

#### Paper # 7

#### **HEALTH TECHNOLOGY IN ONTARIO**

#### Report to the Ontario Health Review Panel

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### HEALTH TECHNOLOGY IN ONTARIO

## REPORT TO THE ONTARIO HEALTH REVIEW PANEL\*

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#### HEALTH TECHNOLOGY IN ONTARIO

#### 1. INTRODUCTION

Technology refers to the body of knowledge concerning the conversion of inputs into outputs. The health-care system produces health-care services. Health-care services in turn, in conjunction with the activities of the patient, her genetic endowment, and a considerable amount of random variation, produce changes in health status in the patient. Improvements in health status are valued by the patient, both intrinsically because health is a basic component of quality of life and because improved health status enhances other production and consumption activities. The desired outcome of the use of health-care resources is improvements in health status that are important to the consumers of health-care services, the patients. Health technology affects this outcome indirectly through the production of health-care services. The indirect nature of the impact invites a focus on process, rather than outcome, that is reflected in practice throughout most of the health-care system. It also suggests challenges in evaluating health-care technologies.

New health-care technologies may represent improvements over existing technologies in one of several ways. Potentially favourable effects may occur when the new technology represents an improvement in quality of existing services or when it represents a less costly method of obtaining the same outcome with no sacrifice in quality. The new technology may also add a whole new capability to the system. Less favourable effects are obtained when new technologies represent no improvement, are more costly yet generate no improvement over existing methods, or add new capabilities that

have no effect on health outcomes. A major challenge for the Ontario health-care system is the early identification of which pattern among these is likely to occur as each new technology becomes available. Although the Ontario health-care system has done relatively well at containing excessive adoption of many important new technologies, it is not clear that the mix of technologies chosen and the subsequent utilization patterns have obtained the greatest value for the level of expenditures. One of the major themes developed in this Report is the need for more thorough clinical and economic evaluation before widespread adoption. The second and third themes follow as implications of that strategy. A heavier reliance on evaluation will generate demands for rigorous and timely information. That information, however, will have little impact unless key actors within the health-care system are given the incentives to use it wisely. Because technology is at the core of the production process for health services, technology policy cannot be divorced from other policy initiatives aimed at rationalizing health-care delivery.

In the sections that follow, a foundation will be laid by discussing definitions and characteristics of technologies, examining typical patterns of diffusion of new technologies, briefly reviewing current policy in Ontario, and considering the role of new technologies in increasing healthcare costs. The fundamentals of an evaluative strategy to establish clinical effectiveness and economic efficiency will then be developed, and their implications explored. Social and ethical issues are then discussed and finally, conclusions are drawn.

### 2. DEFINITIONS OF HEALTH-CARE TECHNOLOGY

Health technology may be defined as "the set of techniques, drugs, equipment, and procedures used by health care professionals in delivering medical care to individuals and the system within which such care is delivered." (Banta and Behney, 1981, p. 447). The definition is a broad one; the focus of this report is on clinical technologies, the drugs, equipment and procedures. The definition invites the reader to include in health-care technologies surgical procedures and not just focus on technologies which are embodied in physical artifacts such as CT scanners, magnetic resonance imagers, or extra-corporeal shock-wave lithotripsy machines. Disembodied technologies that are not contained in physical objects are also important.

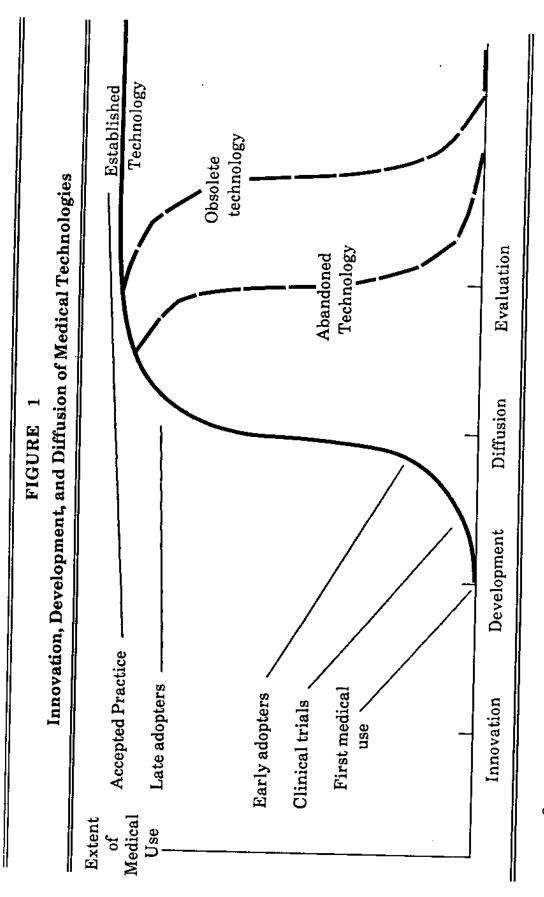
Technologies can also be distinguished on the basis of their use: diagnostic, therapeutic (including curative, preventive, rehabilitative, and palliative), supportive (for instance computer management information systems), and organizational (for instance fee-for-service versus health-service organization). Again, the concept of health-care technology is broader than the common preoccupation with diagnostic machines.

