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**HEALTH TECHNOLOGY ASSESSMENT IN CANADA AND THE G-7 COUNTRIES:
A COMPARATIVE ANALYSIS OF THE ROLE OF HTA AGENCIES
IN THE DECISION MAKING PROCESS**

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Executive summary

With health expenditures taking a growing share of gross domestic products, governments have recognized the importance of better assessing new health technologies. Policy makers, hospital administrators and other decision makers who need reliable information to reduce the uncertainty around the adoption of these technologies have turned to health technology assessment (HTA) bodies for information and advice on how to better manage, replace and exploit technologies to their full potential, and thereby ensure the adoption and diffusion of more cost-effective technologies.

This project has been initiated to fulfill two objectives: 1) to improve our understanding of how new medical technologies are adopted in Canada and abroad, and 2) to better understand the role played by HTA agencies in this process and their impact on policy making.

HTA is a systematic evaluation of the properties and effects of health care technology, with a primary focus on clinical effectiveness. The primary role of HTA is to establish productive links with researchers on the one hand and decision makers on the other. The process examines technologies and their uses, as well as whether technologies are clinically effective and for whom, how they compare with current treatments and whether they are cost effective.

HTA agencies synthesize the many products of research that are available on a particular technology from a variety of available resources (e.g., databases, task forces, controlled studies, literature reviews, meta-analyses, etc.). This technical and scientific information is then combined with a variety of context-specific factors such as the community's needs, the alternative technologies available, the stage of diffusion of the technology, the region's priorities, the availability of human resources and necessary infrastructure, and a variety of additional economic, social and ethical considerations.

HTAs can be used in many instances, including to:

- Make changes in clinical practice guidelines;
- Classify the stage of development of new technologies;
- Limit over-enthusiastic, early use of developing technologies;
- Avoid the purchase of new technologies that will not be used for lack of human or financial resources to operate them; and/or
- Identify knowledge gaps related to new technologies and their potential.

The main audiences for HTA reports include decision makers in the federal, provincial and territorial health ministries; regional health authorities; hospitals and clinical practices. Other interested parties include technology manufacturers who need more information to develop products that meet the needs of the population and to know the potential impact of their new products, private insurers who use HTA products to create benefit packages, consumers, the media, and philanthropic and interest groups.

The Canadian Coordinating Office for Health Technology Assessment (CCOHTA) is a national HTA agency in Canada. In addition, several provincial HTA bodies have been established across the country since the late 1980s (i.e., the Alberta Heritage Foundation for Medical Research, Health Technology Assessment Unit (AHFMR), the Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AETMIS), Ontario's Medical Advisory Secretariat and the PEI Technology Assessment Committee). The British Columbia Office of Health Technology Assessment (BCOHTA) was also a part of the Canadian HTA landscape until quite recently. Although these agencies share, or have shared,

1.0 Introduction

Health care is a highly innovative field. The past few decades have been characterized by rapid technological advances in the health care sector. Treatment has become more technology-intensive and expensive than ever before, and the introduction of new medical technologies has been regarded as a main cause of rising health-care expenditures.² Contrary to other sectors of our economy where technology has often been associated with reduced costs, in the health sector technology is usually not perceived that way.³ As a result, health technology has come under scrutiny. Performance and cost considerations have been given more and more attention, and health technology assessment (HTA) has increasingly been perceived as a necessary function in efforts to achieve a more efficient health care system.

According to the Organisation for Economic Co-operation and Development (OECD) and the former American Office of Health Technology Assessment, health technology is usually defined to cover any method used by those working in health services to promote health, prevent and treat disease, and improve rehabilitation and long-term care. Health technology includes drugs, devices, medical or surgical procedures, as well as any intervention aimed at prevention and rehabilitation of disease. The definition also incorporates the organizational and support systems in which health care is provided.⁴ Given that the adoption and assessment of pharmaceuticals differs somewhat from assessments of other technologies and has been the subject of separate research efforts, and that it was felt necessary to limit the scope of our research, this paper focuses on the role of health technology assessment agencies and their impact on policy making with regard to the adoption and diffusion of medical equipment, devices and procedures.

1.1 Health technology assessment in context

In attempting to address the topic of HTA, it is important to consider the context from which this paper emerges. First and foremost, HTA has been identified in a number of reviews of the health care system as an activity critical to ensuring safety and effectiveness, obtaining the best value for money spent on health technology and achieving improved health outcomes.⁵ However, it appears that the authors of major reports assessing the future of health care in Canada, in particular reports by the Commission on the Future of Health Care in Canada (Romanow Commission) and the Senate Standing Committee on Social Affairs, Science and Technology (Kirby Committee), share the sense that current HTA efforts in Canada are insufficient to meet the needs of policy makers within the health care system and should be expanded. This is due to several factors, including the fact that the level and scope of assessments are generally limited; that assessments are not sufficiently comprehensive with respect to their analysis of economic social, legal and/or ethical issues; that there is a lack of research on the relationship between health technologies and health outcomes; and that not enough attention is paid to identifying and setting priorities for assessment, particularly across jurisdictions.

² A 1998 review (Chernew et al., 1998) of 11 studies pertaining to the cost impact of technology shows that all studies agree that technology had contributed to a substantial increase in expenditures. 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. Other authors such as Joseph Newhouse found that more than half the total rise in real medical care costs (after inflation) is attributable to technological change (Newhouse, 1992).

³ Pritchard, 2002.

⁴ OECD definition of health-related technology.

⁵ See Canada. Commission, 2002, p. 84. See also Canada. Parliament. Senate, 2002, pp. 72-74.

Although the limitations of current HTA activities appear to be clear, the complexity of HTA and the environment within which it is conducted mean that it is extremely difficult to resolve the types of issues identified in reviews of HTA in Canada. There is a need to acknowledge that new and improved health technologies⁶ are emerging at an extremely rapid pace and that it is unrealistic to expect the providers of HTAs to meet societal demand when in fact these providers must operate with limited resources in the face of virtually unlimited demand for reliable assessments.

When considering the findings presented in this paper, it is important to acknowledge that there are multiple challenges facing HTA agencies, not only in Canada, but also around the world. These challenges should be taken into account when considering the activities of the various HTA agencies discussed, the assessments they produce and the overall impact of these assessments on decisions regarding the adoption of health technologies.

Part I of this paper reviews the concept of HTA and identifies the major audiences for HTA. Part II identifies the various bodies conducting HTAs in Canada and discusses their mandates and the role they play in policy making. Part III compares Canada's experience with HTA to that of the other G-7 countries. The paper concludes with a review of the major findings of our analysis.

It is important to recognize that the information presented in this paper is drawn from the available literature. As HTA is a relatively new field, information on the topic is limited and therefore precludes as comprehensive an overview as may be desired. However, increasing interest in HTA appears to be generating new literature on the topic, and a review of this information as it becomes available would assist in providing a more complete picture of the role and/or impact of HTA.

⁶ Although the focus of this paper is mainly on new technologies, the assessment of existing technologies is also an important aspect of HTA, particularly since decisions on technology adoption should include an assessment of the cost-effectiveness of new technologies in relation to existing technologies.

Part I: Health technology and assessment

2.0 Definition of health technology assessment

The term “health technology assessment,” or HTA, was first used in the United States Congress in the late 1960s. At that time, HTA was defined as “a comprehensive form of policy research that examines the short- and long-term social consequences of the application or use of technology.”

Today, HTA is usually seen as a systematic evaluation of the properties and effects of health care technology, and is based on the principles of evidence-based medicine (i.e., the integration of individual clinical expertise with the best available external clinical evidence from systematic research).⁷ The primary role of HTA is to establish productive links with researchers on the one hand and consumers of this information (decision makers) on the other.⁸ The purpose of HTA is to translate both technical and scientific information with a variety of economic, social, ethical and other context-specific factors into language that policy makers understand and with which they are comfortable.⁹ This information, which is largely based upon the assessment of patient health outcomes or cost-effectiveness, can then be used by decision makers. Thus, HTA agencies see their role as providing credible, unbiased, scientifically valid information to the individuals who make health policy decisions in our society.¹⁰ For this reason, HTA is seen as a tool for improving quality and achieving value for money.

The OECD defines health technology assessment as:¹¹

- Identifying evidence or lack of evidence on the benefits and costs of health interventions;
- Synthesizing health research findings about the effectiveness of different health interventions;
- Evaluating the economic implications and analyzing cost and cost-effectiveness; and
- Appraising social and ethical implications of the diffusion and use of health technologies.

Similarly, CCOHTA defines health technology assessment as an evaluation of:¹²

- The technology and its use (e.g., medical procedures, devices, drugs and health systems);
- Which technology is clinically effective;
- For whom;
- How it compares with current treatments; and
- At what cost.

⁷ Gray, 1997.

⁸ Battista et al., 1999.

⁹ Juzwishin, Olmstead and Menon, 1996.

¹⁰ McGregor, 1994.

¹¹ OECD, 2002.

¹² CCOHTA website, “Research - Research Programs”, http://www.ccohta.ca/entry_e.html.

These definitions not only illustrate the growing importance of assessing cost-effectiveness when making decisions about health technology, but also help illustrate the complexity of HTA. Indeed, beyond simply providing definitions, there are different views on what actually constitutes HTA. For example, CCOHTA does not include primary research within its HTA activities; however the Health Technology Assessment Programme in the UK specifically highlights the generation of “original” research as part of its mandate.¹³ Furthermore, the level and quality of assessment activities undertaken by bodies conducting HTAs also tends to vary. For example, agencies conducting HTAs at the national or provincial level are more likely to maintain a clear focus on assessment activities and to dedicate resources exclusively to this task, whereas HTAs conducted at the hospital level are more likely to serve the immediate needs of a hospital facility and less likely to result in a “systematic” evaluation of health technologies.

3.0 Demand for health technology assessment

In the past two decades, most industrialized countries have become increasingly concerned by the rapid technological turnover and the escalating costs of delivering health services. In Canada, there is a strong tendency to question whether the process of adoption and diffusion of new technologies operates efficiently, and a need to understand how technological change can be managed to obtain better value for money.¹⁴ In this context, governments and health care facility administrators have become increasingly interested in the assessment of new health care technologies before they are implemented or used in our health care systems.¹⁵ Indeed, too many adoption and coverage decisions have been (some would argue still are) made in the face of considerable uncertainty about the extent to which specific technologies should be used.¹⁶

Policy makers, hospital administrators and other decision makers who need reliable information to reduce the uncertainty around these new technologies have increasingly turned to HTA bodies for information and advice. HTA has emerged as a way to make progress towards more effective, equitable and sustainable policy making.¹⁷ It also has been identified as an efficient tool to maximize resource allocation, (i.e., to better manage, replace and exploit technologies to their full potential). Indeed, HTA is increasingly perceived as a tool for ensuring the safety and effectiveness of new technologies and for obtaining the best value and clear improvements in health outcomes for investment in new technology.¹⁸

¹³ Health Technology Assessment Programme, 2002.

¹⁴ There is a concern that some technologies could be diffused without evidence of effectiveness or cost-effectiveness, while cost-effective technologies could be underused (Pritchard, 2002).

¹⁵ Medical technology is usually believed to be valuable only if the benefits of medical advances exceed the costs, i.e., the increasing cost of treatment for disease X must be weighted against the benefits of an innovation (e.g., reduce complications and better outcomes). (Cutler and McLellan, 2001).

¹⁶ OECD, 2002.

¹⁷ WHO website, “Rationale for WHO Symposium on Environmental Exposures, Public Health, and the Precautionary Principle”, http://www.euro.who.int/healthimpact/NewsEvents/20020424_2.

¹⁸ Canada. Commission, 2002, pp. 84-85.

Other reasons for utilizing HTA have also gained prominence in recent years. For example, HTA seems to have gained visibility because many countries, including Canada, are facing an ageing population that is likely to lead to increasing demand for resource-intensive services.¹⁹ Furthermore, innovative health technologies, which seem to promise significant health gains, have the potential for adverse effects on human health that can be substantial, far-reaching and irreversible. As underlined by the recent report from the Romanow Commission,²⁰ HTA is likely to be used even more in the future due to the serious social and ethical considerations raised over the years with the introduction of new health care technologies, particularly in areas such as biotechnology where issues such as cloning, eugenics, or new genetic and reproductive technologies raise troubling and complex questions.²¹

4.0 Audiences for and decisions of health technology assessment agencies

In Canada, pharmaceuticals, devices and equipment are licensed by the federal government; however, decisions regarding which pharmaceuticals, devices and equipment are purchased are made at the provincial and territorial level.²² Canadian provincial and territorial governments are responsible for managing and delivering health services; planning, financing²³ and evaluating the provision of hospital care; allocating physician and allied health care services; and managing some aspects of prescription care and public health. The provincial and territorial ministries of Health therefore make decisions regarding which health technologies to include in the health care delivery system for their jurisdiction as well as which services will be eligible for public funding under their respective health insurance plans, and to what extent (e.g., access to a technology may be limited by caps on physician reimbursement, availability of operating dollars, etc.).

According to AETMIS, HTA agencies provide advice to decision makers at three levels:

- The macro level (government) or the level at which health policies are made. At this level decision makers plan and organize services, regulate the introduction and use of these technologies, and make coverage and reimbursement decisions.
- The meso level (hospitals) or the institutional management level. It is at this level that acquisition and monitoring questions are made.
- The micro level (providers of health care) or the clinical practice level at which the quality of the

¹⁹ Sanders, 2002.

²⁰ HTA has now become an important concept in health policy making. It was mentioned in the past five Canadian federal and provincial reports on health care, i.e., in the Commission of Study on Health and Social Services (Clair Commission) in Quebec in 2000, the Saskatchewan Commission on Medicare (Fyke Commission) in Saskatchewan in 2001, the Premier's Advisory Council on Health for Alberta (Mazankowski Council) in Alberta in 2002, the Standing Senate Committee on Social Affairs, Science and Technology review (Kirby Committee) in 2002 and in the Commission on the Future of Health Care in Canada (Romanow Commission) in November 2002.

²¹ Canada. Commission, 2002, p. 83.

²² Sanders, 2002.

²³ It should be noted that the federal government provides funding to provincial and territorial governments, which is then used for the assessment and purchase of health technologies by their respective health departments and health facilities. For further information on the financing of health technologies in Canada, see Kargus, K. and Roehrig, C., *The Impact of Financing on the Adoption of Technology in the Health Sector*, Health Care System Division (forthcoming).

assessment is evaluated and at which clinical practice guidelines are established.²⁴

The AHFMR finds that HTA reports are usually requested for one a variety of reasons, including to:²⁵

- Make decisions about program funding, continuation of a program or program delivery;
- Make changes in clinical practice guidelines;
- Replace obsolete equipment or justify the introduction of a new type of technology and to ensure that cost-effective technologies replace other technologies;
- Choose among different types of available technologies;
- Classify the stage of development of new technologies and limit over-enthusiastic, early use of developing technologies;²⁶
- Prevent widespread application of useless or harmful technologies;²⁷
- Avoid the purchase of new technologies that will not be used for lack of human or financial resources to operate them and/or ensure that new technologies are provided in amounts that correspond to health care needs and that they are appropriately located;²⁸
- Refer patients for treatment outside the province when a technology is not available in that province; and/or
- Provide a basis for coverage decisions.

HTA is used not only at senior institutional levels, but also at different levels of hospital management. Within our system, hospitals and physicians enjoy a certain degree of autonomy in their purchasing decisions, although their ability to acquire technology is limited by budget constraints.²⁹ Since hospitals (and health care providers) are ultimately responsible for implementing treatment, they are also key decision makers in determining whether or not, and the extent to which, a new technology is adopted.³⁰ Although decisions regarding whether a technology is suitable for adoption or should be insured under the publicly funded health care system (i.e., the adoption of technology) are reached at the macro-level

²⁴ Presentation given by AETMIS president Renaldo N. Battista entitled “HTA models used in Québec” during the Journées annuelles de santé publique, at McGill University, Montréal, Québec, November 2002.

²⁵ These are some of the most common practical applications of HTA; however this list is not exhaustive. (AHFMR, HTA Unit, 2002)

²⁶ Technologies can usually be labelled as experimental, innovative or accepted. A technology is classified as “experimental” when the best level of evidence of efficacy available is weak, and is also typically associated with use of the technology on relatively small numbers of patients or clients. A technology is classified as “innovative” when its efficacy is proven but not its effectiveness. A technology is classified as “accepted” when its effectiveness has been established, or at least universally accepted, in the light of accumulated experience (McGregor, 1994). Efficacy is a measure of the ability of a treatment to reduce the duration or severity of a disease, or the ability of a test to detect disease in a clinical setting. Effectiveness is a measure of the overall risks and benefits of a health intervention in the real world (Muennig, 2002).

²⁷ Muennig, 2002.

²⁸ Lehoux, 2002, p. 2.

²⁹ Battista, Jacob and Hodge, 1994.

³⁰ Pritchard, 2002.

(i.e., by federal, provincial and territorial governments), the rate at which approved technologies are diffused is largely the purview of the users of technology, such as physicians and specialists.

Hospitals and physicians are primarily motivated by:³¹

- Technological pre-eminence (hospitals adopt new capital-intensive technologies to establish themselves as technological leaders);
- Clinical excellence (hospitals adopt new technology according to their view of the clinical needs in the population they serve); and
- Profit maximization (this is particularly applicable in the US where hospital behaviour is linked with the financial returns they anticipate).³²

Other parties interested in HTA include technology manufacturers who need more information to develop products that meet the needs of the population and need to know the potential impact of their new products, as well as private insurers who have a great interest in HTA products, which can be used to inform the creation of benefit packages. Consumers,³³ the media, and philanthropic and interest groups have also shown an increasing interest in HTA reports.³⁴

5.0 Basis of health technology assessment recommendations

In order to provide advice, HTA agencies synthesize the many products of research that are available on a particular technology from a variety of available sources such as databases, task forces, consensus conferences, surveys, epidemiological methods, controlled studies, literature reviews, sensitivity analyses, meta-analyses and meta-modelling. This technical and scientific information is then combined with a variety of economic, social, ethical³⁵ and other context-specific factors to produce reports that can help policy makers and health care facility administrators in making decisions about existing or new forms of technology.³⁶ When assessing new technologies, HTA reports usually give particular attention to the technology's impact on the quality of life of the patient and the cost of the technology to the health care system (i.e., cost per quality adjusted life years).

