required to use them. One obvious example is the development of personal computers. Users do not have to master esoteric programming languages, prices are now more accessible, and they are relatively simple to use. An example in the medical field is the development of low-intensity mobile radiology units. They are inexpensive (10% of conventional radiology equipment) and can be used by non-specialized care providers. According to Christensen et al., this sort of project meets with immense resistance from the giants of medical imaging and clashes with corporate mentalities. Another example deserving of more detailed examination is the technological evolution of the management of diabetics. A series of innovations (injection devices, blood glucose monitors, automated monitoring of physiological parameters) has made it possible to expand the role of patients while simplifying and reducing the procedures and material required. It is entirely possible (if the professional corporations agree to revise certain rules governing reserved procedures) that primary care may become an important locus for the development of “disruptive technologies” that could be used in Canada and exported abroad (including to developing countries).

All the same, how would it be possible, in practical terms, for R&D support policies to be linked to public health objectives so as to produce more efficient technologies that contribute to the collective well-being? Three arguments can be made. First, health economists have made it clear that the dynamics of the health care market do not adhere to conventional postulates of markets regulated by the free play of supply and demand (Evans 1984; Contandriopoulos et al. 1993). “Consumption” of care is very often not a matter of choice. Patients generally do not play an informed role because they largely depend on information transmitted by those who prescribe the services or make the equipment. It therefore seems legitimate for the government to intervene, through public policies, to ensure that manufacturers and distributors of biomedical equipment develop technologies that satisfy more explicit health objectives, as opposed to simply regulating access to those technologies entering the market after being developed.

Second, the dynamics that lead to the production of new technological knowledge and innovation have evolved over the past 20 years. Gibbons et al. (1994) stress the new attributes of what they refer to as Mode 2. This is a process of knowledge production that involves closer interaction between universities, government and the private sector. In this context, the creation of new knowledge is clearly oriented toward solving concrete problems, taking various forms such as the search for market outlets for new processes and emerging technologies, or the development of more efficient social programs. Development of such knowledge would require

the formation of heterogeneous and relatively short-lived teams, capable of sharing and integrating a variety of expertise for specific projects. Such focussing of research activities around concrete objectives would legitimize the contribution of non-academic players to assessing the quality and relevance of research work, which would no longer be judged solely by the traditional disciplinary yardstick (originality in terms of advancement of knowledge, methodological rigour, general applicability of results). Under Mode 2, the fact that knowledge is cross-disciplinary and “contextualized” takes on particular importance and tends to erase the traditional boundary between fundamental research (generally in a single discipline) and applied research. Finally, under Mode 2, knowledge is disseminated through more informal channels, outside of scientific institutions (prestigious journals, conferences for informed publics). If this Mode 2 is as prevalent as Gibbons et al. suggest, it would seem not only relevant but necessary for the government to help define the “concrete problems” of our health care systems and to offer objectives to be achieved for the development of new medical technologies. For example, a greater role for the government in piloting projects under a Mode 2 knowledge production would have the advantage of encouraging the development and distribution of “disruptive technologies” capable of generating savings and responding to certain health needs.

Third, it is clear enough that some health innovations – genetics and tissue engineering being the most visible – will raise major ethical and social issues over the next 20 years. The government’s responsibilities with respect to those issues will be of two kinds: (1) limiting the amount of social drift; and (2) defining public access to certain technologies, whether or not they are included in the basket of insured services (Daniels 1993; Callahan 1990). Although moratoriums have been imposed in various industrialized countries (on cloning, for example), public and private research centres are clearly engaged in a fierce competition to be the first to make major breakthroughs and secure associated royalties (Hogle 2000). Furthermore, national borders are proving easily permeable, since science in these sectors is developing solely by means of networks of international co-operation (Guston 1999). What lessons can be drawn from this? The dynamics that underlie the development of socially ambivalent technologies are at once powerful and complex. It would be naïve to think it is possible to control them totally. These research centres will succeed in obtaining the financial resources required, sometimes outside of control mechanisms. It is also probable that patient groups will become increasingly demanding (with or without direct encouragement from the technology promoters; see Blume 1997; Barbot 1998) in a context where they are presented with solutions to their health problems or where the legitimacy of the government as a third-party payer is compromised. The cost argument cannot be the sole reason used to deny access to technology. The state will have to stand as a credible interlocutor, capable of representing the interests of each of its current and future citizens.

In summary, this analysis identifies three reasons why the federal government must revise (if not reinvent) its role in technology regulation: (1) the negative effects of market incentives on the supply of care; (2) the advisability of intervening in innovation processes so as to orient the nature of technologies and their impact on costs; and (3) the social and ethical issues raised by the scope of modern techno-scientific breakthroughs which demand that a collective position be taken. These reasons should convince us of the relevance of government intervention both “upstream” and “downstream” of technology development, but one important question remains: How can the federal government give concrete direction and support for specific R&D projects in the medical field and promote the appropriate use of technology?