## 3. PATTERNS OF DIFFUSION OF NEW TECHNOLOGIES

The process by which a new technology becomes a standard practice is known as diffusion. In general, there are two components in this process. First, as pioneers in the development of the technology first apply it in clinical settings, the technology typically undergoes considerable further modification and development. Initially, diffusion is gradual; as

experience accumulates and the technology is further developed the rate of adoption increases. A period of rapid adoption usually follows as the new technology enjoys widespread use and emerges as standard care (see Figure 1). Later this standard practice may be replaced by a newer technology. Several factors appear to affect the rate of adoption of new technologies. For hospital based technologies, teaching status and size increase the extent and rate of adoption. Reimbursement policies that facilitate the transfer of the cost of the new technology onto third party payers also accelerate adoption. In contrast, prospective reimbursement in New York appears to have limited the extent of adoption of cost-increasing technologies while enhancing the adoption of cost-saving technologies (Romeo, Wagner, and Lee, 1984). Although financial incentives matter, other advantages to hospitals such as improved patient care, teaching, research, and staff recruitment and retention also play a role.

Although adoption is associated with the perception that the decision is consistent with the goals of the health-care provider, in general, the process is rather uncritical. The enthusiasm of health-care professionals for new health-care technologies is, in general, reinforced by the public demand for the latest new advances. Uncontrolled studies suggestive of the efficacy of new technologies are generally taken as compelling evidence for adoption. A theme developed later in this report is that such studies are incomplete and frequently misleading.



Source: Feeny, Guyatt, and Tugwell (1986), p.7.

# 4. THE REGULATION OF ADOPTION AND UTILIZATION IN THE ONTARIO HEALTH-CARE SYSTEM

Experience in Ontario is consistent with the generalizations on the diffusion of new technologies presented above. Yet relative to experience in the United States, adoption in Ontario (and in Canada in general) has been slower, more deliberate, and less extensive. For expensive embodied technologies, the separation of capital and operating budgets have given the Ministry of Health a lever with which to limit adoption. The requirement that hospitals obtain approval from District Health Councils for major new projects has promoted regionalization. Similar policies with respect to specialized facilities (for instance life support systems for coronary surgery) have indirectly limited the extent of utilization of sophisticated surgical procedures (for instance coronary artery bypass grafting). Although these policies have been somewhat successful, their emphasis is on cost containment. A fundamental presumption of such policies is that if unconstrained, actors in the health-care system will generate virtually unlimited demands for the adoption of new technologies. Although realistic the policy fails to consider alternative mechanisms (to be discussed later) for affecting providers' behaviour.

The Ministry's focus on major capital items and facilities places it in a position in which it has a relatively accurate estimate of the inventory of such facilities. Because less expensive equipment and facilities are accommodated within hospital global operating budgets, much less is known about the stock of technologies such as diagnostic ultrasound equipment.

The containment strategy of The Ministry is supported by various advisory committees representing expert providers, clinical users, and sometimes the faculties of health sciences in the province. Without a reliance upon rigorous standards of evidence, such groups tend to endorse demands for adoption, consistent with the interests of expert providers and a sincere concern with enhancing the quality of medical care.

Although the capital-budgeting process, facility plans, and <u>ad hoc</u> advisory groups formed around prominent new technologies (for instance, magnetic resonance imaging) have been relatively successful in containing adoption, issues of effectiveness and efficiency are not an integral part of the decision-making process. There is considerable concern over excess adoption and duplication of facilities while there appears to be relatively little concern over under-utilization of technologies of proven effectiveness and efficiency.