³¹ Pritchard, 2002.

³² Technological competition appears to be a factor militating toward earlier adoption. Recent studies have concluded that hospitals were more likely to adopt early if competing hospitals had already acquired the technology. (Friedman and Goes, 2000).

³³ Today's population is highly educated. People have access to, and understand, health information of a high level of specialization and sophistication. Today's patient population therefore has high expectations on how the health care system should respond to patient needs, concerns and demands. (Sanders, 2002).

³⁴ Pritchard, 2002.

³⁵ Ethical considerations/implications of health care policy have become increasingly important in recent years when making decisions on purchasing new technology (e.g., saving the life of a retired person may produce less direct economic benefits than saving the life of an employed person). (Laupacis, et al., 1992).

³⁶ Battista et al., 1999.

In order to determine whether or not a new technology is effective and its acquisition justifiable, HTA agencies first look at the technology from a clinical and epidemiological perspective. They attempt to assess the broad potential impact of the technology (e.g., change in quality of life of the patient, increased longevity, less time absent from work, reduced number of hospitalization days and emergency visits, etc.), the community's needs for the technology and the alternative technologies available for comparison with the technology being considered. The stage of diffusion of the technology, the region's priorities, the availability of health human resources and the necessary infrastructure to support these technologies may also be considered.

As a major step in an overall assessment, HTA may also include an analysis of the costs related to the introduction and use of the new technology (e.g., equipment, required personnel and training, etc.) and the anticipated benefits.³⁷ Cost-effectiveness analyses are conducted to assess competing alternatives.³⁸ Analyses that compare two or more competing alternatives for preventing or treating a disease tell purchasers how much "bang for their buck" they would receive for each strategy.³⁹ Unfortunately, cost-effectiveness is often left unmeasured once these technologies have been introduced on the market.

Once the clinical benefits and cost-effectiveness of the health technology have been assessed, HTAs attempt to consider the social, legal and ethical⁴⁰ implications of the adoption and use of the technology being assessed, where appropriate.⁴¹ Policy makers are also increasingly sensitive to the need to distribute financial resources fairly between geographical regions and to reduce inequalities in health over the life cycle (e.g., between social classes, ethnic groups, generations, disabled- and able-bodies).⁴²

³⁷ Technologies have numerous associated costs. For example, direct costs (e.g., diagnostic tests, cost of health care products and services), indirect costs (e.g., the time that a patient spends in a doctor's office, cost of travel by the patient and caregivers, cost of the time a patient spends receiving the intervention); intangible costs (such costs are often referred to as morbidity (quality of life), such as emotional grief pain or suffering or mortality cost (costs related to death); lost productivity costs (quality and quantity a person produces, cost of time spent recuperating from illness); and lost leisure time (time spent outside of work, etc.)). (Muennig, 2002).

³⁸ Cost-effectiveness analysis is one of the tools that decision makers can use to assess and potentially improve the performance of their health system. Cost-effectiveness analysis is a research method designed to help determine which health interventions provide the most effective medical care affordable. In other words, it indicates which interventions provide the highest "value for money" and helps decision makers choose the interventions and programs that maximize health for the available resources. (WHO website, <http://www.who.int/health-systems-performance/hsintervene.htm>; Muennig, 2002).

Cost-utility analysis and cost-benefit analysis can also be used for HTA. Cost-utility analysis is a specific type of cost-effectiveness analysis in which the quality of life of the study subjects is taken into account. Cost-benefit analysis places a dollar value on both costs and the effectiveness of an intervention. The final outcome is reported as a monetary value. (Muennig, 2002).

³⁹ Muennig, 2002.

⁴⁰ By ethics, we mean equal access to the technology, principles of beneficence and non-maleficence, informed consent, etc. (Lehoux, 2002).

⁴¹ Green, 2000.

⁴² Cookson and Maynard, 2000.

Part II: Health technology assessment in Canada

The fact that provincial and territorial governments are responsible for the delivery of health care services in Canada has led to the establishment of several HTA agencies across the country, as well as a national HTA agency, CCOHTA. Since the late 1980s, these agencies have assisted decision makers with decisions pertaining to the introduction, diffusion and use of new technologies. They include CCOHTA, AHFMR and AETMIS.⁴³ Until recently, British Columbia also supported its own HTA agency, BCOHTA.

The 2003 first ministers' Accord on Health Care Renewal directs the ministers of Health to develop, by September 2004, a comprehensive strategy for technology assessment to assess the impact of a new technology and to advise on how to maximize its effective utilization in the near future. It is expected that CCOHTA will play a major role, along with other HTA bodies, in implementing the new priorities of an overall Canadian HTA strategy. Accordingly, the 2003 federal budget provides CCOHTA with \$45 million to ensure that CCOHTA, as the only national HTA body, is well positioned to address immediate priorities, and to respond and contribute to the Canadian HTA strategy.

6.0 Mandate and principal bodies in Canada

6.1 National level: the Canadian Coordinating Office for Health Technology Assessment

CCOHTA was established in 1989 by the federal, provincial, and territorial ministers of Health. The agency was established for a three-year trial period with a small budget of approximately \$500,000. In 1993, CCOHTA was made a permanent organization and in 1999 the Deputy Minister of Health renewed its mandate and increased its funding. Today, it is funded on a population proportion basis by both the federal government and the provincial and territorial governments.

CCOHTA fosters and conducts numerous assessment activities. The agency encourages the appropriate use of health technology and strives to influence decision makers through the collection, analysis, creation and dissemination of information concerning the effectiveness and cost of technology and its impact on health. CCOHTA identifies technologies with a potential to have an impact on the health care system and, as much as possible, monitors existing technologies to determine whether a reassessment is needed due to a change in cost-effectiveness or efficacy as a result of new developments. Technologies identified for review by CCOHTA undergo a feasibility review (or pre-assessment) to determine whether a full technology report is needed. Technology reports can be used to improve decision making on health technologies at government, institutional, professional and individual levels to ensure appropriate and cost-effective health care, and to promote an evaluative culture in health care, with shared meaning, norms and practices based on knowledge.⁴⁴

⁴³ AETMIS was formerly known as the Conseil d'Évaluation des Technologies de la Santé du Québec (CETS).

⁴⁴ CCOHTA website, Homepage, <http://www.ccohta.ca>.

As part of its mandate, CCOHTA carries out six core functions: horizon scanning; HTA research; HTA methodology; dissemination of research findings; coordination and collaboration; and encouragement of the use of HTA findings.⁴⁵

Horizon Scanning - Focuses on the early identification of upcoming health technologies likely to have a significant impact on the delivery of health care. As part of this process, CCOHTA established the Canadian Emerging Technologies Assessment Program (CETAP), the only horizon scanning program currently in existence in Canada. Piloted in 1997 and now a permanent part of CCOHTA's research program, CETAP's objectives are to produce and quickly disseminate relevant information on new and emerging technologies. The information provided through CETAP can be used by decision and policy makers to allow more planning and control over the introduction and diffusion of new technologies that might have a future impact on the health care system.

HTA Research - HTA research undertaken by CCOHTA focuses on health technology issues of national concern related to medical devices, pharmaceutical and health systems. Topics proposed for research are screened, selected and prioritized by jurisdictional (i.e., federal/provincial/territorial) committees with additional input from a non-jurisdictional Scientific Advisory Panel. The resulting HTA reports synthesize the findings of relevant literature, and convey information about the technology and its clinical use; whether the technology is efficacious/effective and for whom; how the technology compares with other treatments; the limitations of the research; and a review of the economic, social, ethical and legal issues related to the technology.

HTA Methodology - CCOHTA is actively involved in the development of methods and guidelines for HTA. For example, CCOHTA's *Guidelines for Economic Evaluation of Pharmaceuticals* is acknowledged internationally as a standard guide for conducting economic evaluations.

Dissemination of Research Findings - CCOHTA's research is disseminated to a wide range of stakeholders through a number of methods, including mailed reports, the agency's website, newsletters, presentations and international databases. In an effort to enhance the organization's impact on the health care system, CCOHTA's findings are being directed toward educational institutions, medical practitioners and in some cases the public.⁴⁶

Coordination and Collaboration - One of CCOHTA's primary roles is to coordinate HTA priorities across jurisdictions to minimize duplication with other provincial organizations and foreign HTA bodies. Nationally, CCOHTA coordinates its activities with a number of networks comprised of health assessment and health research organizations. These networks include the Canadian Health Evaluation Forum (CHEF) and the Canadian Coordinating Committee for Health Services Research (CCHSR). Internationally, CCOHTA works with other HTA agencies to encourage coordination and collaboration

⁴⁵ The core values and strategic priorities that follow were adapted from "An Introduction to CCOHTA and Health Technology Assessment", which was presented to the Advisory Committee on Information and Emerging Technologies on May 22, 2003.

⁴⁶ Sanders, 2002.

efforts through groups such as Health Technology Assessment International (HTAi),⁴⁷ the International Network of Agencies for Health Technology Assessment (INAHTA) and Euroscan.⁴⁸

Encouraging the Use of HTA Findings - In order to increase the awareness and thus the utilization of HTA findings, CCOHTA strives to reach decision makers and policy makers in a range of settings, including provincial and territorial health ministries, regional health authorities, other organizations with a role in making decisions about publicly-funded health care (e.g., the Canadian Medical Association (CMA)) and clinical care settings. An outreach program is in place to increase the receptivity of these audiences to CCOHTA's research and to create an educated demand for HTA findings.

CCOHTA has also identified five strategic priorities to guide its further development to help ensure its on-going contribution to health technology assessment. In particular, CCOHTA will seek to increase stakeholder engagement; strengthen HTA research capacity; develop and promote expertise in HTA methodology; increase knowledge transfer activities; and foster continuous improvement in general.

6.2 Provincial level

In addition to using information provided by CCOHTA, several provinces have established HTA bodies to provide policy advice and to guide decisions on health technology. Alberta, British Columbia, Québec, Ontario and Prince Edward Island have all created their own HTA bodies. Ontario, Manitoba and Saskatchewan also conduct HTAs through agencies that do not focus solely on HTA. Although their budgets and funding arrangements differ and their areas of focus appear to be somewhat specialized, the role of provincial HTA agencies is broadly similar across the country.

6.2.1 The Alberta Heritage Foundation for Medical Research, Health Technology Assessment Unit

Alberta's HTA capacity was originally established within the provincial health department in 1993, but was later transferred to AHFMR as a result of a five year Health Research Collaboration Agreement between AHFMR and Alberta Health. This agreement has subsequently been renewed and extended to 2005. The Unit undertakes assessments in response to requests from organizations and individuals, and conducts assessments primarily on topics relevant to policy development and decision making in Alberta's health care system, including on medical devices.⁴⁹ The unit is also actively involved in building capacity and capability for health technology assessment within Alberta and has issued a number of publications on related initiatives (e.g., the *Framework for Regional Health Authorities to Make Optimal Use of Health Technology Assessment*).

⁴⁷ HTAi is a new international HTA organization that has replaced the International Association for Technology Assessment in Health Care (ISTAHC). See section 6.4.3 for further details.

⁴⁸ Euroscan is a consortium of health technology assessment organizations whose members are engaged in horizon scanning and early assessment. See section 18.0 for further information on collaborative efforts centred around the European Union.

⁴⁹ Menon, 2000.

AHFMR is funded through a public trust fund and is accountable to the people of Alberta. Operating funds come from the interest portion of the provincial endowment fund.⁵⁰ The HTA unit is supported through the Health Research and Collaboration Agreement, which is a five-year grant agreement covering the management of the province's Health Research Fund, health technology assessment activities, and dissemination program. In 2000-2001, funding under the Agreement amounted to \$2.7 million.⁵¹

Early reports on the impact of AHFMR's HTA activities prepared by the unit in response to specific requests from the provincial health ministry include a 2000 report on the impact of a series of rapid HTA reports (technotes), which shows that 14 out of 20 reports had exerted some influence on decision making.⁵² Subsequent reports have adopted a more qualitative approach (e.g., interviews with requesters and users of HTA products) in an attempt to provide a more complete picture of how AHFMR's products are utilized by decision and policy makers. These reports have indicated that the majority of clients requested reports to inform decision making; that confidence in the information provided and the timeliness of HTA reports were major factors influencing client satisfaction and utilization; and that AHFMR provided objective, timely, relevant and accurate information to its clients in the majority of cases. However, the reports also acknowledged that AHFMR should take advantage of opportunities to improve its performance, such as improving the timeliness of its reports and regularly promoting its services to HTA clients.⁵³

6.2.2 The British Columbia Office of Health Technology Assessment

BCOHTA was established in 1990 as a government-funded, university-based provincial technology assessment program to promote and encourage the use of HTA research. The role of BCOHTA was to appraise scientific evidence only, without involvement in actual policy development for the requesting agency.⁵⁴ The provincial government no longer funds this organization.

BCOHTA provided advice for policy making on:

- Drugs and medical devices;
- Surgical, medical procedures and tests;
- Clinical practice guidelines; and
- Health administration, delivery and planning.

⁵⁰ The Alberta Heritage Foundation for Medical Research Endowment Fund was created in 1980 to establish a long-term program of medical and health research in the province.

⁵¹ Alberta Science and Research Authority, 2001.

⁵² Hailey et al., 2000.

⁵³ Alberta Heritage Foundation, June 2003.

⁵⁴ Green, 2000.

6.2.3 L'Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé

Formerly known as the Conseil d'Évaluation des Technologies de la Santé (CETS), AETMIS was founded in 1988 by provincial decree. The mandate of CETS was to promote and support HTA, to disseminate the results and to encourage HTA use in decision making by all stakeholders involved in the diffusion of these technologies. CETS was in charge of advising the Minister of health on matters concerning the introduction, diffusion and use of health care technologies and, to this end, giving advice based on assessments of their effectiveness, safety and cost; their impact on the health-care system; and their economic, ethical and social implications. CETS was also required to produce specialized information on medical technologies and to promote a culture of assessment. In March 2001, CETS was replaced by AETMIS.

AETMIS's new mission encompasses an expanded mandate, which takes into consideration the evolution of clinical practices and service organization methods. The Agency also assesses technical aids for disabled persons, previously the responsibility of the Conseil Consultatif sur les Aides Techniques (CCAT). AETMIS is now primarily responsible for providing advice to the Minister of Health and Social Services, as well as to decision makers from the Régie de l'assurance maladie du Québec and to interested parties in the field of HTA. The mandate of AETMIS can be divided into:

- Production of HTA products;
- Transfer of knowledge and the promotion of a culture of assessment;
- Training in HTA; and
- Diffusion of Quebec's expertise in this field.

The board of AETMIS consists of experts who are appointed by the council of ministers. Board members specify the orientation of the agency's work, ensure that the content and the quality of the reports are appropriate, and ensure results are diffused to targeted audiences. AETMIS also has a permanent secretariat consisting of civil servants who assist in the preparation of the agency's reports. AETMIS' budget for 2000-2001 amounted to \$1.6 million.⁵⁵

⁵⁵ Québec (Province), 2001.

With the selection of a new Québec Cabinet on April 30, 2003, AETMIS was placed within the portfolio of the new Minister of Health and Social Services, a position that it had previously occupied until the late 1990s. This recent shift is perceived as being a positive one for the Agency: “This transfer of ministerial jurisdiction is a kind of full-circle development for the Agency, which reported to the Minister of Health and Social Services from its creation in 1988 until 1998. It is also excellent news for AETMIS, because the Agency’s association with the health portfolio brings it closer to the decision-making centres and reinforces its role with key players in the Québec health system.”⁵⁶ AETMIS’s HTA results appear to have important policy consequences as a result of direct links with policy makers. Assessments are produced at the request of the Minister of Health and Social Services, of partners in the health care network or on the initiative of AETMIS. Battista et al. (1999) have documented the relationship between AETMIS and the decision-making process. They argue, for example, that the AETMIS report on prostate cancer screening resulted in clinical guidelines being developed and “enabled the Ministry of Health and Social Services to decide not to launch a province wide screening program.”

6.2.4. The Medical Advisory Secretariat (Ontario)⁵⁷

The mandate of the Medical Advisory Secretariat is to advise the Deputy Minister of Health and Long-Term Care and other Ministry senior management, operational divisions and government agencies on the delivery of medical services, particularly cancer services and new health technologies. The Health Technology Evaluation and Assessment program has been established in the Secretariat to ensure a coordinated approach to policy decision making on the introduction of new health technologies and the retirement of obsolescent technologies. This is achieved by fostering collaboration among relevant program areas, consulting with external stakeholders, conducting technology assessments and leading field research on technologies for which there is insufficient evidence of effectiveness. The Secretariat coordinates its activities with other jurisdictions to ensure consistency with the National Agenda for technology assessment.

6.2.5 The Prince Edward Island Technology Assessment Committee

The Prince Edward Island Technology Assessment Committee, which was established in 1995, coordinates HTA in Prince Edward Island and provides the liaison between CCOHTA and the provincial Department of Health and Social Services. The Committee’s mission is to gather information and advice on new technologies and to provide assessments on their effectiveness and impact on health outcomes.

⁵⁶ AETMIS news release 2003-05-02, “Under the new Québec Government: AETMIS will now report to the Minister of Health and Social Services”, <http://www.aetmis.gouv.qc.ca/en/article.php?sid=47>.