New Policy Instruments for Regulating Innovation

I mentioned earlier that the main issue for technology and health spending is not to control the adoption of the technologies, but to more finely regulate the patients for whom and the organizational clinical conditions under which the technologies should be used. To clarify this change of perspective, we should first summarize the current instruments for “downstream” regulation, and then define the forms that new “upstream” regulatory mechanisms might take.

“Downstream” Regulation

The usual mechanisms for regulating technology use are largely based on professional colleges, specialists’ associations, hospital administrations, payer agencies (physician reimbursement, specific insurers such as occupational health and safety, automobile insurance, offices for disabled persons, etc.) and provincial and territorial health departments (including other administrative levels such as regional boards or councils) (Davies 1999). Table 2 indicates the principal existing mechanisms and offers examples of technologies which, by virtue of their nature and cost level, are candidates for regulation through these mechanisms (Battista, Lance, Lehoux et al. 1999). Very often, to better manage the use of a technology, more than one mechanism has to be applied. Table 2 also indicates the main players likely to influence decisions and contribute to policy implementation. At each of these decision-making levels, there are effectiveness, cost and ethical criteria (accessibility, fairness, principles of beneficence and non-maleficence, informed consent) in play. The overall objective is to guarantee that technologies are used to provide health status gains to those persons who can benefit from them, through competent professionals, within appropriate infrastructures and at an acceptable cost.

As stated earlier, fine regulation of the use of technologies and of the introduction of new modes of treatment will be necessary. This type of regulation assumes that training, guidelines and health protocols will play a more important role. In the home care sector, for instance, intravenous antibiotic therapy can be administered by different means (programmable pump, elastomeric or mechanical devices, gravity). Very often, however, nurses do not have access to protocols issued by professional organizations and mainly resort to “in-house” protocols which vary from one physician or hospital to another and are not systematically updated (Lehoux et al., 2001). In addition, the number of devices available makes it more complicated for nurses to use them (increasing the risk of error), since each one has features that are slightly different (alarms, programming, tube insertion, etc.).

Table 2 Instruments of “Downstream” Regulation		
Decision-making levels	Instruments	Examples
Macro: Provincial departments Interlocutors: Specialists’ associations and institutions	Procurement policy	Distribution of radiology equipment (TEP, magnetic resonance, etc.)
Interlocutors: College of physicians, specialists’/GPs’ associations	Public health policy	Prostate cancer screening program
Interlocutors: Specialists’ associations and institutions	Policy on the organization of specialized care	Organ transplant centres
Meso: Institutions Interlocutors: Specialists	Routine examination policy	Pre-operative chest X-rays
Interlocutors: Hospital programs and patient groups	Reimbursement of equipment used at home	Use of portable oxygen therapy cylinders
Interlocutors: Specialists	Resource utilization policy	Reuse of biomedical instruments (catheters, pacemakers, etc.)
Micro: Clinical practice Interlocutors: Specialists’ associations and patient groups	Reimbursement of medical interventions	Laparoscopic cholecystectomy
Interlocutors: College of physicians, specialists’ associations and patient groups	Guidelines	Breast cancer screening
Interlocutors: Specialists in private practice and patients	None (apart from public information)	Laser vision correction

“Upstream” Regulation

This study suggests that new instruments or mechanisms have to be devised to guide the development of technology and modes of treatment. Such a proposal requires substantial reflection and analysis, which was not possible within the scope of this study. However, the following avenues might be explored. First, in a context of Mode 2 knowledge production, the state’s role should be redefined to ensure that current R&D initiatives support not only the sectors that have commercial opportunities, but above all those that are likely to yield public health and efficiency gains. In telemedicine, for example, there must be currently almost a hundred pilot projects across Canada, to which various governments are making financial contributions. Is it possible to better target the distance services that can be offered and the regions where such services are desirable? How can we ensure that these projects are accompanied by evaluative research that allows us to improve technology decisions and know the conditions under which use of these technologies will be beneficial? A complete analysis of the benefits of projects funded through the Health Transition Fund (HTA), which have featured some of the elements suggested above, should help to identify success factors for this type of initiatives (Joubert 2001).