Finally, although the Ministry monitors the development and utilization of specialized and sophisticated surgical facilities, its reliance on this control mechanism and HMRI (Hospital Medical Records Institute) data on utilization by procedure may place it in the position of "discovering" a major new surgical procedure only after it is fairly well entrenched. If a new procedure requires the same facilities as certain existing ones, it can come on the scene "without warning". It will also take time before a new code is added to HMRI; thus again it could "escape detection". Thus controls of major disembodied technological developments are potentially less powerful than those for major embodied technologies.

5. THE ROLE OF TECHNOLOGICAL CHANGE IN ACCOUNTING FOR INCREASES IN THE COST OF HEALTH CARE.

A perennial issue in health technology is its role in accounting for cost The concern is, of course, justified but focuses attention on only half of the equation and ignores the consequences of the use of the A variety of approaches have been used in empirical studies of technology. the effects of technology on cost. A number of studies have focused on hospitals. A recent study by the Office of Technology Assessment in the U.S. concluded that 24% of the 93% increase in per capita Medicare hospital costs between 1977 and 1982 was associated with increases in service intensity, a proxy for technological change (U.S. Congress, 1984). Broadly similar results were obtained in other U.S. studies. Again for the U.S. for ambulatory care, as in hospital care, increases in ancillary services such as laboratory tests were an important part of the increases in cost. More recent evidence, however, reveals a more moderate role for such ancillary services and focuses attention on increased utilization of certain procedures such as caesarean section and coronary artery bypass grafting (Scitovsky, 1985).

The U.S. evidence points to a substantial role for new technologies in accounting for cost increases. As reimbursement policies have become more stringent, however, that role may be becoming less prominent. Furthermore, the results depend on the time period under review. Mushkin (1979) found that for the period 1930 to 1975, biomedical research (note that this is broader than health-care technology) on balance tended to reduce health-care

expenditures, especially for infectious and parasitic diseases. These results are consistent with the observation that the period under review was one that saw the introduction of a series of effective immunizations and antibiotic drugs. As infectious and communicable diseases have been (with a few prominent exceptions) brought under control, the health-care system has become more specialized in treating chronic diseases for which there are as yet few effective therapies.

International evidence then indicates that new technologies play an important role in generating cost increases, but are far from the sole cause of the increases. Does this evidence generalize to Canada? It probably does. Evans (1984, p.162-163) found that in Canada increases in service intensity account for approximately 38% of the 1971-1980 increase in the real cost per patient day in hospital. This result is broadly similar to the results of U.S. studies. Although it is unlikely that the patterns for Ontario are markedly different, the role of technology increases in health care costs in Ontario is not known with much precision. Yet, it is likely that a conclusion of an important but not primary role is warranted for the Ontario situation.

6. THE NEED FOR CLINICAL AND ECONOMIC EVALUATION PRIOR TO WIDESPREAD ADOPTION AND UTILIZATION.

Historical patterns of relatively uncritical adoption, when linked with the relative absence of error-correcting mechanisms within the health-care system, underscore the importance of rigorous ex ante evaluation. Weak evidence based on uncontrolled studies has been accepted as sufficient for

most adoption decisions. More rigorous evaluation comes later, if at all. To date, there are few studies which demonstrate that for specific indications the use of CT scanners improves patient outcome; while magnetic resonance imaging provides "pretty pictures" and its use in certain cases may represent an improvement over CT scanning, its effects on patient outcome are yet to be demonstrated. (The potential for uncontrolled studies to be misleading will be discussed below.)

The need for careful evaluation prior to widespread adoption is particularly acute in health care. This is the standard already required for new drugs in Canada yet new diagnostic, surgical and therapeutic technologies are seldom subjected to the same standards of evidence.

In many sectors outside of health care, errors in judgement about technological adoption are "self-correcting". For example, the automobile body shop that purchases a new welding technology which subsequently proves to be ineffective or inefficient will tend to be driven out of business. In the health-care sector, however, we have focused attention towards goals other than "the bottom line" (i.e. clinical effectiveness) and, in general, done so for good reasons. Thus, ineffective and inefficient practices are allowed to persist. Once established, programs tend to become entrenched and difficult to remove. Thus there is less scope for "not getting it right at the beginning".