⁵⁷ The information that follows is taken directly from the Government of Ontario website, “Services and Offices Directory, Health and Long-Term Care: Deputy Minister’s Office: Medical Advisory Secretariat”, http://www.infogo.gov.on.ca/paceweb/owa/intersrv_en.disp_service_unit?IN_UNIT_ID=UNT0022285.

6.3 Institutional level

6.3.1 Hospital-based technology assessment⁵⁸

The literature reviewed for this paper suggests that hospitals conduct their own HTAs in order to facilitate decision making on specific technologies, although these assessments may simply be part of an overall decision-making process for technology acquisition as opposed to a formal process of assessment. It should be noted that HTAs at the hospital level appear to be a relatively recent phenomenon, and one that might be explained, at least in part, by the devolution of decision-making responsibilities to regional health authorities and through the creation of larger hospital facilities and networks.⁵⁹ As these groups acquire greater responsibility for coordinating care in accordance with the needs of local populations, but must do so with limited budgets, the need to assess the clinical and cost effectiveness of technologies will increase in importance. It is for this reason that groups such as the Calgary Regional Health Authority in Alberta have begun work on integrating HTA into regional business plans.⁶⁰ Recent literature on the topic of the evaluation of health technologies in hospital settings suggests that there is an increasing emphasis on the performance of HTAs at the institutional level. Indeed, a report by AETMIS points out that university hospitals in Québec have had a legal obligation to conduct evaluations of medical technologies since 1992, although it appears that efforts to integrate this function into the operation of such hospitals are only now under way.⁶¹ A committee consisting of representatives for AETMIS and researchers affiliated with other health organizations and institutions in Quebec is currently examining the topic of HTA in hospital settings and has put forward several options for further consideration by policy makers.⁶²

Little evidence is available on the topic of hospital-based technology assessment in Canada; however, research conducted in the early- to mid-1990s suggests that hospitals usually conduct HTAs to help control costs, to make prudent purchasing decisions and to identify new technologies. In particular, a 1990 survey of 50 Canadian hospitals revealed there was strong agreement that medical technologies should be evaluated before adoption. A majority of the respondents (86%) declared there was some form of assessment being conducted in their institutions. About half (46%) reported that a formal management structure existed for HTA, predominantly a committee structure. About a quarter of the respondents reported having funding specifically for HTA activity.⁶³

⁵⁸ Juzwinshin, Olmstead and Menon, 1994.

⁵⁹ Consider, for example, proposals for the construction of two “super hospitals” in Montreal. For additional information, see news coverage including: <http://montreal.cbc.ca/regional/servlet/View?filename=superhosp021105>.

⁶⁰ Information on HTA and business planning in regional health authorities is based on a poster presentation by Robert Lee, Cam Waddell and Don Juzwishin. Poster #97 “Integration of Health Technology Assessment and Implementation into Health Region Business Planning”, at the 19th Annual Meeting of the International Society of Technology Assessment in Health Care, Canmore, Alberta, June 22-25, 2003.

⁶¹ Québec (Province), 2003.

⁶² Québec (Province), 2003.

⁶³ These findings were based on a survey of teaching hospitals in Canada. Surveys were mailed to 84 institutions in nine provinces, with sizes ranging from 76 to 1190 beds. Survey questions were used to determine the types of assessments being conducted, how the assessments were administered, how they were funded and the extent to which the findings of assessments were used to make decisions regarding new technology acquisitions. (Marshall and Menon, 1990).

The decisions of hospitals are usually based on whether the technology is effective and its acquisition is justifiable from a clinical and epidemiological perspective. External factors that may affect the success of technological acquisitions (e.g., community needs and alternate providers), are also evaluated. As well, hospital committees analyze costs, anticipated revenues and other financial aspects of the technology (e.g., cost-effectiveness, cost-benefit, etc) and determine how much physical space, utilities, personnel, training and other practical requirements will be needed. Finally, they identify prospective vendors and evaluate the specific equipment or systems being considered for acquisition.

It must be noted, however, that available research suggests there is a lack of expertise on these hospital committees. They appear to rely heavily on manufacturers and on staff who request the technology for information. Furthermore, although hospital decision makers accept the concept of HTA, they often do not seem to have adequate organizational structures to implement such assessments.⁶⁴

A survey conducted by Deber et al. in 1995⁶⁵ revealed that the most important factors to hospital administrators in the process of technology adoption are the quality of care, need and compatibility with their institution's role and mission. However, because information about costs and consequences are often unclear, hospital decision makers must balance many internal and external factors. As a result, numerous other factors are also considered, such as availability of similar services elsewhere in the region, priorities of provincial and territorial governments, revenue potential, reimbursement regulations, fear of malpractice/liability, completeness of application, priorities of regional planning bodies, community pressure, desire to please medical staff, sense of equity, prestige of the proposed project item and the prestige of the requesting unit.⁶⁶

Studies also suggest that hospitals and physicians are often driven by the “technological imperative,” or the desire to do anything and everything possible for a patient. At the physician level, there appears to be an inverse correlation between the time since completion of medical training and the adoption of medical innovations. Furthermore, physicians with academic or national affiliation also have a tendency to adopt new technology faster.⁶⁷ This last point in particular highlights the possibility for tension between cost-effectiveness research and the “technological imperative.”

Overall, there appears to be little information on the performance of HTAs in hospital settings, perhaps in large part due to the relative novelty of this practice, or perhaps as a result of the complexities involved in studying HTA processes spread across numerous hospitals as opposed to processes in more formalized settings (i.e., HTA agencies). Nevertheless, recent literature, such as the report by AETMIS on HTA in university hospitals, suggests that hospitals are likely to become increasingly involved in HTA and that more research in this area is likely on the horizon. In addition, recent funding for research

⁶⁴ Juzwinshin, Olmstead and Menon, 1996.

⁶⁵ Deber et al., 1995.

⁶⁶ Deber et al., 1995.

⁶⁷ Fendrick and Schwartz, 1994.

in hospitals, through the \$500 million allocated to the Canada Foundation for Innovation as part of the 2003 Accord on Health Care Renewal may assist with the support of HTA capacity in hospital settings.⁶⁸

6.3.2 University health centres

Several university-based bodies such as the Manitoba Centre for Health Policy and Evaluation (MCHPE)⁶⁹ are also giving advice on coverage, diffusion and utilization of health technologies. MCHPE receives \$1.9 million per year from the province. The directors' salaries are covered by Health Canada's National Health Research and Development Program. The Organization also receives close to \$1 million from sources other than the provincial government. University health centres often assess major equipment and usually specialize in specific areas of HTA. These bodies often also cooperate with the above-mentioned HTA bodies by offering their expertise to decision makers. In Alberta for example, AHFMR collaborates with the University of Alberta Public Health Sciences department to build capacity for HTA in the province and to guide decisions about technology acquisition and diffusion.⁷⁰ Indeed, there appears to be room for increasing collaboration between university-based researchers and HTA agencies in conducting assessments.

University health centres also play a role in HTA related education. Several universities in Canada (such as McGill University, l'Université de Montréal and the University of Ottawa) have recently established graduate programs in health technology and management.

6.3.3 Other bodies

Numerous other HTA initiatives have been undertaken in Canada in the past decade. They include the creation of ICES in Ontario, the Institute for Work and Health of Ontario, and the Health Services Utilization and Research Commission (HSURC) in Saskatchewan.⁷¹ These groups do not, however, focus exclusively on HTA.

ICES was created in 1992 as an independent, non-profit organization and is primarily funded by the Ontario Ministry of Health and Long-Term Care. Its core business is to conduct research that contributes to the effectiveness, quality, equity and efficiency of health services in the province. Over the years, ICES has conducted numerous studies relevant to clinical practice and public policy, including on topics such as arthritis and related conditions, cardiovascular health and care, and most recently, physician supply.⁷²

⁶⁸ The Canada Foundation for Innovation's Research Hospital Fund is designed to contribute to research hospital-based projects that support innovative research and training, which involves taking full advantage of cutting-edge equipment and research practices. For additional information, see <http://www.innovation.ca>.

⁶⁹ MCHPE is a research unit in the University of Manitoba's Faculty of Medicine. It receives a third of its budget from the provincial government. For additional information, see <http://www.umanitoba.ca/centres/mchp/>.

⁷⁰ Battista et al., 1999.

⁷¹ HSURC was recently divided into two separate agencies: the Health Quality Council and the Saskatchewan Health Research Foundation.

⁷² ICES website, Homepage and "Who We Are", <http://www.ices.on.ca/>.

The Institute for Work and Health of Ontario⁷³ is another not-for-profit organization that has been providing research and evidence-based practical tools for clinicians, policy makers, employees and managers since 1990. Its mission is to research and promote new ways to prevent workplace disability, provide improved treatment, and encourage optimal recovery and safe return-to-work. The Organization works with four universities in Ontario: the University of Toronto, the University of Waterloo, McMaster University and York University.

Saskatchewan's HSURC was established in 1992 by the province, through an order-in-council, to assess the provincial health system and to make recommendations for evidence-based change. Recommendations from HSURC were provided to the Minister of Health. The organization also developed some links with the University of Saskatchewan and the University of Regina. HSURC studied factors affecting the health of individuals or groups; factors affecting the use of health services and health service resources; the effectiveness of health procedures, practices and technologies; and practical means to better utilize health services and health service resources. It also provided reports, research and consulting services to other interested parties in Saskatchewan, and served as the provincial health research granting agency.⁷⁴

As of the fall of 2002, HSURC began winding down its operations in preparation for the creation of two separate agencies that will assume its duties: the Health Quality Council and the Saskatchewan Health Research Foundation.⁷⁵ The Health Quality Council will report on and recommend innovative ways to improve quality and performance within Saskatchewan's health system. The Saskatchewan Health Research Foundation will be responsible for funding health research in the province.

6.4 Others

6.4.1 Health technology manufacturers

Health technology manufacturers conduct HTAs to assess the potential impact of new products, to position them in the market and to obtain regulatory approval for their products. The multinational pharmaceutical and medical device industries (at least for innovative devices) spend nearly 20% of gross sales on research and development (R&D), although not all of their spending in this area is dedicated to HTA activities.⁷⁶ The information generated as a result of R&D serves needs both internal and external to the manufacturers (i.e., to further the development of health products and/or to meet regulatory, coverage and/or reimbursement requirements). Work for internal use tends to be carried out in-house or through commercial research organizations with strict confidentiality agreements. Work for external use tends to be contracted to universities to increase credibility. HTAs conducted by health technology manufacturers, however, are often not widely distributed or publicly available. Research in these areas suggests that these reports are usually produced to meet their own organizational needs and are

⁷³ IWHCO website, "Welcome to the Institute for Work & Health", <http://www.iwh.on.ca>.

⁷⁴ HSURC website, "About HSURC", <http://www.hsurc.sk.ca/about/index.php3>.

⁷⁵ For additional information, see the HSURC website, "Contact Us", <http://www.hsurc.sk.ca/contactus.php>.

⁷⁶ Approximately 30% of R&D budgets are allocated to pre- and post-marketing clinical trials, which are generally not undertaken by HTA's (Gelijns et al., 2002).

considered proprietary. Furthermore, there is often a belief that manufacturers do not always publish clear and transparent information on the costs and outcomes of their technology.⁷⁷

6.4.2 The Canadian Cochrane Network and Centre

The Canadian Cochrane Network and Centre is part of the Cochrane Collaboration, which is a large network of organizations involved in HTA that was formed in 1993. The mission of the Canadian Cochrane Network and Centre is to foster evidence-based health care decision making by identifying and supporting individuals in Canada who wish to become involved with the Cochrane Collaboration, and by promoting the awareness, appreciation, distribution and use of Cochrane systematic reviews of health care interventions.⁷⁸

6.4.3 International linkages

It is interesting to note that three Canadian HTA bodies (CCOHTA, AHFMR and AETMIS) are currently members of the International Network of Agencies for Health Technology Assessment (INAHTA). The Network was created in 1993 to encourage international cooperation and sharing of information on HTA. Its membership includes the main publicly funded HTA agencies worldwide. INAHTA has 40 members in 20 countries including in North America, Latin America, Europe, the Middle East, Australia and New Zealand.⁷⁹

International linkages have also been maintained through the International Society for Technology Assessment in Health Care (ISTAHC), which has been replaced by a new international society, Health Technology Assessment International (HTAi). HTAi plans to focus on HTA through supporting and promoting the development, communication, understanding and use of HTA internationally.⁸⁰ Over the next five years, HTAi's aims include building a society that will serve as a primary professional and scientific forum for HTA stakeholders (e.g., business, governments, academic researchers, etc.); conducting annual international meetings to address HTA issues; distributing an international journal on HTA; supporting the exchange of information and expertise related to HTA; and developing HTA as a useful means of informing health policy.⁸¹ As of June 2003, it was determined that Alberta's Institute of Health Economics would provide Secretariat support for the new society.⁸²

⁷⁷ Elhauge, 2002.

⁷⁸ Cochrane Collaboration website, "The Cochrane Collaboration Brochure", <http://www.cochrane.org/cochrane/cc-broch.htm#R2>; and The Canadian Cochrane Network and Centre website, "About Us", <http://cochrane.mcmaster.ca/about.asp>.

⁷⁹ INAHTA website, Homepage, <http://www.inahta.org>.

⁸⁰ HTAi website, "About HTAi", <http://www.htai.org/abouthtai/mission.asp>.

⁸¹ HTAi website, "About HTAi", <http://www.htai.org/abouthtai/mission.asp>.

⁸² IHE website, "News", <http://www.ihe.ca/news/index.cfm#34>.

7.0 Content and characteristics of Canadian HTA reports

In order to identify areas of focus and trends in Canadian HTA, Menon reviewed 117 reports issued by AHFMR, BCOHTA, CCOHTA and AETMIS between 1988 and 1998.⁸³ The analysis revealed that all Canadian agencies had primarily concentrated on therapeutic technologies (technologies used to treat diseases). Two-thirds or more of the CCOHTA and AETMIS reports, and an even greater number of the BCOHTA and AHFMR reports, dealt with this aspect over time. However, all of the agencies appear to have concentrated on particular areas for assessment. CCOHTA, for example, tends to have completed a greater number of assessments on drugs (55%) and AHFMR on devices (56%), while BCOHTA and AETMIS have focused on procedures (50% and 69% respectively). BCOHTA assessments also reviewed screening technologies more often than the other agencies.⁸⁴

Cost, effectiveness and safety were important aspects in most of the reports issued by the agencies. Effectiveness was assessed in at least 60% of all the reports of these agencies. Effectiveness analyses were included more often in CCOHTA, BCOHTA and AHFMR reports than in AETMIS reports. Of all the Canadian HTA agencies, AETMIS and CCOHTA gave the most attention to costing, cost analysis and economic evaluation.⁸⁵ It appears that respectively 64% and 89% of their reports focussed on these aspects.⁸⁶ Either a cost analysis or an economic evaluation was included in 32% of all Canadian HTAs.⁸⁷ Another 29% of all reports focussed on at least one other aspect such as utilization, quality of life, policy analysis or program issues.

7.1 Selection of topics

Topics suggested for assessment come from many different sources, such as board members representing ministries of health, staff, external applicants (e.g., policy makers) or even the general public. Topics are usually prioritized and approved by an agency's board of directors according to various characteristics including the possibility of significant health repercussions, variation in the frequency of use, doubts about misuse, the high cost of acquisition and use, and the probability that the results will influence the decision making process or be relevant for a certain period.⁸⁸ Topics are also selected and/or prioritized according to the availability of high quality information, whether other agencies have recently conducted an assessment on that technology and whether the technology is within the scope of the agency's mandate.⁸⁹

⁸³ Out of 117 reports, 18 were issued by AHFMR, 22 by BCOHTA, 38 by CCOHTA and 39 by AETMIS.

⁸⁴ Menon, 2000.

⁸⁵ Menon, 2000.

⁸⁶ Figures for CCOHTA are based on the period from 1988-1998. In more recent years, the majority of CCOHTA reports have not had an economic component. CCOHTA has indicated that they are currently taking steps to increase the use of economic analysis, where appropriate.

⁸⁷ Menon and Topfer, 2000.

⁸⁸ AETMIS website, "Attentive to the needs of the health sector", http://www.aetmis.gouv.qc.ca/en/mod.php?mod=userpage&menu=2301&page_id=29.

⁸⁹ Chinneck, April 2003.

Recent Canadian HTAs have covered magnetic resonance imaging (MRI) scanners,⁹⁰ computed tomography (CT) scanners,⁹¹ positron emission tomography (PET) scanners,⁹² angio suites (angiography),⁹³ catheterization laboratories, nuclear medicine (NM cameras) and lithotripsy (litho) equipment.

7.2 Information used

HTA reports are based on an exhaustive search of international scientific documentation produced by recognized impartial organizations. Information for HTA reports is systematically retrieved from a variety of sources, including both published and unpublished reports. The relevant information is then sorted, compared and systematically evaluated in a critical manner. These techniques take into consideration numerous parameters affecting the effectiveness, safety and efficiency of the technologies or intervention methods involved, as well as their ethical, social, organizational and economic repercussions.⁹⁴ This analysis is then completed and validated by an examination of the situation in the province using meaningful data such as hospital files or any other relevant databases.⁹⁵ Almost all the reports issued by Canadian HTA agencies have included a literature review (e.g., systematic review, annotated bibliography). Between 1988 and 1998, 84% of all reports included such a review.⁹⁶

7.3 Audiences

According to our review of the literature, HTA reports are primarily intended for federal, provincial and territorial government policy makers. It is interesting to note that out of 117 reports, 112 provided conclusions and/or recommendations for policy makers.⁹⁷ The extent to which this group was targeted ranged from 32% of all BCOHTA reports to 85% of all AETMIS reports. The next most common audiences were health institutions and authorities; 11% of all CCOHTA reports and up to 39% of AHFMR reports targeted these groups. It also appears that the focus of CCOHTA reports on health institutions and authorities has decreased over the years, while the focus of AETMIS reports on health professionals has increased. However, CCOHTA has recently been promoting increased emphasis on knowledge transfer to a range of stakeholders, including health authorities and institutions.