Second, the market logics that preside over the development of medical technologies impose certain constraints that are detrimental to or limit the marketing of “disruptive technologies.” Indeed, why would firms agree to commit to the production of technologies likely to reduce the market share of other products they manufacture? Why would small and medium-sized businesses take the risk of developing a technology that generates little profit and whose sales are expected to be low? If our society is relying on innovation to such an extent to resolve health problems while being reluctant to spend more, is it not necessary in turn for it to call into question some of the forces driving that innovation? In other words, it may be that the development of technologies which more clearly contribute to the collective well-being has to be supported by incentives other than just profit. For example, guaranteed markets, tax credits and special subsidies (SME-oriented R&D support) could be granted in order to reduce commercial constraints that now stand in the way of these initiatives. The federal government seems particularly well positioned to design and introduce such instruments, which should necessarily proceed from joint efforts of the business and health sectors.

In summary, the second part of the study has tried to demonstrate that the issue of technology’s impact on costs can only be resolved by agreeing to examine all the factors that influence both the “supply” of and the “demand” for technologies. This perspective forces us to acknowledge the “schizophrenic” character of public policies which, on the one hand, encourage R&D likely to lead to commercial applications and, on the other, impose a rationalization of health spending. Given that the health “market” is imperfect, a general policy of laissez-faire would be a dangerous proposition; we feel it is important to point out that the state and civil society must intervene “upstream” of technological development in order to facilitate the design and use of technologies and modes of intervention that are beneficial to health and socially legitimate. This latter point implies the establishment of cross-sectoral regulatory instruments but also mechanisms of public consultation (Bohman 1996).

Recommendations

This final section contains a series of recommendations that aim to promote innovative activities, within a cross-sectoral approach whose objective it is to reconcile the market, clinical and social values of technologies. Three sets of recommendations are offered. The first is to support the “upstream” regulation of technology by developing an environment conducive to the design of efficient technologies. These recommendations imply an analysis of current trade and commerce legislation. The second is to harmonize and consolidate “downstream” regulatory instruments so as to refine our capacity to manage the use of technologies. The third is to promote a culture that is critical of technology by expanding the target publics of HTA and creating expanded forums for public debate.

Beyond these three sets of recommendations, and given that the study suggests a new role for the federal government in the technology sector, it would also be helpful to assess the advisability of creating an independent cross-sectoral agency at the national level with the mandate to:

- Examine all commercial and health policies that impact on the design and marketing of health technologies;
- Identify the public health and efficiency objectives to which medical technologies introduced and used in Canada should contribute;
- Work closely with divisions at Health Canada responsible for the approval of biomedical equipment and the introduction of drugs on the Canadian market; and
- Develop commercial and legal strategies and incentives for private firms and multidisciplinary teams to design and market technologies that contribute to the efficiency of health care systems.

Recommendation 1: Encourage Innovation where It Matters for the Canadian Population

This study postulates that national and provincial departments of health can play a greater role in R&D activities in order to target sectors where there are few or no therapeutic options and where more cost-effective technologies and modes of treatment could be developed. This assumes that the government can hire specialist resources that are competent to identify and prioritize promising projects.

Research

- Support research that documents and clarifies the views of patients and the population on the usefulness and relevance of medical innovations.
- Inform the population and clinicians of the results of this research.
- Encourage the development of results measurement that takes better account of the practical consequences of treatments on patients’ lives.
- Support the use of such results measurement in clinical, administrative and policy decisions.

Trade and Health

- Support firms that are interested in developing technologies that can better meet the expectations of the population and patients.
- Reward innovations, including new modes of intervention, that meet public health objectives and serve to minimize costs by granting their manufacturers special subsidies.
- Provide forms of tax credits to compensate manufacturers who select technological niches where the profit margin is limited but health needs are high.
- Identify collective purchasing strategies to increase bargaining power in order to reduce the costs of acquiring technologies.

Recommendation 2: Manage the Complexity of Technological Systems

This study has stressed that the technological developments we are now witnessing are of unprecedented nature and scope. The medical imaging sector aptly illustrates the need to review the ways in which we acquire, finance, manage and use health technologies. The following recommendations are therefore intended to suggest an organizational framework that includes all of the elements for offering safe, effective and quality care.

Training (support for provincial initiatives)

- Consolidate all training programs (including continuing education) in the health sector and strengthen the human capital required for the appropriate use of technologies (physicians, nurses, biomedical engineers, managers).
- Increase the number of biomedical engineers and ensure that sufficient trained technology maintenance staff is available to guarantee the equipment's technical compliance.
- Ensure that nurses have access to provincially proven and standardized care protocols.

Technology Funding Policies

- Harmonize terms and conditions for the funding (combination of federal, provincial and private sources) of very expensive equipment such as that used in medical imaging.
- At the time of acquisition, provide for funding of the replacement of technologies and of their careful and regular maintenance.

Technology Distribution Policies

- Develop specific distribution plans for specialized technologies that take account of the needs of the population and the availability of human resources and necessary infrastructures.
- Encourage the concentration of specialized technologies in major centres.
- Make managers and clinicians accountable for the proper operation and compliance with safety rules of technologies they adopt and use.
- Penalize establishments that adopt technologies without making use of protocols and guidelines validated by professional organizations and without maintaining strict quality standards.