#### 6.1 FALLACIES OF UNCONTROLLED STUDIES

The production of improvements in health status is subject to considerable

variation. This pervasive uncertainty means that it is difficult to ascribe changes in health status to specific clinical maneuvers. Several examples may serve to expose the weaknesses of uncontrolled studies for the evaluation of technologies in the post-exploratory phase. Extra cranialintra cranial bypass surgery was widely accepted by neurosurgeons as an effective treatment for the prevention of strokes in patients with previous The results of a recent major international randomized controlled strokes. clinical trial (RCT) have, however, demonstrated that patients treated with standard medical care (ASA), experienced lower mortality with no sacrifice in functional status. The patients in this trial were randomly allocated between surgical and medical care; thus the study design afforded the power to reach unambiguous conclusions. Earlier uncontrolled studies had indicated that surgical treatment was promising; some unintentional bias such as offering surgery to relatively healthier patients may account for the discrepancy.

An even more striking example is mammary artery ligation. Again, uncontrolled studies indicated that this surgical procedure, popular in the 1950s, relieved angina. An RCT in which all patients underwent exposure of the mammary artery in the operating theatre and were then randomly allocated between receiving the actual procedure and a sham one, however, indicated that patients who received the sham operation experienced declines in angina and increases in exercise capacity basically equivalent to those obtained among patients who received the actual procedure. Although striking, these examples are not unique. Sacks, Chalmers, and Smith (1983) examined controlled and uncontrolled studies of the same six therapies. While 79% of

the uncontrolled studies were favourable to the therapies under review, only 20% of the controlled studies were.

Among the potential biases that contribute to these persistent discrepancies are placebo (Hawthorne) effects, natural history of the disorder (the patient would have improved anyway), biases in measurement or in the attention patients received, biases in patient selection, and co-interventions. The use of concurrent randomized controls and other aspects of rigorous study design serve to ameliorate these biases.

Thus there is a powerful argument for increased use of RCTs to demonstrate clinical effectivness of new technologies relative to existing ones. The implications of this strategy will be considered below. Characteristics of and further justification for rigorous study design are discussed in Feeny, Guyatt and Tugwell, (1986); and Guyatt, Drummond, and Feeny et al (1986).

#### 6.2 EVALUATION OF DIAGNOSTIC TECHNOLOGIES

Randomized controlled trials are routinely used to establish the safety and efficacy of drug therapies. They are used, if not as frequently as they might be, to investigate efficacy and effectiveness for other therapeutic technologies. They are seldom used in the evaluation of new diagnostic technologies.

Several factors are responsible for this pattern. First, many diagnostic technologies have a large variety of uses; mounting separate studies for each use would, in most cases, be prohibitive. Second, the enthusiastic

embrace of new diagnostic technologies has in general been based on an incomplete but necessary set of criteria reflecting the concerns of providers and a focus on process rather than outcome. Studies of diagnostic technologies have typically focused upon technological capability (performance specifications) and diagnostic accuracy concerning the presence and severity of disease. Little attention is focused on the rigorous demonstration that the new diagnostic technology provides new information that affects patient management. This too is only an intermediate outcome. The ultimate criterion is that the use of the diagnostic technology actually affects patient outcome. Although provider and patient reassurance may be valuable, it is unclear that the use of expensive diagnostic technologies can be justified solely on such grounds.

RCTs of selected important "tracer" indications for the use of new diagnostic technologies which include follow-up on therapeutic decisions and patient outcome have an important role in health-technology assessment. As in the case of therapeutic technologies, concurrent randomized controls offer the ability to reach definitive conclusions in a timely manner. (For more on methodological criteria for the evaluation of diagnostic technologies see Guyatt, Tugwell, Feeny, Haynes, and Drummond, 1986a, 1986b, Feeny, Guyatt and Tugwell, 1986).

#### 6.3 THE ROLE OF ECONOMIC EVALUATION

The demonstration of clinical effectiveness, while necessary, is not sufficient for decision-making purposes. Ineffective technologies are clearly not efficient, but effective technologies may or may not be.

There are two important sets of questions in economic evaluation in the context of health technology assessment. First, how does the technology under question compare to relevant alternatives aimed at the same health care problem? What are the costs and effects among relevant alternatives? Answers to these questions provide guidance concerning choice of technique for a specific health care problem.

The second set of questions addresses comparisons to alternative uses of health-care resources. How do the costs and effects of resources devoted to one problem compare with the cost and effects for other health-care problems? Answers here help to inform allocation decisions within the health-care sector.