⁹⁰ Magnetic resonance imaging (MRI) is a type of diagnostic imaging that does not use x-ray beams but provides detailed pictures of tissue using magnetic fields.

⁹¹ Computed tomography (CT) obtains internal body images using x-ray beams and computerized imaging.

⁹² Positron emission tomography (PET) is an imaging scan that shows differences in metabolic activity in tissues. Cancer cells often demonstrate high metabolic activity.

⁹³ Angiography is a type of radiographic (e.g., x-ray) imaging that illuminates blood vessels following the injection of a dye into the bloodstream.

⁹⁴ Lehoux, 2002, p. v.

⁹⁵ AETMIS website, "A rigorous analytical method", http://www.aetmis.gouv.qc.ca/en/mod.php?mod=userpage&menu=23&page_id=27.

⁹⁶ This figure ranged from 79% for CCOHTA reports to 95% for BCOHTA reports (Menon, 2000).

⁹⁷ Menon, 2000.

7.4 Time frames

Depending on the topic, HTAs usually include a review of at least 10 years of literature and an examination of the relevant databases. Brief reports intended to provide short-term advice in response to urgent requests related to policy or administrative decisions are also extensively used. Technotes usually take two to three months to complete, generally cover approximately 5 years of literature, and use HTA databases such as MEDLINE, EMBASE or the Internet for reference.⁹⁸ In Canada, HTAs take on average a year to complete, with this time frame extending to up to 18 months for more detailed reports.

HTA agencies are faced with the difficult challenge of balancing the depth, scope, content and scientific rigour of an assessment with the need for a relatively rapid turn-around time for HTA products. For example, an emerging technology report takes relatively little time to complete, but it does not supply decision makers with a detailed review of the available evidence for the technology being examined. By contrast, a full HTA assessment that would be detailed enough to lead to journal submission would likely take several months to complete, whereas decision makers may be facing immediate pressure to adopt the technology being examined.

8.0 **Interaction with decision makers and influences on decision making**

As previously stated, the mission of HTA agencies is to provide advice on existing and emerging technologies to decision makers. The extent to which the information is used by decision makers remains difficult to assess and varies considerably depending on the type of technology being considered and on the decision maker. It appears, though, that the sharing of HTA results among jurisdictions is limited, largely because most decisions regarding the adoption and diffusion of new technologies in Canada are taken at the level of the provincial and territorial governments, regional health authorities and/or individual hospitals, and also because reports are often intended for specific audiences.⁹⁹

Moreover, the impact of HTA on policies regarding urgent requests for assessment by provincial and territorial health ministries and health authorities appears to be weak, as HTA bodies have limited assessment capacity due to both financial and human resources constraints. Furthermore, although decision makers require fairly comprehensive reports to support their decisions, it may not be possible for HTA agencies to collect this information within the time lines specified. Decision makers often need quick advice from HTA agencies, which is not always feasible given that HTAs usually take a year or more to be conducted. As a result, numerous technologies could potentially get accepted for use or get over-supplied relative to estimates of the population's health needs before evaluations are completed.¹⁰⁰ Several authors also argue that clinicians have not yet changed their practices to agree with HTA results and in many instances they have adopted technologies (e.g., computed tomography) before evidence on effectiveness and cost-effectiveness was available.¹⁰¹

⁹⁸ AHFMR, Report, 2002.

⁹⁹ Canada. Commission, 2002.

¹⁰⁰ Pritchard, 2002, p. 25.

¹⁰¹ Drummond and Weatherly, 2000.

In addition, Hofman argues that technology adoption and diffusion is often not based on rational assessments and is regularly applied due to the aggregate decisions of physicians or because of pressure from product champions, health care

Also of importance is the fact that HTA products may not adequately address the needs of their audiences and are not always presented in a format that facilitates decision making. This view is supported by the findings of the Standing Senate Committee on Social Affairs, Science and Technology, which cites “poor dissemination of the evidence generated by HTA activities to health care providers and managers.”¹⁰² The kind of information provided does not always respond to the needs of decision makers and does not necessarily flow well between HTA agencies and target audiences in government and health care facilities. As a result, the recommendations provided by HTA reports are often not reflected in their decisions.¹⁰³ Recent work by researchers at the University of Montreal suggests that although the intended audiences of HTAs certainly acknowledge the scientific credibility of HTA agencies, their ability to use this information is constrained by factors such as the timeliness of HTA reports, the agencies’ limited knowledge of the organizational and social environment within which health care services are delivered, and difficulties associated with applying assessments to local contexts. The users identified in the research also indicated that they wished to play a greater role in directing and disseminating HTAs.¹⁰⁴

Nevertheless, it is clear that provincial governments and regional health authorities responsible for the delivery of health services within the provinces have shown a growing interest in obtaining advice on emerging technologies from HTA agencies to support health care planning.¹⁰⁵ Numerous technologies that are being assessed in HTA reports appear to receive regulatory approval (marketing or licensing).¹⁰⁶ However, there is still little evidence on the direct impact of HTA results on policy making.

Existing evidence includes research conducted by McDaid, which suggests that AETMIS has been perceived as an important contributor to policy making in the field of health technology.¹⁰⁷ A 1997 evaluation of AETMIS revealed that 12 out of 16 studies examined had a “considerable impact” on decision makers.¹⁰⁸ The impact of HTA results from AHFMR or BCOHTA is less conclusive,¹⁰⁹ although a study conducted by AHFMR on the impact of its assessments indicates high levels of satisfaction for both requesters and users of their HTA products and that “most” clients used the information that they

politicians, patient advocate groups or health authorities (Hofman, 2002).

¹⁰² Canada. Parliament. Senate, April 2002, p-74.

¹⁰³ Hailey, Topfer and Wills, 2001.

¹⁰⁴ Myriam Hivon, Pascale Lehoux, Jean-Louis Denis and Stéphanie Tailliez presented the findings of their research at the 19th Annual Meeting of the International Society for Technology Assessment in Health Care in Canmore, Alberta, June 22-25, 2003. A paper entitled “Dissemination of Health Technology Assessment in Canada: Do Visions Match Strategies” has also been submitted to the *Journal of Health Politics, Policy and Law*.

¹⁰⁵ Hailey, Topfer and Wills, 2001.

¹⁰⁶ Hailey, Topfer and Wills, 2001.

¹⁰⁷ McDaid, 2003.

¹⁰⁸ Jacob and McGregor, 1997.

¹⁰⁹ McDaid, 2003.

had received.¹¹⁰ In fact, AHFMR has worked with a consulting firm to create the basis for an on-going impact analysis of AHFMR's HTA products; however, there are limitations to the analysis (e.g., limited ability to detect utilization of HTA products outside of 11 requesters and users interviewed, etc.) and the results do not connect the findings of assessments to specific policy or purchasing decisions.¹¹¹

It is also important to bear in mind that, given the complexities of decision making, and of uptake and diffusion processes, a multitude of factors other than HTA influence policy making. Indeed, the literature shows that economic, regulatory, cultural, professional and institutional factors all play a role in the decisions pertaining to the adoption and diffusion of health technologies. Decision makers often use information and evidence other than that provided in HTA reports. Furthermore, adoption and diffusion decisions are often not based on rational assessments. In many cases, technologies appear to be adopted on a "political," "informal" or "ad hoc" basis.¹¹² Instead of focussing on financial considerations (e.g., budgetary caps),¹¹³ feasibility, patient care, risk or ethical considerations, decisions can often depend on the credibility of the requesting physician, the perceived impact of a project on patient care or a project's contribution to an essential hospital function.¹¹⁴ Many decisions may also be the result of pressures from product champions, patient advocate groups or health authorities.

Because HTA is a relatively recent discipline and new technologies are being introduced at a fast pace, it is often difficult to measure the long-term impact of HTA.¹¹⁵ Consequently, adoption and coverage decisions are made in the face of considerable uncertainty. HTA should not ignore both the learning curve phenomenon and the fact that the process of innovation in medical devices is one of continuous, often incremental, improvements. Indeed, HTAs often fail to consider technological improvements over their entire life cycle and do not acknowledge the fact that the effectiveness of a new technology depends to a large degree on the user's experience with it.¹¹⁶ HTA agencies should make an effort to regularly update the information provided in their studies to optimize the usefulness of their assessments. The rapid pace of innovation in the field of health technology and its relationship to HTA is of particular concern to the health technology industry, since the failure to consider improvements to technologies and

¹¹⁰ AHFMR, June 2003.

¹¹¹ AHFMR, June 2003.

¹¹² Juzwinshin, Olmstead and Menon, 1996.

¹¹³ Choices among technologies are influenced by budgetary caps at the national, regional or hospital level. For further information on financing, see Kargus, K., Roehrig, C. *The Impact of Financing on the Adoption of Technology in the Health Sector*. Health Care System Division, Health Canada (forthcoming).

¹¹⁴ Deber et al., 1995.

¹¹⁵ Elhauge argues that "Further testing after the product's widespread marketing might discover new data that could change conclusions about the technology's safety or efficacy. This is particularly likely, since premarketing studies are relatively short-term, thus missing long-term effects" (Elhauge, 2002).

¹¹⁶ Siebert et al., 2002.

their use could have a negative impact on decisions relating to adoption and diffusion, including coverage decisions.¹¹⁷

Although Canadian HTA agencies appear to have made serious efforts to guide the decisions of policy makers, there is room for further improvement in terms of improving contacts with decision makers, providing them with user-friendly assessments to facilitate decision making and improving linkages among HTA agencies. Furthermore, coordination of the research efforts of the various Canadian HTA bodies will need to be improved to avoid duplication of research and inefficient use of human and financial resources.

Finally, it is important to underline the fact that technology assessment research is expensive. Assessments that use existing data generally cost between US\$40,000 and US\$50,000. Prospective research (e.g., controlled, random clinical trials) is considerably more expensive and can cost upward of US\$500,000. Because payers have limited resources, they tend to rely on other sources of information on medical innovations such as health technology manufacturers.¹¹⁸ As explained earlier, the information provided by these manufacturers may be less thorough than those conducted by HTA agencies.¹¹⁹

9.0 Factors influencing the introduction of technology

As discussed throughout this paper, decisions pertaining to the introduction and/or replacement of technologies are influenced by considerations related to effectiveness, economics, efficiency, ethics and politics. The relative contribution of each factor varies from situation to situation.¹²⁰

In Canada, new health technologies appear to diffuse rapidly whenever the quality of the product is not contested and it is determined that the technology meets the needs of a targeted audience.¹²¹ As mentioned earlier, therapeutic technologies in Canada have historically received more attention from decision makers than diagnostic, screening and preventive technologies.¹²² Technologies related to the management of major health care problems affecting large numbers of people,¹²³ as well as medium and less capital intensive technologies (e.g., ultrasound),¹²⁴ tend to diffuse at a much more rapid pace. The problem with some of the more expensive technologies that are identified as having potential benefits for larger patient groups (e.g., positron emission tomography) is that they are often cost-effective only when

¹¹⁷ In considering these points, it is also important to recall earlier discussions in this paper regarding the tension between the demand for HTA and the resources available to carry out reliable assessments. Given this environment, it is necessary for HTA agencies to prioritize various needs, meaning that some activities, such as updates to existing reports, may receive less attention.

¹¹⁸ Luce and Brown, 1994.

¹¹⁹ Evans, 1995.

¹²⁰ Laupacis et al., 1992.

¹²¹ Menon, 2000.

¹²² Menon and Topfer, 2000.

¹²³ Hailey, Topfer and Wills, 2001.

¹²⁴ Battista, Jacob and Hodge, 1994.

they are restricted to specific indications or populations.¹²⁵

Generally, whenever a technology has a high cost, or when there is uncertainty regarding the advantages it offers, diffusion seems to be less rapid. Again, there are some exceptions. For example, some hospitals strive to be perceived as technology leaders. These generally larger institutions sometimes acquire expensive technologies early.¹²⁶

Various factors can interfere in the process of adopting technologies, resulting in postponement of adoption or diffusion. Some of the barriers affecting the introduction and diffusion of new health technologies will be discussed in later papers on the regulation and financing of health technology. At this stage we can, however, briefly highlight several barriers identified as contributing to a delay in the introduction of new equipment, devices or procedures in Canada.

The Canadian health care system is characterized by universality and single-payer funding derived from general revenues; however, the system is not “centralized.” The provinces and territories maintain responsibility for the delivery of health services and the general allocation of financial resources within their respective health care systems.¹²⁷ In this type of system based on general taxation and global budgets, adoption and diffusion are controlled by budgetary caps at the national, regional and hospital levels. The governments also control expenditures on technology through pre-marketing controls (which are aimed at determining whether a new technology is safe and efficacious for a particular use), and planning tools (which are aimed at determining the geographic distribution of medical services, particularly “big-ticket” technologies).¹²⁸ Governments also directly or indirectly influence who can purchase medical technology, where it can be installed and how many health personnel will be available to operate these new technologies. This is particularly true in the case of expensive technologies such as MRI.

A recent study¹²⁹ suggests that countries that have relatively “weak” supply-side restrictions on the adoption of intensive treatments such as the US or Taiwan, have relatively rapid rates of diffusion. Countries that have stricter supply-side restrictions (e.g., global budgets for hospitals and central planning of the availability of intensive services) such as Canada, Sweden, Denmark, Finland and Norway, have considerably slower rates of diffusion, although low-cost technologies appear to be less

¹²⁵ For instance, PET is very cost-effective for the treatment of non-resectable or benign tumors and could preclude the use of prolonged chemotherapy for treatment failures. However, because a PET scanner has relatively high acquisition costs and low operating costs, there are strong incentives for hospitals to expand its use to broader categories of patients for which it might not be as cost-effective (Mohr et al., 2001).

¹²⁶ Teplensky et al., 1995.

¹²⁷ It should be noted that although the provinces and territories assume responsibility for determining the allocation of financial resources in general (e.g., budgets for specific programs, global budgets for hospital facilities, etc.), health care institutions such as hospitals also maintain responsibility for the purchase of specific health technologies, particularly those that are less expensive.

¹²⁸ Gelijns et al., 2002.

¹²⁹ McClellan and Kessler, 2001.

influenced by supply-side restrictions. The study also suggests that institutional and cultural forces might have an influence.

In an AHFMR survey,¹³⁰ HTA clients revealed that the following had influenced the decisions of policy makers and/or hospital administrators on whether or not to adopt a specific technology:

- Difficulties in getting funding for new technologies and funding cuts to established programs;
- Pressures exercised by advocacy and lobbying groups;
- An upcoming provincial election that influenced policy, funding and program decisions; and
- A court ruling set a precedence that influenced a decision to offer programs.

The adoption of new technologies was also delayed when: decision makers did not have easy access to relevant HTAs; HTA reports were too complex or were presented in a format that was too “technical,” the quality of the data was questionable; the information provided could not easily be applied to the real world; and the focus of the report was too narrow.¹³¹ The adoption of health technology also appeared to be strongly conditioned by the practices of other provinces, alternative treatments that were available at the time of the evaluation and by established models of program delivery.

Even if some of these considerations do not directly affect the work of HTA agencies, they can influence the adoption of technology and therefore alter the impact of HTA recommendations.

Part III: Health Technology Assessment in the G-7 countries

Several trends can be observed in the way that particularly expensive technologies are adopted in developed countries. In the US, Japan and in some cases France, technologies have historically been adopted early and have diffused quickly. In Canada, on the other hand, technologies have been adopted later, but diffused quickly.¹³² Some other countries such as the United Kingdom and most Scandinavian countries have adopted technologies at a later stage and have also diffused them slowly.¹³³

Although a culture of evaluation seems to be developing in many countries, HTA remains largely undefined. Its structure is largely dependent on the health care system in which it operates.¹³⁴ Factors such as regulatory mechanisms in national health care systems, economic incentives for providers of health care services, private versus public systems, number and distribution of medical specialists, influence of opinion leaders, patients and the media, and the role of the country’s big-ticket technologies manufacturing industry all have a certain influence on the impact of HTA on policy making.

¹³⁰ AHFMR, January 2002.

¹³¹ Burns et al., 2000.

¹³² In Canada, big-ticket technologies are not widely distributed compared to other industrialized countries, particularly the US and Japan. For more information, refer to Nguyen, A. *Some Evidence on the Adoption of Medical Technologies in Canada*. Health Care System Division, September 2002.

¹³³ McClellan and Kessler, 2001.

¹³⁴ Banta, 2003.

While industrialized countries face many common pressures, there is considerable variation in HTA practices and outcomes among the G-7 countries. The following tables summarize findings with respect to the way health technologies are adopted and/or diffused and the role of the various HTA agencies in the G-7 countries. The tables provide some background information on the various health care systems and their characteristics. They identify the major HTA bodies and their respective mandates, and assess their impact on policy making.¹³⁵

Overall, our comparative study revealed that among the G-7 countries, HTA is increasingly perceived as a good instrument for policy making, except in the US and Japan where interest in HTA has been relatively limited. The comparison also suggests that HTA in Canada appears to be well organized relative to the other G-7 countries.

¹³⁵ A more detailed version of this information is provided in appendices 1-6.