**Recommendation 3:
Enhance the Process of Rational Assessment by Organizing
Structures for Public Deliberation**

The final set of recommendations is based on the idea that a culture that takes a critical stance toward technology can contribute to better use of technologies by clinicians and patients and to better public policies. Moreover, the social and ethical issues surrounding new technologies require that structures for public deliberation be put in place.

Research

- Consolidate HTA capacity at the national, provincial and local levels (particularly in university hospitals).
- Strengthen interdisciplinary efforts in HTA activities.
- Develop analyses that encompass the notion of fairness in technology assessment.

Training (support for provincial initiatives)

- Introduce HTA concepts in medical, nursing and biomedical engineering teaching curricula.
- Encourage specialized training programs in HTA.
- Strengthen the capacity of planners and managers to use HTA results and develop incentives that can strengthen the role of assessment in administrative and clinical policies and decisions.

Communication and Consultation

- Increase the dissemination of HTA results to decision makers.
- Support adapted dissemination of HTA results to the population and patient groups.
- Set up structures for public consultation and deliberation.
- Release to the media the results of these consultation proceedings.

Conclusion

This study sought to offer a rigorous and useful analysis of technological issues that the Commission is mandated to scrutinize, by addressing the following question: Could the design of new regulatory instruments benefit from a critical assessment of the value of innovative technologies and processes? To enrich the discussion, we have tapped a body of multidisciplinary literature, including work on the sociology of innovation. A major emphasis has also been placed on R&D activities that generally take place “upstream” from clinical adoption of technologies. Finally, three sets of recommendations have been developed.

The issue of the cost impact of technologies may well remain on the agenda of provincial and federal governments for decades to come. Nothing indicates that our health care systems have reached a state of balance with respect to structural and technological change. One might even be tempted to venture the opposite, in view of the strength of innovative activities and the growing pressure from budget constraints. Many are taking advantage of this period of tension to suggest greater privatization of the supply and funding of health care. In this study, we have deliberately avoided a discussion of this issue. The private sector is behind every technological innovation: without a for-profit market, there would simply be no manufacturing firms and no technologies. With regard to medical technologies, however, the question as we see it is not to determine whether increasing to role of the private sector is likely to improve the performance of our health care systems, but rather to examine how public health concerns can be harmonized with the constraints and interests of the technology market.

This paper proposes a new role for the federal government, that is to pilot the development of technologies that are more efficient and more socially legitimate. It also suggests some innovative and, indeed, surprising actions. However, it seems useful to give closer consideration to the financial, legal and commercial instruments that would allow manufacturers and distributors to benefit from producing technologies which, instead of magnifying the negative effects of budget constraints, could more clearly contribute to the collective well-being. Obviously, this will require a transformation of the commercial culture of manufacturing firms. In this turbulent era, therefore, we will have to introduce new ways of regulating technologies, while re-examining the incentives and constraints that structure the ways they are designed, purchased, managed and used.

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Appendix:

Specific Terms of Reference for the Paper as Defined by the Commission

Theme of the Paper

How will diagnostic and therapeutic technologies and procedures drive costs in the foreseeable future?

Background and Context

Health care is increasingly costly and many predict that the built-in cost drivers will create even greater pressures for further spending on top of the major reinvestments already made. Three prominently noted cost drivers are diagnostic technologies; therapeutic technologies and procedures; and drugs (the latter is not covered in this paper). Ageing is a fourth but will be examined in a separate paper. These innovations build on science but are often diffused through intensive private sector marketing efforts. Many factors influence both the supply and demand for these technologies, and it is important to understand and to relate the technical qualities and costs of the new developments to their anticipated health impact.

General Question

How will diagnostic and therapeutic technologies and procedures affect the need for and costs of health care services in the next ten to twenty years?

Specific Questions

- 1. What new diagnostic technologies are on the horizon, specifically in the areas of medical imaging and laboratory testing? What is their likely impact on system costs? To what extent will the costs of technologies be offset by reduced needs for subsequent health care interventions?*
- 2. What new therapeutic technologies and procedures are on the horizon? What is their likely impact on system costs? To what extent will the costs be offset by health status gains that defer further needs for services, and/or reductions in length-of-stay in hospitals and other service needs?*
- 3. To what extent can technology assessment frameworks and criteria ensure that new technologies are adopted prudently? To what extent can price be based on added benefit (better diagnostic or therapeutic effect) instead of cost of production?*
- 4. What approaches to containing the growth in technology costs have been tried in other advanced countries? How have they worked? Are there any lessons for Canada in these experiences?*