Within economic evaluation there are three families of evaluation techniques: cost-effectiveness analysis, cost-utility analysis, and cost-benefit analysis. In cost-effectiveness analysis costs and effects of various alternatives are compared. The effects may be measured in clinical units such as reduction in blood pressure measured in millimeters of mercury or in more generalizable units such as life-years gained. For comparisons among alternative strategies for the control of hypertension the former may suffice but the ability to compare hypertension control programs to (say) dietary management of cholesterol will be forgone.

Even broader measures of effects such as life-years, however, may not be comprehensive enough. A life year in dialysis may be very different than a

life-year spent as a survivor of meonatal intensive care. Cost-utility analysis was designed to address this problem by comparing effects to quality-adjusted life-years gained. Techniques for obtaining quality-of-life scores for various health states from patient or general public populations have been developed and successfully applied in a number of important areas (see Torrance, 1986). When it is recognized that improvement in quality of life rather than, or in addition to, postponement of mortality is a primary objective of medical care, the reliable and valid measurement of quality-of-life impact becomes essential.

In cost-benefit analysis, costs are compared to effects measured in pecuniary (dollar) terms. For some of the effects of health care such as reduction in costs of health care through earlier cure or gains in production by returning healthy patients to the labour force sooner, the pecuniary measure of effects is appropriate. For other effects such as reductions in pain and suffering or postponement of mortality, pecuniary measures available to date fail to provide accurate estimates. Although incomplete, a comparison of pecuniary costs and benefits among alternatives can be quite informative.

Hybrids of these three types of evaluations have been developed. One useful variation combines cost-benefit and cost-utility analysis to obtain an estimate of net cost per quality-adjusted life-year gained. In this measure the numerator summarizes the information from the cost-benefit analysis which compares pecuniary costs and benefits; the denominator summarizes the quality-of-life effects from the utility analysis. This measure provides a

basis for making broad comparisons about the efficiency of the allocation of health-care resources among specific programs throughout the sector.

The costs included in the analysis may be measured from one of several viewpoints: a specific health-care institution, the Ministry of Health, the government, or society as a whole. More narrow viewpoints such as the hospital or the Ministry are important but can be misleading at the broad level of making decisions about resource allocation. Home care for the elderly, for example, may reduce cost to the Ministry of Health but part of those savings are offset by costs borne by other social agencies and family members in providing care.

The components in the cost estimates include direct costs such as salaries and fees for personnel, materials and supplies, use of capital facilities and space, and overhead such as administration. Indirect costs include cost borne by patients in obtaining care in the form of forgone earnings during the period of illness.

Because costs and effects may occur in different time periods and because the structure of human preferences is that people prefer benefits sooner rather than later, an important component of an economic analysis is the allowance for differential timing in the flows of costs and benefits. The approach used to take this into account is known as discounting, a process which converts future costs and effects to their present value so that all costs and effects may be compared, regardless of when they occur.

Sensitivity analysis allows the analyst to explore the impact of alternative assumptions about key parameter estimates. It is especially important in the context of assessment of new technologies. Because of their very novelty, there will be uncertainty about some of the components of the cost and effects estimates. Sensitivity analysis can reveal how much the final answer is affected by alternative assumptions and can identify key items for which more precise estimates are especially important. (For more on techniques of economic evaluation in health care see Drummond, Stoddart, and Torrance, 1987).

### 6.4 THE INTEGRATION OF CLINICAL AND ECONOMIC EVALUATION

Techniques for the assessment of clinical effectiveness and economic efficiency of new or well-established technologies complement each other. Controlled studies provide precise and unbiased estimates of effects for comparison with the resource requirements necessary to obtain those effects.

This complementarity implies that it will frequently be advantageous to integrate economic analysis into clinical trials. Although this adds to the complexity of the study design and to the size of the investigative team, it does offer distinct advantages. First, the economic evaluation will be based upon more rigorous clinical evidence. Second, the results of both investigations will be available for decision-making purposes at approximately the same time, avoiding further delays. If the results of such analyses are to affect decisions, timeliness is important. Third, the prospective design of the study allows for more convenient and accurate measurement of costs, especially costs borne by patients. (For more on

integrating economic and clinical evaluations see Feeny, Guyatt, and Tugwell, 1986, and Drummond and Stoddart, 1984).