10.0 Table 1: Health technology assessment in the G-7 countries

	United Kingdom	Canada	France	Italy	Germany	United States	Japan
Type of health care system	Beveridge*	Beveridge*	Bismarck***	Beveridge*	Bismarck***	Private insurance**	Bismarck***
Central HTA agency	NCCHTA	CCOHTA	No	No	No	No	No
Other national agencies	MDA, MRC, SGHT, NCCHTA, NHSCRD, NHS Exec.	No	ANAES, INSERM	The Centre for Info. and Evaluation of Biomedical Equipment, AREAS	TAB	NIH, AHRQ, VHA, DOD	PMDEC, JAAME
Regional governmental HTA agencies	NICE, DEC	AHFMR, BCOHTA, AETMIS, Medical Advisory Secretariat (ON), PEI Technology Assessment Committee	No	Centre for TA and Quality Improvement in Health Care (Veneto region)	Working Group on Social Science Of Technology in Lower Saxony	ICSI, Minnesota HT Advisory Committee, Oregon Health Resources Commission	No
Other HTA bodies	UK Cochrane Centre	ICES, HSURC, MCHPE, Canadian Cochrane Centre	SOFESTEC	Italian Cochrane Centre, Consulting firms	DIMDI, ITAS, ISI, BIOGUM, IMOR, German Cochrane Centre	Insurance companies, consulting firms, health professional societies	No evidence
Health technology manufacturers	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Hospital-based HTAs	Yes	Yes	Yes	Yes	Yes	Yes	Limited
University-based HTA	Yes, (e.g., York U., Sheffield U., Oxford U., U. College of London)	Yes, (e.g., U. of Alberta, McGill U., U. of Montreal, U. of Ottawa)	Yes, (e.g., National School of Public Health (ENAP))	Yes, (e.g., Università Bocconi)	Little evidence	Yes (very active)	Limited
Impact on policy making	Moderate	Moderate	Moderate	Moderate / limited	Moderate / limited	Limited	Practically none

* The Beveridge model (i.e., the National Health Service) is characterized by universal coverage, financing by national general taxes and some form of national ownership/control of factors of production.

** Private insurance health care systems are characterized by individual or employer-based purchase of private health insurance coverage, financing through individual and/or employer contributions, and ownership of the factors of production by the private sector.

*** Bismarkian health care systems (i.e., social insurance systems) are characterized by compulsory universal coverage within a social security framework, financing by employer and individual contributions through non-profit insurance funds, and a combination of public and private ownership of the factors of production.

NB: A list of abbreviations is included on pages 63-64. Further explanation is also provided in the tables prepared for individual countries and in the appendices.

similar goals, their areas of focus appear to be somewhat specialized.

Numerous other entities also conduct HTAs in Canada. Many hospitals conduct their own HTAs in order to facilitate decision making regarding specific technologies. These assessments are conducted to promote the efficient allocation of resources in a cost-conscious environment, as well as to identify new technologies. About half of Canadian hospitals appear to have a formal management structure for HTA, predominantly a committee structure.

Several university-based bodies also give advice on coverage, diffusion and utilization of health technologies. These bodies often assess major equipment and are usually specialized in specific areas of HTA. The Manitoba Centre for Health Policy and Evaluation (MCHPE), McGill University, McMaster University, l'Université de Montréal and the University of Ottawa all conduct HTAs.

Numerous other HTA initiatives have been undertaken in Canada in the past decade. These include work conducted by the Ontario Institute for Clinical Evaluative Sciences (ICES), the Institute for Work and Health of Ontario, the Health Services Utilization and Research Commission (HSURC) and the Canadian Cochrane Centre and Network, all of which have provided research and evidence-based practical tools for clinicians, policy makers, employees and managers since the early 1990s. However, it should be noted that these groups have a broader focus than that of HTA alone.

Health technology manufacturers also conduct HTAs to assess the potential impact of new products in order to position them in the market and to seek regulatory approval for their products. It has been estimated that the multinational pharmaceutical and medical device industries (at least for innovative devices) spend nearly 20% of gross sales on research and development¹. HTAs conducted by health technology manufacturers are, however, not widely distributed and their results are often considered proprietary.

Even though decision makers generally perceive HTA agencies as good providers of information on emerging technologies, their impact on policy making remains difficult to assess. In particular, while the information produced by these agencies is considered useful, there is a concern that the content and timeliness of their efforts may not be sufficient to allow for a notable impact on decisions related to the adoption and diffusion of health technologies. Recent research suggests that HTA agencies in Canada appear to have limited contact with decision makers, planners, health care providers, and other HTA agencies, and may thus be unaware of the information needs of stakeholders. Moreover, the impact of HTAs on urgent requests by provincial health ministries and health authorities appears to be limited by the fact that HTAs usually take on average a year or more to be conducted.

The use and impact of HTAs in the other G-7 countries (US, UK, Germany, France, Italy and Japan) were also examined. While industrialized countries face many common issues, there are considerable variations in HTA practices and outcomes among the G-7 countries. Overall, the impact of HTA agencies was found to be the strongest in Canada, the UK and France. In Italy and Germany, their impact on policy making seems to be limited, while little evidence was found of the impact of HTAs on policy making in the US and Japan.

¹ Gelijns et al., 2002.

12.0 Table 3: Canada's experience

	Canada
Background information/ characteristics of the health care system	Beveridge system; characterized by universal coverage for all Canadian residents, financing by national general taxes, and some form of national ownership/control of the factors of production. In Canada, the adoption of new technologies is controlled by governments either through pre-marketing controls (which are aimed at determining whether a new technology is safe and efficacious for a particular use) and/or planning tools (which are aimed at determining the geographic distribution of medical services, particularly expensive technologies).
Major public HTA bodies	<p><u>Federal level:</u></p> <p>a) The Canadian Coordinating Office for Health Technology Assessment (CCOHTA)– Established in 1989 by federal, provincial, and territorial ministers of Health. The 2003 federal budget provides CCOHTA with \$45 over five years to develop a Canadian Strategy for Health Technology Assessment. CCOHTA's mandate includes six core functions: horizon scanning, HTA research, HTA methodology, dissemination of research findings, coordination and collaboration, and encouragement of the use of HTA findings.</p> <p><u>Provincial level:</u></p> <p>a) The Alberta Heritage Foundation for Medical Research (AHFMR), HTA unit– Established in 1996 to undertake assessments in response to requests from organizations and individuals that are of interest to Alberta health care.</p> <p>b) The British Columbia Office of Health Technology Assessment (BCOHTA) – Established in 1990 to promote and encourage the use of HTA research appropriate to issues of policy and planning at the government level, and in policy acquisition and utilization at governmental, operational and clinical levels. BCOHTA is no longer operational.</p> <p>c) L'Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (AETMIS) – Established in 1988 to promote and support health technology assessment, to disseminate the results of the assessments and to encourage their use in decision making by all stakeholders involved in the diffusion of these technologies. In 2000-2001, its budget amounted to \$1. 6 million.</p> <p>d) The Medical Advisory Secretariat. Recently established body in Ontarioproviding advice to the Deputy Minister of Health and Long-Term Care and other senior officials within the Ministry. A Health Technology Evaluation and Assessment program has been established in the Secretariat to ensure a coordinated approach to decisions related to emerging and existing health technologies.</p> <p>e) The Prince Edward Island Technology Assessment Committee. Established in 1995 to coordinate HTA in the province and provide liaison between the CCOHTA and the provincial Department of Health and Social Services. It gathers information and advice on new technologies and provides assessments on their effectiveness and impact on health outcomes.</p>
Private HTA bodies	<p>a) Numerous health technology manufacturers conduct HTAs to assess the potential impact of new products, to position products in the market and to diffuse the results of their evaluations to interested parties.</p> <p>b) The Canadian Cochrane Centre fosters evidence-based health care decision making by identifying and supporting individuals in Canada who wish to become involved with the Cochrane Collaboration. It promotes the awareness, appreciation, distribution and use of Cochrane systematic reviews of health care interventions.</p>

11.0 Table 2: The United Kingdom’s experience

	United Kingdom
Background information/ characteristics of the health care system	Beveridge system; universal coverage for all UK residents (provided by the National Health Service (NHS)), financing by national general taxes, and some form of national ownership/control of the factors of production.
Major public HTA bodies	<p>a) The National Horizon Scanning Centre (NHSC) aims to provide advance notice of new and emerging health technologies requiring assessment. The Centre’s horizon scanning activities encompass a wide range of health technologies, including, pharmaceuticals, devices, diagnostic tests and procedures, surgical interventions and public health and promotion activities.</p> <p>b) The National Co-ordinating Centre for Health Technology Assessment (NCCHTA) is responsible for coordinating HTA in the UK.</p> <p>c) The Standing Group on Health Technology (SGHT) identifies and prioritizes technologies in need of assessment; identifies emerging technologies with potentially major implications to the NHS; and prioritizes the need for research and development in methods used to perform HTA.</p> <p>d) The National Health Services Centre for Reviews and Dissemination (NHSCRD) conducts and commissions systematic reviews of effectiveness and cost-effectiveness for the NHS. It responds in a relatively short time to pressing problems faced by decision makers by drawing on all relevant evidence, including primary research and the work of the Cochrane groups.</p> <p>e) The NHS Executive’s role is to purchase high-quality HTAs in areas of greatest need from the most competitive provider.</p> <p>NB: The NHS Health Technology Assessment Programme was launched to promote effective practice and to control the diffusion of ineffective or poorly evaluated technology. The program has links to many of the HTA bodies listed in this table, including NCCHTA, NHSCRD and university-based research units.</p>
Private HTA bodies	<p>a) Numerous HTAs conducted by health technology manufacturers.</p> <p>b) The UK Cochrane Centre facilitates and coordinates systematic reviews of randomized controlled trials.</p>
Universities	Numerous university-based bodies give advice on coverage, diffusion and utilization of health technologies in the UK, including the Medical Care Research Unit (University of Sheffield), the Centre for Health Economics (University of York), the National Perinatal Epidemiology Unit (University of Oxford) and the Clinical Operational Research Unit (University College of London).

<p>HTA at the regional level</p>	<p>HTAs are regularly conducted at the regional and local level. A highly organized response to the need for timely information is provided by the Development and Evaluation Service, funded by the Research and Development Directorate of the South and West Regional Office of the NHS Executive. The Development and Evaluation Committee (DEC) is one of three initiatives in English regions that evaluate new technologies for the benefit of purchasers.</p> <p>The National Institute for Clinical Excellence (NICE) is a Special Health Authority for England and Wales. It is part of NHS, and its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current “best practices.” NICE covers both individual health technologies (e. g., medicines, medical devices, diagnostic techniques and procedures) and the clinical management of specific conditions. NICE is also closely affiliated with the NHS Health Technology Assessment Programme.</p>
<p>Impact on policy making</p>	<p>Health technology assessment in the UK is perceived as a useful and recognized instrument that yields valuable information to assist health care professionals, providers and payers to make decisions. There is clear evidence that HTA initiatives, including the NHS Health Technology Assessment Programme, have had a considerable impact on policy making.</p> <p>Overall, the impact of HTA agencies on policy making in the UK is comparable to that of Canadian HTA agencies. Although there appear to be far more competent bodies in this field in the UK, the extent of links between HTA agencies and decision makers is not clear. However, it should be noted that the UK is working to improve linkages between agencies through measures such as the establishment of an HTA affiliate organization.</p>

Universities	<p>Numerous university-based bodies give advice on coverage, diffusion and utilization of health technologies in Canada. The AHFMR, for example, collaborates with the University of Alberta’s Public Health Sciences program to build capacity for HTA in the province and to guide decisions about technology acquisition and diffusion. Other universities involved in HTA include McGill University, l’Université de Montréal and the University of Ottawa.</p>
HTA at the regional level	<p>a) The Institute for Clinical Evaluative Sciences (ICES) is an independent, non-profit organization, created in 1992. ICES is primarily funded by the Ontario Ministry of Health and Long-Term Care. Its core business is to conduct research that contributes to the effectiveness, quality, equity and efficiency of health services in the province of Ontario, which may be broadly considered as HTA.</p> <p>b) The Health Services Utilization and Research Commission (HSURC), which was established in 1992, is a Saskatchewan-based organization whose mission is to assess the province’s health system and to make recommendations for evidence-based change.</p> <p>c) The Institute for Work and Health of Ontario</p> <p>d) The Manitoba Centre for Health Policy and Evaluation (MCHPE)</p> <p>NB: These groups do not focus exclusively on HTA.</p>
Impact on policy making	<p>Health technology assessment in Canada is relatively well organized compared to other G-7 countries. There appears to be little duplication of HTA in Canada. HTA is perceived as a useful and recognized instrument that yields valuable information to assist health care professionals, providers, and payers to make decisions.</p> <p>The impact of Canadian HTA bodies on policy making appears to be moderate, although some bodies do seem to have more impact on policy making than others (e.g., AETMIS) due to their tight links with those making decisions about the acquisition or utilization of new health technologies. The impact of HTA bodies in Canada is, however, limited by financial, human resource and time constraints.</p>

13.0 Table 4: France's experience

	France
Background information/ characteristics of the health care system	Bismark system; characterized by compulsory universal coverage within a social security framework, financing by employer and individual contributions through non-profit insurance funds, and a combination of public and private ownership of the factors of production.
Major public HTA bodies	a) The Agence Nationale d'Accréditation et d'Évaluation en Santé (ANAES, previously ANDEM) provides its various institutional partners, mainly the Ministry of Health and the National Health Insurance Fund, with scientific evidence concerning the safety and cost-effectiveness of health technologies. It also provides assistance with dissemination and financing of such technologies in the health care system. b) The Institut National de la Santé et la Recherche Médicale (INSERM) conducts HTAs aimed at helping decision makers improve quality of care and satisfaction of patients with regard to the treatment received.
Private HTA bodies	a) The Comité d'Évaluation et de Diffusion des Innovations Technologiques (CEDIT) of the hospitals of Paris helps make decisions for investments in new and costly medical technologies. b) A number of medical or surgical scientific associations such as the Société Française pour l'Évaluation des Soins et des Technologies Médicales (SOFESTEC) have begun to promote activities related to HTA. These associations are usually involved in the dissemination of methods and results of both French and foreign assessments, and in the production of clinical practice guidelines or consensus conferences. NB: The French Cochrane Center was closed in September 2002.
Universities	a) The National School of Public Health develops research activities in the quality of health care assessment. b) Departments in various universities are now offering courses in evaluation and postgraduate degrees in health care evaluation.
HTA at the regional level	No
Impact on policy making	Even though HTA does not seem to be as well organized in France as it is in Canada, HTA results appear to have a large impact on policy making due to the fact that HTA agencies have close links with decision makers. The impact of HTA in France is growing quickly, particularly due to cost containment concerns and to an emphasis on quality of care. ¹³⁶

¹³⁶ Rosenau, 2000.

14.0 Table 5: Italy's experience

	Italy
Background information/ characteristics of the health care system	Beveridge system; the Italian Servizio Sanitario Nazionale (SSN) is characterized by universal coverage for all Italian residents, financing by national general taxes, and some form of national ownership/control of the factors of production.
Major public HTA bodies	The Centre for Information and Evaluation of Biomedical Equipment focusses primarily on developing a database on biomedical equipment, accessories and materials, as well as on forecasting SSNs needs for health technologies. The Centre also monitors the diffusion of major health technologies, particularly equipment, and collects data on the technical characteristics and average purchase prices of these technologies, and their accessories and materials.
Private HTA bodies	a) The Italian Cochrane Centre increases sensitivity to HTA in policy makers, and health care operators and their organizations. b) The Association for Research on Effectiveness of Health Care (AREAS) supports the activities of the Italian Cochrane Centre and promotes the practice of evidence-based medicine. c) Numerous consulting firms also conduct HTAs in Italy.
Universities	The Università Bocconi in Milan conducts clinical and economic evaluative work for the Centre for Information and Evaluation of Biomedical Equipment. Numerous universities and regional epidemiological institutes collaborate with the AREAS and the Italian Cochrane Centre to raise the quality of published research on clinical effectiveness.
HTA at the regional level	A few HTA bodies operate in the regions (e.g., Centre for Technology Assessment and Quality Improvement in the Veneto region, agencies in the Friuli-Venezia-Giulia and the Emilia Romagna regions). These activities are relatively untargeted, uncoordinated and without priorities.
Impact on policy making	HTA has so far had a moderate to limited impact on the health policy process at both the national and regional levels of government. Growing pressures to make choices on what to provide, where, in what quantities and under which clinical conditions have forced decision makers to become more sensitive to the need to apply clinical and cost-effectiveness criteria. Like Canadians, Italians are strongly attached to universal coverage and solidarity, and HTA is perceived as a good tool for achieving a better allocation of limited resources. However, Italian HTA agencies appear to have a lesser impact on policy making than agencies in Canada since they are not as closely connected to decision makers.

15.0 Table 6: Germany's experience

	Germany
Background information/ characteristics of the health care system	Bismark system; the German health care system is characterized by compulsory universal coverage within a social security framework, financing by employer and individual contributions through non-profit insurance funds, and a combination of public and private ownership of the factors of production.
Major public HTA bodies	The Parliamentary Office of Technology Assessment (TAB) is in charge of improving the information base for the parliament's deliberations and decision making processes on research and technology. TAB is primarily concerned with designing and implementing technology assessment projects, and with monitoring and analyzing major scientific and technical trends and related societal development.
Private HTA bodies	<ul style="list-style-type: none"> a) The Institute for Medical Documentation and Information (DIMDI) b) The Institute for Technology Assessment and System Analysis (ITAS) c) The Fraunhofer Institute for Systems and Innovation Research (ISI) d) The Research Centre on Technology Assessment on Biotechnology (BIOGUM) e) The Institute for Medical Outcomes Research (IMOR) f) The Potsdam Institute of Pharmaco-epidemiology and Technology Assessment, g) The German Scientific Working Group of Technology Assessment in Health Care h) The German Cochrane Centre Numerous health technology manufacturers also conduct HTAs.
Universities	Little evidence of university-based health technology assessment in Germany.
HTA at the regional level	Some (e. g., Working Group on Social Science of Technology in Lower Saxony)
Impact on policy making	HTA in Germany to this date, is not organized in any concerted way. However, HTA is increasingly perceived as a useful and recognized instrument that could assist health care professionals, providers, and payers in making decisions on the adoption and diffusion of new health technologies.