# 6.5 CLINICAL AND ECONOMIC EVALUATION AS A BASIC TOOL IN TECHNOLOGY ADOPTION AND UTILIZATION DECISIONS

If the widespread adoption of technologies can be delayed pending the availability of solid evaluative evidence (this topic will be discussed below), such evidence may then be used by clinicians and other health-care providers, hospital administrators, District Health Councils, and Ministry officials to make more informed and rational decisions. The adoption of cost-effective technologies may be encouraged while less cost-effective ones can be discouraged.

Because technologies often have multiple potential uses, part of the synthesis of evaluative evidence should be the identification of the indications for the use of the particular technology. Those indications, when linked with evidence of epidemiological data on the burden of such illness, may then be used for facilities planning for the introduction of new technologies.

The emphasis here is on the use of technology-assessment evidence as an important, but not the only, component in making decisions to adopt and utilize new technologies. If properly implemented, the thrust of policy (other than during the early period of delay pending evaluation) will be more even-handed than the current containment policy. If evaluation is to become a useful tool, it must be a means to obtain approval when the

evidence warrants it and rejection when it does not, not just another way to deny requests. All actors in the system would have access to and therefore potentially be held accountable to relatively objective evidence. This may reduce the discretionary power of some officials; it may also make certain political lobbying efforts less attractive. Accordingly, support for such an approach will not be unanimous.

#### 7. IMPLICATIONS OF EVALUATION

A number of additional implications flow from the adoption of a strategy of evaluation prior to widespread adoption. If decision makers are to rely on evaluative studies then a system for providing and disseminating such information in a timely manner needs to be organized. The capacity to produce such studies will have to be upgraded. The capacity of decision makers throughout the health-care system to make intelligent use of the results of such studies will also have to be augmented. Finally, decision makers will need to be given the incentives to use this information.

7.1 ORGANIZING THE PROVISION OF TIMELY TECHNOLOGY-ASSESSMENT INFORMATION

If useful evaluation information is to be available, major new health-care technologies suitable for evaluation will have to be identified while they are still emerging. One policy option is to contain adoption pending evaluation. The existing system in Ontario has already demonstrated substantial capacity for containment.

Internationally there is growing awareness of the need for technology assessment and increasing activity (see for instance Banta and Russell,

1981). The Netherlands and Sweden have relatively well developed systems. The European office of the World Health Organization and the European Economic Community are also involved.

For a pluralistic setting such as that found the U.S., various offices within the National Center for Health Services Research, U.S. Congress (Office of Technology Assessment), National Institutes of Health, and Institute of Medicine/National Academy of Sciences are active in organizing technology assessments and disseminating results. These activities by public agencies are complemented by activities of private third-party payers and various professional societies.

In Canada, at the federal level, the Medical Research Council and the National Health and Research Development Program of National Health and Welfare provide funding for some technology assessment studies. In Ontario the Health Services Research Program funds research and has been among the most receptive of the funding agencies to proposals involving the integration of clinical and economic evaluation. Like the situation in other countries, these efforts by public agencies in Canada are complemented by studies supported by professional groups and charitable organizations.

This brief review of current activities in technology assessment has several implications. First, a solid foundation exists in Canada and Ontario upon which to base further expansion in technology-assessment capacity. Second, vigorous international co-operation and liaison will allow Canada to economize on its technology-assessment efforts by adapting off-shore

research studies for use in Canada. The capacity to combine Canadian cost data with data on effects from a well designed U.S. study would avoid expensive duplication. Third, the growing level of international activity greatly reduces one of the most difficult problems in technology assessment, the early identification of emerging technologies. Because many technologies used in Canada originate elsewhere, Canadian evaluators have additional lead time to decide which technologies are good candidates for technology assessment.

#### 7.2 AN AGENCY FOR TECHNOLOGY ASSESSMENT

The ideal technology-assessment agency would be responsible for identifying emerging technologies, adapting off-shore study results for use in Canada, organizing intra-mural and, more importantly, extra-mural technology-assessment research, synthesizing results, holding consensus conferences, and disseminating information. The agency would need to develop criteria for deciding which technologies to evaluate and for which uses. The timing of evaluation for emerging technologies is also a relevant issue. At present these activities are fragmented across many agencies and levels of government.

The mandate of such an agency would be broad and formidable. If it is to succeed it would need to be held strictly accountable for those activities, and only those. One of the problems in the current funding system for clinical trials is that, for instance, the Medical Research Council has such a broad mandate of basic and applied research that it is always faced with difficult trade-offs. A mission-oriented agency whose mandate was to

generate and disseminate rigorous and timely information could be held accountable much more readily.