16.0 Table 7: The United States' experience

	United States
Background information/ characteristics of the health care system	Private insurance; the US health care system is characterized by individual or employer-based purchase of private health insurance coverage, financing through individual and/or employer contributions, and ownership of the factors of production by the private sector. There are two significant public programs, Medicare and Medicaid, which provide assistance to older and low-income people.
Major public HTA bodies	<p>a) The National Institute of Health (NIH) is mainly responsible for conducting clinical evaluative research.</p> <p>b) The Agency for Health Care Research and Quality (AHRQ) conducts assessments for clinical decision makers, health plan and delivery system administrators, as well as public policy makers. The agency supports research designed to improve the outcomes and quality of health care, reduce its costs, address patient safety and medical errors, and broaden access to effective services.</p> <p>c) Some HTAs are also conducted by the Veterans' Health Administration (VHA) and the Department of Defence (DOD), which are both major providers of health care services.</p> <p>N.B.: The two most visible government agencies in the field of HTA in the US, the Congressional Office of Technology Assessment and the Office of Health Technology Assessment (OHTA) of the Agency for Health Care Policy, both ceased to exist in 1997.</p>
Private HTA bodies	<p>A multitude of private bodies, including insurance companies, medical/device manufacturers, consulting firms, and health professional societies conduct HTAs (e. g., large private employers are increasingly demanding evidence of value for their expenditures on employee health).</p> <p>HTAs conducted by private health insurers have often led them to not cover, or to exclude, new and experimental technologies for the privately insured population. The Blue Cross and Blue Shield Association, Technology Evaluation Center (TEC) for example provides scientific analyses and opinions on complex medical issues.</p> <p>Numerous HTAs are also conducted by ECRI (formerly the Emergency Care Research Institute) whose mission is to improve the safety, quality, and cost-effectiveness of healthcare. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, voluntary sector organizations, associations and accrediting agencies worldwide.</p> <p>Industry plays a key part in HTA in the United States. It is one of the most important funders of evaluative research, much of which is required in the regulatory process. However, HTAs conducted by private organizations are not always widely distributed or publicly available, since they are produced to meet their own organizational needs and are considered proprietary.</p>
Universities	Regularly conducted.
HTA at the regional level	Some HTA groups are quite active in their respective states, including the Minnesota Health Technology Advisory Committee, the Institute for Clinical Systems Improvement (ICSI) and the Oregon Health Resources Commission.
Impact on policy making	Health technology assessment in the US is not well coordinated, with the result being a great deal of duplication. The lack of coordination between HTA agencies and the fact that HTAs are usually conducted by private bodies appear to be the major reasons for this poor impact on policy making. Most of these organizations have specific goals and use different methods.

17.0 Table 8: Japan's experience

	Japan
Background information/ characteristics of the health care system	Japan's health care system is based on the Bismarck model and is characterized by compulsory universal coverage within a social security framework, financing by employer and individual contributions through non-profit insurance funds, and a combination of public and private ownership of the factors of production.
Major public HTA bodies	<p>a) The Pharmaceutical and Medical Devices Evaluation Center (PMDEC) evaluates the quality, efficacy and safety of each prescription drug and medical device as well as proprietary drugs, quasi-drugs and cosmetics that are purchased directly by the general public. However, it is not clear whether the activities carried out by this group should be considered HTA or are regulatory in nature.</p> <p>b) The Japan Association for the Advancement of Medical Equipment (JAAME) is a governmental agency that conducts HTAs. It usually receives requests for evaluation from the PMDEC. JAAME is responsible for evaluating the structure, intended use, efficacy, effectiveness, performance and other factors of medical devices for which an application for manufacturing (import) approval has been submitted. The goal is to determine equivalency to products that have already obtained manufacturing or import approval as medical devices.</p>
Private HTA bodies	<p>a) Some HTAs are conducted by physicians. The value of these assessments is, however, dubious as many physicians do not fully understand the principles of economic evaluation. Many evaluations tend to reflect their own medical research interests rather than any fundamental drive to estimate the most rational use of resources across the whole health care system.</p> <p>b) There is clear evidence that HTAs are conducted by technology manufacturers. However, because little attention is generally given in Japan to the quality of the intervention (e.g., their degree of efficacy, effectiveness and/or cost-effectiveness), there are fewer incentives for manufacturers of health care interventions to demonstrate the usefulness of their products.</p>
Universities	Little evidence
HTA at the regional level	No evidence
Impact on policy making	Since the competitive market for health technology keeps prices low, there is little incentive for government, insurers and manufacturers to commission HTAs in Japan. Furthermore, there appears to be a strong cultural bias in favour of technology.

18.0 Collaborative efforts in the European Union

Industrialized countries have demonstrated a shared interest in HTA. Some European Union (EU) member states are already deeply involved in HTA, while others have just begun to support or use HTA. Over the past two decades, HTA has become increasingly important in the EU as an aid to decision making and as a means of addressing three primary concerns of policy makers in the European Union:¹³⁷ expenditure control or cost containment; efficiency; and equity.¹³⁸ As agencies and programs have been established in many of the member states, there has been an increasing attention to the coordination of HTA at the European level to address the observed overuse and inappropriate use of health technology.¹³⁹

Following the acceptance of the Maastricht Treaty in 1991, the EU and the European Commission have gradually become more active in health care. In November of that year, the Council of Ministers for Health recognized that it was a matter for the member states to determine the organization and funding of their health care systems and to make fundamental choices in health policy. HTA was identified as a good tool to improve the management of scarce health care resources. Cooperation and collaboration between member states was recommended to achieve better value for money.

The EUR-ASSESS project was created to promote coordination of HTA in Europe, mainly to improve methods of assessment, set priorities and disseminate the results of HTAs, particularly as a means of facilitating insurance coverage decisions. In pursuing this project, the EU not only hoped to organize HTA activities in Europe, it also aimed to stimulate the development of HTA activities in countries where they did not exist. Six workshops relating to HTA were organized within this framework.¹⁴⁰ Another factor that contributed to an increased interest in HTA was the issuance of a report by the Directorate General V (DGV) which was oriented toward improving health policy at the European level. This report highlighted the importance of coordinating the research efforts of the various European HTA bodies and made several recommendations relevant to HTA (i.e., the Commission should coordinate technology assessment throughout the Union).

The goal of EUR-ASSESS was to:

- Contribute to the effectiveness and cost-effectiveness of health care in Europe through improved HTA;
- Contribute to the development of institutions for HTA in Europe;
- Contribute to the development of methods of information transfer between European countries; and,

¹³⁷ As of 2002, three European directives regulated all medical devices in the European Union. The Council Directive 93/42/EEC of June 14, 1993, concerns medical devices. Council Directive 90/385/EEC of June 20, 1990, relates to active implantable medical devices and Council Directive 98/79/EEC of October 27, 1998, to in vitro diagnostic medical devices. (Siebert et al., 2002).

¹³⁸ Cookson and Maynard, 2000.

¹³⁹ Banta and Oortwijn, 2000.

¹⁴⁰ The six workshops that were organized were: Future changes in health care in Europe and their relation to HTA; The use of health outcomes information in health care systems; Opportunities for international assessments; Identifying future health technology; Improving preventive services through HTA; and Education needs in HTA in Europe.

- Furnish guidance to the European Commission on how to strengthen and aid coordination of HTA activities in Europe.¹⁴¹

Of the studies reported in EU countries and financed by governments, the EUR-ASSESS Network Report found that 44% were considered to have affected policy. All studies deemed to have affected policy and that were financed by government or public research organizations had the goal of informing government health policy makers. The same report indicated, however, that out of all of the studies conducted in EU countries for general scientific interest, only 6% were considered to have influenced policy.

At the conclusion of the EUR-ASSESS project (in 1997), a survey was conducted to re-assess the importance of the project's original objectives in light of the experience of those who took part in it and to determine whether and to what extent EUR-ASSESS had an impact, or may have an impact in the future, on the way technology assessment activities are organized and carried out in Europe. The project was generally found to be successful in creating an informal network of people and organizations; improving the understanding of the work of others; facilitating the sharing of experience and mutual learning opportunities; exchanging ideas on research agendas; and developing a common language. One of the most important consequences was the European Commission's increased awareness of the importance of HTA. The impact of EUR-ASSESS was, however, limited by the diversity of approaches adopted to conduct HTAs, and by the background and roles of those involved in the project. There are significant differences in the way that academics, health service administrators, clinicians and others perform and/or use HTAs.¹⁴²

A number of other European projects are also worth mentioning, such as the European Information Network on New and Changing Health Technologies (EuroScan), which is a collaborative initiative by a number of HTA organizations to share information on important emerging technologies via an on-line database. More recently the European Collaboration for Health Technology Assessment/Assessment of Health Interventions (ECHTA/ECAHI) was created by the EU to improve coordination and communication between national activities on HTA.

The Analysis of the Scientific and Technical Evaluation of Health Care Interventions (ASTECH) of the EU recently concluded that there has been a strong but uneven growth in the production and systematic dissemination of evidence about clinical interventions across the EU; that there are wide variations in evaluation activity between member states; and that growth has concentrated on evaluation of comparative effectiveness, with selective attention to budget impact and cost-effectiveness. Research capacity is uneven and skill shortages are common due to a lack of long term opportunities for promotion and prestige in health services research.¹⁴³

¹⁴¹ Banta and Oortwijn, 2000.

¹⁴² Sassi, 2000.

¹⁴³ McDaid and Cookson, 2003.

In Europe, HTA is slowly moving from a set of national or local initiatives with relatively limited impact to a truly integrated movement with strong links and coordination between its individual components.¹⁴⁴ Although the impact of HTAs on policy making in the EU remains difficult to assess at this point,¹⁴⁵ it appears that, overall, HTA is relatively well organized in Europe.

Conclusion

Canadian HTA agencies are perceived as providing useful information to decision makers wishing to introduce effective technologies rapidly, to delay those of questionable value and to replace those that are no longer useful. However, there is still progress to be made on many fronts. There has been little evidence on the impact of HTA results on policy making, with the exception of some evidence on the impact of assessments by AETMIS on policy making in Quebec and higher-level impact assessments conducted by AHFMR in Alberta. Indeed, data provided by HTA agencies suggests that assessments may be used selectively by policy makers and hospital administrators because the HTA process can, at times, reach unpopular conclusions. In other cases, social and ethical considerations can outweigh cost considerations (e.g., quality of life), resulting in the adoption of new technologies.

Although Canadian HTA agencies appear to have made serious efforts to guide the decisions of policy makers, there is room for further development in terms of improving contacts with decision makers, providing user-friendly assessments to facilitate decision making and improving linkages among HTA agencies. Some effort is also required to provide decision makers with timely assessments, although consideration must be given to the fact that HTA is subject to certain limitations and that more timely assessment would require trade-offs in relation to the scientific rigour of assessments. Furthermore, despite best efforts to assess health technologies quickly, the rapid pace of innovation means that, given their limited capacity, HTA agencies will continue to be unable to assess all technologies and to meet the increasing demand for reliable assessments.

Our comparative analysis of the role of HTA agencies in the policy-making process of the other G-7 countries revealed that out of all G-7 countries, Canada, the UK and France are the countries in which HTA seems to be best organized. The UK has a large number of competent HTA bodies that provide advice to policy makers, health care professionals and providers. Connections between these bodies and decision makers is not clear, and it is possible that the existence of a wide range of HTA bodies might lead to a greater potential for duplication with respect to HTA activities. In France, there are presently relatively few HTA agencies; however, they appear to have a large impact on policy making due to their close ties with decision makers, who are increasingly sensitive to the need to apply and to respect clinical and cost-effectiveness criteria.

Italian HTA agencies, on the other hand, are present at both the national and regional levels of government. HTA in Italy is perceived as a good tool for achieving a better allocation of the limited health care resources; however, Italian HTA agencies appear to have less impact on policy making than agencies in Canada and in France since they are not as closely connected to decision makers. Although HTA is increasingly perceived as a useful and recognized tool to make decisions related to the adoption of health technology, HTA is not yet organized in any concerted way in Germany. HTA agencies in the US appear to have a poor impact on policy making since they are usually conducted by private bodies. Finally, fierce competition between manufacturers and cultural bias results in the commission of few HTAs in Japan.

¹⁴⁴ Sassi, 2000.

¹⁴⁵ McDaid and Cookson, 2003.

HTA is a relatively new discipline and its overall impact on policy making remains difficult to assess. Overall, research conducted for this paper suggests that, although HTA is generally recognized as a useful tool for assisting decision makers, the work of HTA agencies in Canada and the other G-7 countries would benefit from efforts to improve their visibility and influence within health care systems. Nevertheless, when considering the future role of HTA, it will be necessary to consider the complexity of HTA and the factors that limit its impact on decision making when determining how best to manage the potential contribution of HTA in the context of the rapid pace of innovation.

Appendix 1: The United Kingdom¹⁴⁶

1.1 Background information

The National Health Service (NHS) provides universal health coverage to all citizens of the UK. Most services are free of charge, although modest co-payments are sometimes applied. Decisions on overall funding, policy and priorities are made at the national level, but day-to-day decisions on how resources are spent and which services are provided are generally made at the local level. General practitioners, hospital specialists and the professional organizations that represent them are seen by many as the most powerful influential force in the NHS.

1.2 Health technology assessment

Limited health care resources and large increases in health technology spending are the major reasons behind the growing interest in HTA of policy makers and health care professionals in the UK. The government has historically exercised limited control over the introduction of technology with respect to formal HTA initiatives, relying on informed purchasing and clinical decision making at the local practice level to limit overutilization.¹⁴⁷ However, the financing of health technologies in the UK is centralized (i.e., amounts available and the allocation of funds for larger capital purchases are largely controlled at higher levels of government), thereby placing notable limitations on the ability of health care providers to purchase health technologies.¹⁴⁸

Effectiveness has become an important focus of NHS policy and programs in the past two decades. There is presently widespread agreement that resources should concentrate on interventions that offer patients affordable benefits. The NHS judges its performance on the basis of three central criteria: equity, efficiency and responsiveness. In this context, HTA has become an analytical tool for improving both quality and value for money.

The NHS Health Technology Assessment Programme was stimulated mostly by concerns about the lack of rigorous evaluation of existing practices and the proliferation of new technologies or multiple interventions for the same condition. The Programme was primarily launched to promote effective practice and to control the diffusion of ineffective or poorly evaluated technologies, and is considered to be the centerpiece of the NHS Research and Development Program. The NHS Executive's role in running the Programme is to purchase high-quality HTAs in areas of greatest need from the most competitive provider. Advice on topics and on the general direction of the Programme comes from an independent committee, the Standing Group on Health Technology (SGHT). The Programme is coordinated by the National Coordinating Centre for Health Technology Assessment (NCCHTA) under contract from the Department of Health's Research and Development Division. According to the NCCHTA, approximately UK£10 million is allocated to HTA projects each year.¹⁴⁹

In the UK there is no single organization responsible for HTA. Technology assessments originate from teams

¹⁴⁶ The information presented in this section strongly reflects the article "Health Technology Assessment in the United Kingdom" by Steven Woolf and Chris Henshall. For a complete overview of this topic, see Woolf and Henshall, 2000.

¹⁴⁷ Woolf and Henshall, 2000.

¹⁴⁸ For further information, see Kargus, K. and Roehrig, C. *The Impact of Financing on the Adoption of Technology in the Health Sector*. Health Care System Division (forthcoming).

¹⁴⁹ Correspondence with NCCHTA's Communications Manager, July 28, 2003.

in the pharmaceutical and medical devices industry, universities¹⁵⁰ and medical schools, independent (both for-profit and non-profit) research institutions, the Department of Health, health authorities and NHS providers. A large number of charities also invest in HTA.¹⁵¹ Contrary to many other countries interested in developing or attempting to develop a single common approach to HTA, the UK is strongly attached to independent clinical and university research. Descriptions of various groups supporting HTA activities follow.

The National Horizon Scanning Centre (NHSC) is funded under contract with the Department of Health's Research and Development Directorate. The NHSC aims to provide advance notice of new and emerging health technologies requiring assessment. The Centre's horizon scanning activities encompass a wide range of health technologies, broadly defined, including pharmaceuticals, devices, diagnostic tests and procedures, surgical interventions, and public health and promotion activities.¹⁵²

The Department of Health also funds a range of research activities, the most relevant to HTA being the Policy Research Program. This program provides an evidence base for the development and evaluation of central policy for public health, and for health and social services. Much of this work could be defined as HTA in the broad sense. The Policy Research Program budget amounts to £29 million per annum.

SGHT was established in 1993 with the main objectives of: identifying and prioritizing technologies in need of assessment; advising, when necessary, to control diffusion of a technology until better evidence becomes available; identifying emerging technologies with potentially major implications to the NHS; and identifying and prioritizing the need for research and development in methods used to perform HTA. The members of SGHT include experts in the delivery and assessment of interventions, purchasers and providers, and scientists to advise on future developments. The research agenda of SGHT is very large. Criteria for setting priorities include: outcomes for patients, including acceptability of the intervention; quality of life and effectiveness; population-based cost-effectiveness to the NHS; targeting of services; methodological gains through assessment; the time needed to perform an assessment; the time needed to bring about a change in practice; the cost of not doing the assessment now; the likely level of demand and the time trend of use; the need for the assessment to be performed "now or never," the health of the nation or other policy considerations; prevalence of the disease and/or condition; and social and/or ethical considerations.

The NHS Research and Development Program has also recently developed an information strategy that supports the dissemination of evidence on effectiveness. The strategy has three components: the National Research Register; the Cochrane Centre; and the NHS Centre for Reviews and Dissemination. The NHS Centre for Reviews and Dissemination (NHSCRD)¹⁵³ was established in 1994 by the Research and Development Program. The Centre, which is based at the University of York, conducts and commissions

¹⁵⁰ Many universities receive core support for their teaching and research from government through the Higher Education Funding Councils. This core support is supplemented with grants from the research councils, government departments and industrial and charitable sources.

¹⁵¹ Together, all these charitable organizations spend more on biomedical research than the government-funded Medical Research Council.

¹⁵² National Horizon Scanning Centre, "Providing advance notice of significant new and emerging health technologies to the United Kingdom's Department of Health", <http://www.publichealth.bham.ac.uk/horizon/>.

¹⁵³ For further information, refer to the following websites: <http://www.york.ac.uk/inst/crd/>; and <http://nhscrd.york.ac.uk/>.

systematic reviews of effectiveness and cost-effectiveness. NHSCRD, like the Cochrane Centre, is funded to undertake complementary roles within the NHS. However, the focus of the Cochrane Centre is on supporting investigator-led, continuously updated reviews of all trials in particular areas. In contrast, the focus of NHSCRD is to respond in a relatively short time to pressing problems faced by decision makers by drawing on all relevant evidence, including primary research and the work of the Cochrane groups.

The UK Cochrane Centre, which was established in 1992, facilitates and coordinates systematic reviews of randomized controlled trials. The Centre is based in Oxford and is funded by the NHS. It is part of the Cochrane Collaboration, an international collaborative endeavour by clinicians and researchers to prepare and maintain systematic reviews on virtually every topic in medicine. The Collaboration supports review groups in Europe, North America, Australia and other regions. Reviewers follow a systematic methodology (detailed in the Cochrane Collaboration Handbook) and uses common meta-analysis software (e.g., Review Manager) to conduct reviews.

A number of university departments and centres play an important role in HTA. The Medical Care Research Unit of the Sheffield Centre for Health and Related Research at the University of Sheffield, the Centre for Health Economics at the University of York,¹⁵⁴ the National Perinatal Epidemiology Unit at the University of Oxford, the Clinical Operational Research Unit at the University College of London and the Cancer Screening Evaluation Unit at the Institute of Cancer Research all conduct HTAs. Several programs have also been established by the NHS to encourage and train clinicians and researchers to conduct systematic reviews. The Centre for Evidence-Based Medicine at Oxford University is one example.

HTAs are also regularly conducted at the regional and local level in the UK. The National Institute for Clinical Excellence (NICE)¹⁵⁵ is the most active regional “HTA agency” in the UK. The Institute was set up in 1999 as a Special Health Authority for England and Wales. It is part of the NHS, and its role is to provide patients, health professionals and the public with authoritative, robust and reliable guidance on current “best practice.” NICE covers both individual health technologies (e.g., medicines, medical devices, diagnostic techniques and procedures) and the clinical management of specific conditions. The work conducted by NICE is also closely affiliated with the NHS Health Technology Assessment Programme. The Programme acts as the interface between NICE and the review groups under contract with the Programme to produce assessment reports.¹⁵⁶ Approximately half of the assessments published by the Programme were commissioned by NICE to inform guidance for the NHS.¹⁵⁷

A highly organized response to the need for timely information is also provided by the Development and Evaluation Committee,¹⁵⁸ which is funded by the Research and Development Directorate of the South and West Regional Office of the NHS Executive. This service was established to produce quick evaluations of

¹⁵⁴ For further information, refer to the following websites: <http://www.york.ac.uk/inst/che/index.htm>; <http://www.york.ac.uk/inst/che/teehta.htm>; and <http://www.york.ac.uk/inst/che/public.htm>.

¹⁵⁵ For further information, refer to <http://www.nice.org.uk/Cat.asp?pn=public&cn=toplevel&ln=en>.

¹⁵⁶ Health Technology Assessment Programme website, “HTA programme support for the work of NICE. What is NICE?”, www.hta.nhsweb.nhs.uk/nice/nice.htm.

¹⁵⁷ Health Technology Assessment Programme, 2002.

¹⁵⁸ Dixon et al., 2003.

new or established health technologies that are identified by purchasers and providers in the south and west regions.

1.3 Impact on policy making

HTA results appear to have provided guidance for policy making particularly on the safety of drugs, implants and other devices. The NHS Executive has been using HTAs to inform policy development for many years. One example would be the use of information provided by the National Screening Committee (NSC) which was established in 1996 to advise the NHS on PSA screening for prostate cancer. On the basis of the NSC recommendations, a decision was made to not set up a national screening program in this area. There is also clear evidence that the work of the NHS Research and Development Program has received considerable attention from policy makers. Indeed, its work is cited in numerous health policy, clinical and government publications. Its work is also often referred to at international conferences on HTA and in evidence-based health policy. In October 1995 more than 1,000 delegates from 40 countries attended a London conference on the scientific basis of health services, organized by the NHS Research and Development Program.

The extent to which HTA results influence decisions at the local level is less conclusive. Health authorities usually cite the lack of evidence of effectiveness as the reason for not purchasing specific technologies. There are, however, numerous examples where HTA results have influenced regional decisions related to technology adoption.¹⁵⁹

The use of HTAs by purchasers remains uneven. The impact of HTA varies from one locality to another and there is, currently, no mechanism to ensure systematic use nationwide. Many interventions that require rapid HTAs cannot always be conducted in reasonable time periods, and information is presented in a format that is not always suitable. Furthermore, high quality scientific evidence is often unavailable and this indirectly limits the impact of HTAs on policy making. There also appears to be a lack of linkages between HTA agencies and a potential for duplication, which may lessen the impact of HTAs on policy making. However, steps have been taken by the NHS HTA Programme recently to improve linkages and coordination between groups involved in the HTA process. The HTA Affiliate Organization was established in the last year to develop partnerships between a range of different organizations with links to HTA, including Royal Colleges, patient organizations, professional bodies and NHS trusts. As of the publication of the HTA Programme's 2002 Annual Report, 25 bodies had agreed to become members of the Affiliate Organization and will be working to systematically identify the most important evidence gaps requiring the attention of the HTA Programme.¹⁶⁰

Overall, there is a strong commitment to HTA in the UK. A variety of structured activities have been established to determine which topics should receive priority, to use high-quality methods for finding evidence, to coordinate the work of the various organizations involved in HTA, to disseminate the results to relevant audiences, and to promote implementation of the evidence at the policy and clinical practice levels. The progress made in this field is to a large extent attributable to the government's commitment to a knowledge-based health service. Based on the available literature, and despite the fact that the existence of

¹⁵⁹ For example, the effect of the use of grommets (tympanostomy tubes) for glue ear following the publication of an *Effective Health Care* Bulletin about the limitations in the evidence for the procedure. Similar decisions have been made concerning mass screening for elevated blood cholesterol in low-risk adults, and the performance of dilation and curettage in women under the age of 40. There is also evidence that HTA results have had a positive impact on the adoption of interventions such as the use of adjuvant chemotherapy for breast cancer, the use of prenatal steroids in preterm labour, antibiotic therapy for infection with *Helicobacter pylori* and the use of nicotine replacement therapy.

¹⁶⁰ Health Technology Assessment Programme, 2002.

a wide range of HTA agencies could present opportunities for duplication of HTA efforts, the UK, along with Canada, appears to have one of the most organized systems of competent HTA bodies in the G-7.

Appendix 2: France¹⁶¹

2.1 Background information

Under the French constitution, health is a fundamental right and all residents are guaranteed health protection and medical care from the state. The French health care system combines freedom of medical practice within nationwide social security. Health care is provided by both public and private institutions. More than 70% of all health expenditures are covered by public sector mechanisms; the remainder are covered by private individuals or complementary private insurance schemes.

Public and private hospitals are controlled by the Health Map (*carte sanitaire*). In every region the Health Map quantifies the needs for: services (e.g., opening of new departments as well as extensions, reorganizations, or conversions) in one of the basic disciplines such as medicine, surgery, obstetrics, etc; heavy equipment including extracorporeal heart-lung machines, hyperbaric chambers, hemodialysis apparatus, blood product separators, centrifuges, cyclotrons, nuclear medical devices, CT scanners, numeric angiography, MRI equipment, radioactive monitoring devices, lithotripter and imaging networks; and major care, including organ and bone-marrow transplants, burn treatment, cardiac surgery, neurosurgery, emergency and trauma care, intensive care, radiotherapy, nuclear medicine treatment for cancer, neonatal care, chronic renal failure treatment, reproduction treatment, and research, and rehabilitation. Since June 1998, even if medical devices are less regulated than pharmaceuticals, they need to receive European Community marking¹⁶² prior to authorization for marketing. The Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS) is responsible for premarketing approval of these products.

2.2 Health technology assessment

Interest in HTA began appearing in France in the 1970s due to concern about quality of health care services and increases in health care costs. In 1987, the government set up the National Committee for Medical Evaluation in Health Care to discuss ethical issues and methods of evaluation in health care and to develop priorities. Committee members included leading figures and official representatives of the health care system, but the committee had neither a budget nor an official agenda.

In 1989, a national agency was created to launch medical technology evaluation as a national project. The same year, the Agence Nationale pour le Développement de l'Évaluation Médicale (ANDEM) was established by law as a nonprofit, independent association in charge of leading all technology and health care assessment programs that had an impact on public health (with the exception of pharmaceuticals). ANDEM's budget amounted to US\$ 1.5 million in 1990 and increased to US\$ 6 million in 1996. The agency had a full-time staff of 30, mostly physicians, who collaborated with many extramural scientific experts and health professionals. ANDEM's main purpose was to provide its various institutional partners (mainly the Ministry of Health and the National Health Insurance Fund) with scientific evidence concerning the safety and cost-effectiveness of health technologies. It also provided help with dissemination and financing of such technologies in the health care system. The methods combined critical appraisal of published literature with

¹⁶¹ The information presented in this section strongly reflects the article by Frédéric Fleurette and David Banta. For a complete overview of this topic, see Fleurette and Banta, 2000.

¹⁶² The European Community mark is a symbol stamped on all equipment sold in the European Union, certifying that the product meets European Union standards. The marking is proof that the technology meets essential requirements for safety and performance in relation to the risks and benefits it represents for patients and users. (European Medical Technology Industry Association, 1995).

expert and professional opinions. The aim was to define the role of each new technology in relation to existing alternative techniques.

Between 1991 and 1997, ANDEM issued 29 HTA reports and also worked on developing clinical practice guidelines. ANDEM produced 40 new sets of medical guidelines between 1995 and 1997. The agency also helped develop evaluation activities in public and private hospitals. In the 1996 Health Care Reform, the Agence Nationale d'Accréditation et d'Évaluation en Santé took on ANDEM's activities and ANDEM moved to hospital accreditation.

Several groups, including researchers, clinical physicians, medical school public health departments, hospitals and private consultants are also involved in HTA. For example, the Institut National de la Santé et la Recherche Médicale conducts HTAs aimed at helping decision makers improve the quality of care and satisfaction of patients with regard to treatments received; the National School of Public Health develops research activities in the quality of health care assessment; and the Comité d'Évaluation et de Diffusion des Innovations Technologiques of the hospitals of Paris helps make decisions for investment in new and costly medical technologies.

A number of medical or surgical scientific associations, such as the French Society for Evaluation in Health Care and Technology Assessment (Société Française pour l'Évaluation des Soins et des Technologies Médicales, have begun to promote activities related to HTA. These associations are usually involved in the dissemination of methods and results of both French and foreign assessments, and in the production of clinical practice guidelines or consensus conferences. Departments in various universities are now creating courses in evaluation and postgraduate degrees in health care evaluation are now offered.¹⁶³

2.3 Impact on policy making

Even though HTA does not seem to be as well organized in France as it is in Canada, HTA results appear to have a large impact on policy making due to the fact that HTA agencies have close links with decision makers. The impact of HTA in France is growing quickly, particularly due to cost containment concerns and to an emphasis on quality of care.¹⁶⁴

¹⁶³ Fleurette and Banta, 2000.

¹⁶⁴ Rosenau, 2000.

Appendix 3: Italy¹⁶⁵

3.1 Background information

The Italian national health service (Servizio Sanitario Nazionale (SSN)), which was created in 1978, is characterized by a rather high degree of decentralization. Most responsibilities for health care have been delegated to the regions. The state has only limited coordinating and supervisory powers.

Italy applies European Union regulations for the certification of medical technologies with the European Community mark. Regulation of placement of services is a planning function and is the responsibility of both the Ministry of Health (the Istituto di Sanità performs this function) and the regions. The Istituto di Sanità is also responsible for developing and testing methodologies used for evaluating the essential characteristics of devices. The Italian Ministry of Health has been relatively passive regarding the regulation of medical equipment once it is on the market.

3.2 Health technology assessment

A survey conducted for the European Community Network on Economic Appraisal of Health Technology found that 15 HTA studies on pharmaceuticals, devices and organizational systems had been conducted in Italy between 1987 and early 1991. Procedures were less studied. Since 1991, activity has intensified in the field of HTA, particularly in the field of pharmaceuticals due to the need for drugs to meet clinical and cost-effectiveness criteria to be included on the list of pharmaceuticals covered by the SSN.

There is no national agency responsible for conducting, promoting and/or financing HTA in Italy. However several agencies have been involved in HTA since the mid-1970s, including the National Research Council, which financed a major project (Progetto finalizzato tecnologia biomedica) that covered a wide range of HTA dimensions but which gave little attention to questions related to ethics and cost-effectiveness. In Trieste, the Centre for Information and Evaluation of Biomedical Equipment was then created and financed in part by the National Research Council and by the region. Its scope was broadened in 1989. The Centre has conducted several HTAs on extracorporeal lithotripsy, multiple sequence analyzers, surgical lasers, and picture archiving and communication systems. The HTAs involved clinical, economic, technical and managerial dimensions. Between 1990 and 1995, the Centre primarily focussed on developing a database on biomedical equipment, accessories and materials, and on forecasting SSN needs for health technologies. The clinical and economic evaluative work was then subcontracted to the Università Bocconi in Milan. Since 1997, the centre (which is funded by the Ministry of Health), has been monitoring diffusion of major health technologies, particularly equipment, and collecting data on the technical characteristics and average purchase prices of these technologies, and their accessories and materials. The main purpose is to assist with cost containment.

The Italian Cochrane Centre¹⁶⁶ was founded in 1994 to increase sensitivity to HTA in policy makers and health care operators and their organizations. In 1996, the Association for Research on Effectiveness of Health Care (AREAS) was set up to support the activities of the Italian Cochrane Centre and to promote the practice of evidence-based medicine. AREAS and the Italian Cochrane Centre have also set up a network of universities and regional epidemiological institutes to raise the quality of published research on clinical

¹⁶⁵ The information presented in this section strongly reflects the article by George France. For a complete overview of this topic, see France, 2000.

¹⁶⁶ Centro Cochrane Italiano, “Associazione per la Ricerca sull’Efficacia dell’Assistenza Sanitaria”, <http://www.areas.it/index.asp?IDL=ITA>.

effectiveness. As mentioned above, numerous consulting firms and universities (e.g., the Università Bocconi) have conducted HTAs including assessments of chemistry laboratories and automatic analysers.

A few HTA bodies also operate in the regions. One example would be the Centre for Technology Assessment and Quality Improvement in Health Care, which started its operations in the region of Veneto in 1993. This region has been one of the most active in the field of technology assessment.

Although health technology assessment activities in Italy have expanded since the early 1990s, the adoption and diffusion of health technologies has been uncontrolled in many regions (except for a few, such as Friuli-Venezia-Giulia, Veneto, and Emilia Romagna).¹⁶⁷ To date, it appears that these activities are still relatively untargeted, uncoordinated and without priorities.

3.3 Impact on policy making

The European Community Network study for Italy found that HTA has so far had a moderate to limited impact on health policy process at both the national and regional levels of government. Due to growing pressure to make choices regarding what to provide, where, in what quantities and under which clinical conditions, Italian decision makers appear to have become increasingly sensitive to the need to apply and/or to respect clinical and cost-effectiveness criteria. Like Canadians, Italians are strongly attached to universal coverage and solidarity, and HTA is perceived as a good tool for achieving a better allocation of the limited resources of the state for health care.¹⁶⁸

¹⁶⁷ These regions have pursued coherent health technology policies and have set up tight central constraints on capital spending.

¹⁶⁸ France, 2000.

Appendix 4: Germany¹⁶⁹

4.1 Background information

The German health care system is based on statutory social insurance (Gesetzliche Krankenversicherung, SHI) that currently covers 90% of the population. The Federal Ministry of Health is responsible for setting the legal framework of the health care system; for supervision of six federal agencies, including agencies that licence pharmaceuticals, sera and vaccines; and for supervision of medical devices. The states are responsible for maintaining the hospital infrastructure by fulfilling hospital plans and paying for investments according to these plans. They are also responsible for public health; undergraduate medical, dental and pharmaceutical education; and supervision of regional physician chambers, regional association of sickness fund-affiliated physicians and sickness funds operating in the states.

4.2 Health Technology Assessment

Germany has no national agency dedicated to HTA and little data is presently available on the amounts spent on HTA. The term “health technology assessment” is not even routinely used in the German scientific community or among health care decision makers. The only agency explicitly linked to HTA at the federal level is the parliamentary Office of Technology Assessment (TAB). The Office was established in 1990 to improve the information base for parliamentary deliberations and decision-making processes on research and technology. TAB is primarily in charge of designing and implementing technology assessment projects, and of monitoring and analyzing major scientific and technical trends and related societal development. The Office has been involved in issues such as genome analysis, gene therapy and safety of genetic engineering.

Many organizations and institutions are concerned with the evaluation of different aspects of HTA. These include the German Institute for Medical Documentation and Information, the Institute for Technology Assessment and System Analysis; the Fraunhofer Institute for Systems and Innovation Research; the Research Centre on Technology Assessment on Biotechnology (BIOGUM), the Institute for Medical Outcomes Research; the Potsdam Institute of Pharmaco-epidemiology and Technology Assessment; the Working Group on Social Science of Technology in Lower Saxony; and the German Scientific Working Group of Technology Assessment in Health Care. Until recently the evaluations of these agencies primarily focused on biotechnology and contributed to discussions about the value of these technologies from a societal perspective. They now appear to be playing a growing role in coverage decisions, diffusion and utilization of health technologies. These activities are unfortunately not carried out in any concerted way.

¹⁶⁹ The information presented in this section strongly reflects the article by Matthias Perleth and Reinhard Busse. For a complete overview of this topic, see Perleth and Busse, 2000.

4.3 Impact on policy making

Even though there is currently no institution in Germany that exclusively specializes on HTA, there is a growing interest in information provided by HTA agencies and economic evaluations. Awareness among decision makers is, however, still limited and the quality of HTA reports is not considered to be satisfactory by most decision makers.¹⁷⁰ HTA is not yet systematically used to make decisions pertaining to the adoption of new or established medical technologies.

¹⁷⁰ A survey conducted in 1996 by the German Scientific Working Group of Technology Assessment in Health Care found that 98% of the respondents looked for information in scientific journals, 80% in medical congress reports and educational material, and about 50% of the information came from electronic sources. The survey revealed there was considerable dissatisfaction with the quality of these information sources. About 90% of the respondents would have welcomed an additional information resource, such as an HTA database. Information was particularly needed in the field of quality management of medical services, decision making in health politics, clinical practice, and input for science and investigation.

Appendix 5: The United States¹⁷¹

5.1 Background information

High technology medicine is particularly intensive in the US.¹⁷² The adoption and diffusion of health care technologies is influenced by a wide range of behavioural and contextual factors in the US, including pressures from the media and patient organizations. Diffusion is also strongly affected by the high degree of competition between providers and between hospitals.¹⁷³ This “technology competition” is an important factor that militates toward early adoption. Indeed, it appears that the likelihood of adoption increases with the importance to the hospital’s market development strategy of being perceived as a technology leader.¹⁷⁴ Reinhard comments that, in the US, instead of competing on price, hospitals seek to compete with sophisticated technology, a practice known as the “medical race.” In addition, physicians are often influenced by peers who have been trained in settings that emphasize the use of the latest technologies regardless of cost.¹⁷⁵ The impact of such influences are compounded by the fact that fee-for-service remuneration tends to increase the volume of medical services, including the use of technology.

5.2 Health Technology Assessment

The US spends the greatest amounts of money (in absolute terms) on HTA. Contrary to the other G-7 countries, where HTA conducted by the government is on the rise, the number of public sector technology assessment organizations in the US has declined.¹⁷⁶ However, the assessment of technologies is spread out over a combination of several public and numerous private sector groups, meaning that spending on HTA is derived from a variety of sources and is still substantial relative to spending by other countries.

Although there is no longer any central agency to coordinate and/or distribute the results of HTA, there are presently two major public HTA agencies in the US. The National Institute of Health (NIH) is mainly responsible for supporting the conduct of clinical evaluative research. In 1999, it spent about 10% (US\$ 1.47

¹⁷¹ The information presented in this section strongly reflects the article by John M. Eisenberg and Deborah Zarin. For a complete overview of this topic, see Eisenberg and Zarin, 2002.

¹⁷² The US is, however, characterized by “uncoordinated abundance” ... “excess of cutting edge medical technology ... but a worrisome range of variation in its use” (Rosenau, 2000). In 2000, the US Food and Drug Administration approved 30 new molecular entities, 90 new drug applications, 32 new biotechnology agents and new indications, and nearly 4,500 new or modified devices. This is in addition to many advances in clinical procedures.

¹⁷³ Pritchard, 2002.

¹⁷⁴ Pritchard, 2002.

¹⁷⁵ Fuchs, 1996.

¹⁷⁶ This decline can be explained more by political than scientific reasons. In 1997, the Congressional Office of Technology Assessment, the most visible government agency in the field (at the time), ceased to exist. Its budget was eliminated altogether by Congress, for reasons that are unclear but were rumored to include both general deficit reduction and pressure from lobbyists. The Office of Health Technology Assessment of the Agency for Health Care Policy, which had been established in 1989 to produce clinical technology assessments and practice guidelines and to make recommendations about medical technology to the Secretary of Health and Human Services, ceased to do so in 1997 (Pritchard, 2002).

billion) of its overall budget on HTA. The Agency for Health Care Research and Quality (AHRQ),¹⁷⁷ which was created in 1989, conducts assessments for clinical decision makers, health plan and delivery system administrators, and public policy makers. The Agency supports research designed to improve the outcomes and quality of health care, reduce its health care costs, address patient safety and medical errors, and broaden access to effective services. The AHRQ assessments¹⁷⁸ are conducted either internally by staff or through contract and collaboration with evidence practice centers (EPCs), which are mainly university-based centers that perform focused reviews and analyses of scientific literature on particular topics. The agency has 12 EPCs and a budget of US\$ 270 million. The results of its HTAs are used to inform national coverage decisions for the Medicare program as well as to provide information to Medicare carriers. Some HTAs are also conducted by the Veterans' Health Administration and the Department of Defence, which are both major providers of health care services.

In addition, there are some HTA groups that are quite active in their respective states, including the Minnesota Health Technology Advisory Committee,¹⁷⁹ the Institute for Clinical Systems Improvement¹⁸⁰ and the Oregon Health Resources Commission.¹⁸¹ Public HTAs are important because they have a different focus than private sector trials in that they support evaluations of major clinical procedures and off-label therapies.

Another very active non-profit health services research agency is the ECRI (formerly the Emergency Care Research Institute) whose mission is to improve the safety, quality and cost-effectiveness of healthcare. One of the agency's areas of focus is healthcare technology. ECRI provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, voluntary sector organizations, associations and accrediting agencies worldwide.

A multitude of private bodies,¹⁸² including insurance companies, hospitals, medical device manufacturers, consulting firms and health professional societies also conduct HTAs.¹⁸³ Large private employers, for example, are reluctant to bear the costs of new technology and treatment passively and without question, and are now increasingly demanding evidence of value for their expenditures on employee health benefits in terms of quality, appropriateness and outcomes.¹⁸⁴ Large private clinics such as the Cleveland and Mayo Clinics, have also been known to perform assessments.

¹⁷⁷ Agency for Healthcare Research and Quality, Homepage, <http://www.ahrq.gov/>.

¹⁷⁸ Recent AHRQ HTAs include actinic keratoses, PET for breast cancer, pneumatic compression for treatment of chronic venous insufficiency and ulcers. (Eisenberg and Zarin, 2002; <http://www.ahrq.gov/about/>).

¹⁷⁹ Minnesota Department of Health, "Health Technology Advisory Committee", <http://www.health.state.mn.us/htac/index.htm>.

¹⁸⁰ Institute for Clinical Systems Improvement, Homepage, <http://www.icsi.org/index.asp>.

¹⁸¹ The Office for Oregon Health Policy & Research, "Reports Index", http://www.ohppr.state.or.us/hrc/welcome_hrcreport.htm.

¹⁸² In 2000, it was estimated that there were at least 53 HTA organizations in the US, mainly in the private sector (Rosenau, 2000).

¹⁸³ Perry and Thamer, 1997.

¹⁸⁴ Eisenberg and Zarin, 2002.

Many private health insurers also conduct HTAs. For example, the Blue Cross and Blue Shield Association's Technology Evaluation Center¹⁸⁵ provides scientific analyses and opinions on complex medical issues. These include procedures for diagnostic and therapeutic purposes, and the drugs that might be a part of the procedures. This information is then used to make decisions about which treatments should be used for specific conditions and to encourage more efficient use of health care resources. The results of assessments by private insurers have often led those insurers to not cover, or to exclude, new and experimental technologies from their policies. For example, heart transplants were excluded from many private insurers' coverage until the Health Care Financing Administration agreed to include them in Medicare benefits.¹⁸⁶

Industry also plays a key part in HTA in the US. It is one of the most important funders of evaluative research, much of which is required in the regulatory process. Most of the assessments performed by these private bodies rely on cost-effectiveness analyses and on synthesizing existing information. The problem with these private companies is that most of their activities consider only safety and efficacy questions.¹⁸⁷ Furthermore, HTAs conducted by private organizations are not always widely distributed or publicly available. Indeed, most of these organizations' HTA results are not revealed to the public. They are produced to meet their own organizational needs and are considered proprietary.¹⁸⁸

5.3 Impact on policy making

Although HTA is considered by many as being a good tool to allocate health technologies in a more cost-effective, responsible and equitable way, and to thereby help achieve a better balance among the diverse values of efficiency, justice, freedom, and security, HTA appears to have a rather limited impact on policy making in the US.¹⁸⁹ NIH for example, which plays an important role in HTA in the US,¹⁹⁰ has no direct link with those who make decisions about acquisition or utilization. The fact that HTAs are conducted by a large array of (often private) organizations results in the poor impact of their recommendations on policy making. This tendency is unlikely to change in the future due to the elimination of previously highly visible public HTA bodies. Even though health spending is greater in the US than anywhere else in the world, public and private clinical evaluative research efforts amount to less than 1% of total health care expenditures. It is argued that if these efforts were deemed more important and were funded accordingly, they would result in greater returns to clinical and policy decision makers.¹⁹¹

¹⁸⁵ BlueCross BlueShield Association, "ConsumerTec Information", <http://www.bluecares.com/consumertec/index.html>.

¹⁸⁶ Eisenberg and Zarin, 2002.

¹⁸⁷ Banta, 2003.

¹⁸⁸ Banta, 2003.

¹⁸⁹ Fuchs, 1996.

¹⁹⁰ Perry and Thamer, 1997.

¹⁹¹ Gelijns et al., 2002.

Appendix 6: Japan

6.1 Background information

Japan provides universal insurance coverage, which has entitled everybody to the same health care treatments since 1961. The fees for medical procedures are defined under a uniform reimbursement system. The macro health indicators of life expectancy and infant mortality are among the best in the world. Nevertheless, Japan spends a relatively low proportion of its GDP on health care. Japan is also the world's second largest health care market. Of all OECD countries, Japan is the most technology-intensive. It constantly ranks at the top of the list for the number of high-tech pieces of equipment (e.g., CT, MRI, etc.) per capita.

Even though health care expenditures have been successfully contained in the past, there is a strong belief that poor economic performance in recent years, the rapidly ageing Japanese population and the fact that new medical technologies continue to be developed at an ever increasing rate will increase pressure for a more rational use of health care resources (that is, a better assessment of the value for money of new and existing health care technologies).¹⁹²

6.2 Health Technology Assessment

The Japanese Ministry of Health and Welfare has historically maintained a laissez-faire policy regarding the adoption of high technology medicine by individual hospitals or clinics. Few HTAs have been undertaken in Japan and there is no sign of an increasing number of studies published over time in this field. This can be explained in part by the fact that most decision makers appear to be satisfied with the current organization of their health care system.¹⁹³ The lack of interest in HTA may also be due in part to the fact that policy makers appear to strongly believe that the country's strict price regulation, which characterizes health care financing, and fierce competition between manufacturers are sufficient to control the introduction of cost-effective technologies.¹⁹⁴

The lack of HTA can also be explained by the desire to acquire and use health technologies. In addition to the system of fee-for-service remuneration, which appears to be a factor encouraging the use of health technology, in Japan there is also a "new is best" culture.¹⁹⁵ Japanese hospitals and physicians appear to strongly believe that more sophisticated developments in medical technology are necessarily highly effective and desirable. This appears to be particularly true in large hospitals with a desire to maintain an image of prestige. An extensive system of insurer subsidization by the government has also weakened incentives for insurers to weigh the outcomes of medical interventions against costs.¹⁹⁶

¹⁹² Yoshikawa, 1993.

¹⁹³ Oliver, 2003.

¹⁹⁴ Due to fierce competition on the Japanese market, manufacturers of high technologies have developed more compact and cheaper machines of reasonable quality (e.g., MRI). These manufacturers also have much lower service maintenance fees in Japan than in the USA. In addition, because most advanced medical technologies, such as MRIs, are essentially hospital-based and usually have lower capital costs in Japan, the average global charge per procedure tends to be lower in Japan than in the other G-7 countries (Korogi and Takahashi, 1997).

¹⁹⁵ Oliver, 2003.

¹⁹⁶ Oliver, 2003.

At the government level, there appear to be only two bodies involved in HTA. The Pharmaceutical and Medical Devices Evaluation Centre (PMDEC) was established in 1997 to strengthen the government's evaluation capacity for securing safety and preventing harmful side effects of pharmaceuticals and medical devices. The Centre is in charge of evaluating the quality, efficacy and safety of each prescription drug and medical device, as well as proprietary drugs, quasi-drugs and cosmetics that are purchased directly by the general public. PMDEC conducts HTAs on chemotherapeutics; anticancer agents; cardiovascular agents; agents affecting urinary and genital organs; biological products; blood products; in vitro diagnostics; medical devices; and all types of pharmaceuticals. However, it is not clear whether PMDEC should be considered an HTA agency as defined by this paper, or whether the work of the Center is more closely related to the type of evaluation that is conducted by the Food and Drug Administration in the United States or to the review of health products in Canada (i. e., review for the purpose of regulation).

The Japan Association for the Advancement of Medical Equipment is another agency that conducts HTAs. It usually receives requests for evaluation from the PMDEC. The Agency is responsible for evaluating the structure, intended use, efficacy, effectiveness, performance and other factors related to medical devices for which an application for manufacturing (import) approval has been submitted. The goal is to determine equivalency to products that have already obtained manufacturing or import approval as medical devices.¹⁹⁷

HTAs can also be conducted by physicians. The value of these assessments, however, is questionable as many physicians do not fully understand the principles of economic evaluation. As a result, their evaluations tend to reflect medical research interests rather than any fundamental drive to estimate the most rational use of resources across the health care system.¹⁹⁸

There is clear evidence that HTAs are also conducted by technology manufacturers in Japan. However, because an intervention's quality (in terms of its degree of efficacy, effectiveness and/or cost effectiveness) is not reflected in the fee schedule, there are fewer incentives for manufacturers of health care interventions to demonstrate the usefulness of their products.¹⁹⁹

With respect to the content of HTAs, it appears that the primary interest of HTAs conducted in Japan is screening and diagnostics technologies. Cancer is the most frequently analyzed disease.²⁰⁰

6.3 Impact on policy making

As discussed above, the competitive market for health technology has kept prices down and has resulted in few incentives for government, insurers and manufacturers to commission HTAs in Japan. Furthermore, there appears to be a strong cultural bias in favour of technology.²⁰¹

¹⁹⁷ Japan Association for the Advancement of Medical Equipment, "Evaluation of Medical Devices for Equivalency Determination", <http://www.jaame.or.jp/english/annai/ch.html>.

¹⁹⁸ Oliver, 2003.

¹⁹⁹ Oliver, 2003.

²⁰⁰ Oliver, 2003.

²⁰¹ Oliver, 2003.

Abbreviations

AETMIS	Agence d'Évaluation des Technologies et des Modes d'Intervention en Santé (Québec)
AFSSAPS	Agence Française de Sécurité Sanitaire des Produits de Santé (France)
AHCPR	Agency for Health Care Policy (US)
AHFMR	Alberta Heritage Foundation for Medical Research
AHRQ	Agency for Health care Research and Quality (US)
ANAES	Agence Nationale d'Accréditation et d'Évaluation en Santé (France)
ANDEM	Agence Nationale pour le Développement de l'Évaluation Médicale (France)
AREAS	Association for Research on Effectiveness of Health Care (Italy)
BCOHTA	British Columbia Office of Health Technology Assessment
BIOGUM	Research Centre on Technology Assessment on Biotechnology (Germany)
CCAT	Conseil Consultatif sur les Aides Techniques (Québec)
CCOHTA	Canadian Coordinating Office for Health Technology Assessment
CEDIT	Comité d'Évaluation et de Diffusion des Innovations Technologiques (France)
CETS	Conseil d'Évaluation des Technologies de la Santé (Québec)
CMS	Centers for Medicare and Medicaid (US)
CT	Computed Tomography
CU	Cobalt units
DEC	Development and Evaluation Committee (UK)
DIMDI	German Institute for Medical Documentation and Information
EPC	Evidence Practice Center (US)
ESWL	Extracorporeal shock wave lithotripters
GDP	Gross Domestic Product
HSURC	Health Services Utilization and Research Commission (Saskatchewan)
ICES	Institute for Clinical Evaluative Sciences (Ontario)
IMOR	Institute for Medical Outcomes Research (Germany)
INAHTA	International Network of Agencies for Health Technology Assessment
INSERM	Institut National de la Santé et la Recherche Médicale (France)
ISI	Fraunhofer Institute for Systems and Innovation Research (Germany)
ITAS	Institute for Technology Assessment and System Analysis (Germany)
JAAME	Japan Association for the Advancement of Medical Equipment
MCHPE	Manitoba Centre for Health Policy and Evaluation
MDA	Medical Devices Agency (UK)
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
NCCHTA	National Coordinating Centre for Health Technology Assessment (UK)
NHS	National Health Services (UK)
NHSCRDP	National Health Services Center for Reviews and Dissemination (UK)
NHSRDP	National Health Services Research and Development Programme (UK)
NICE	National Institute for Clinical Excellence (UK)
NIH	National Institute of Health (US)
NM	Nuclear medicine
NSC	National Screening Committee (UK)
OECD	Organization for Economic Cooperation and Development
OHTA	Office of Health Technology Assessment (US)
PMDEC	Pharmaceutical and Medical Devices Evaluation Center (Japan)
R&D	Research and Development

SGHT	Standing Group on Health Technology (UK)
SOFESTEC	Société Française pour l'Évaluation des Soins et des Technologies Médicales (France)
SSN	Servizio Sanitario Nazionale (Italy)
TAB	German Parliament Office of Technology Assessment
TEC	Technology Evaluation Center (US)
UNHC	University health centres
VHA	Veterans' Health Administration (US)
WHO	World Health Organization

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