Such mission-oriented approaches have been successful in organizing applied research in agriculture (see Hayami and Ruttan, 1985; Ruttan, 1982). Like the technology-assessment case, these agencies rely heavily on experimental evidence and are organized around a particular problem (for instance, increasing efficiency in rice production). As in the technology-assessment case, these agencies combine the talents of a variety of disciplines and types of investigators focused on a common problem. A reasonable institutional format exists.

# 7.3 WHAT LEVEL OF GOVERNMENT SHOULD CREATE AN AGENCY FOR TECHNOLOGY ASSESSMENT?

A technology-assessment agency is organized to produce information of high integrity. Information is a public good; my use of the information does not reduce the amount left for you to consume. Because it is difficult to exclude those who do not pay for information from obtaining it, each level of government has an incentive to underinvest in producing information. Why should Ontario fund an expensive clinical and economic trial if it can wait and obtain the results from a study being supported by the Province of British Columbia? A problem arises, obviously, if each province decides to free-ride and no one undertakes the study. The implication is that although it is necessary for the Ministry of Health to create a technology-assessment office, it is not sufficient. Ontario can provide the leadership to pressure for the organization of an agency at the national level, perhaps

directed by a board with representation from the users of technology-assessment reports, the Ministries of Health in each province. The national level agency could specialize in international liaison, identification of emerging technologies, technology assessments requiring large sample sizes involving multiple sites, and national dissemination activities. (A proposal for the formation of a National Health Technology Assessment Council is found in Feeny, Guyatt, and Tugwell, 1986).

The counterpart agency in Ontario could focus on smaller-scale assessment, facilities planning, and information dissemination. It would also channel information on new candidates for assessment to the national level.

At both the national and provincial levels the capacities of these agencies would have to be developed gradually. Each would rely heavily on extramural research. Applied researchers in health sciences and health services will respond to the incentives provided by new mission-oriented grant money. The methodological soundness of the initial peer review process for allocating funding for extra-mural research will be crucial in setting the standards for high quality studies. Over time, investigators learn and master the required techniques. In spite of the urgency of technology assessment, the establishment of agencies and the building of research capacity will have to be a gradual process. Parallel with the development of the capacity to produce information, key personnel throughout the health-care system will have to be given the skills to be critical and informed users of technology-assessment studies.

#### 7.4 INCENTIVES TO USE EVALUATIVE EVIDENCE

Even if the production of rigorous and timely information is achieved and even if potential users are aware of and are capable of understanding the evidence, it does not necessarily follow that they will use it. In the period before global budgeting, the period of explicit cost reimbursement, the signals provided to clinicians and hospital administrators indicated that if it was better, adopt it, even if it costs more. Little justification was needed and evidence from uncontrolled studies was deemed sufficient.

More recently under global budgeting the focus has been on cost, not effectiveness or efficiency. The environment is one in which each institution attempts through its proposals for new programs to capture as much of the Ministry budget as possible. The demanders of new programs are given weak incentives to temper their requests. The Ministry is put in the unhappy situation of denying the requests most of the time. The potential for conflict is inherent. A reliance on evaluative evidence channels some of that conflict into debate about the quality of the evidence, a debate which is more objectively resolvable.

The discussion implicitly presumes the retention (at least for large-ticket items) of the current system of centralized controls by the Ministry. If armed with a solid base of evaluative evidence, the Ministry would indeed be in a better position to make better informed choices than it is today. It would also use such evidence to promote efficient technologies when requests were absent as well as to deny ineffective and inefficient ones in the face

of requests.

More indirect methods are also warranted. One option would be to allot each hospital a stable multi-period capital budget with a firm commitment to be intolerant of deficits. If hospitals were allowed to carry over their budget or spend as they saw fit, they would not have the same strong incentive to capture Ministry funds through proposals. Within the hospital there would be a mechanism to reveal the opportunity cost of approving a particular project: the rejection of one of its competitors under review. Evaluative evidence could inform those choices. Once clinicians became convinced that rigorous evidence on effectiveness and efficiency is required to obtain approval, they would assemble it. Again the evidence needs to exist and be accessible. Such requirements will also affect the pool of technologies actively considered for adoption.

The granting of capital budgets could be organized at the hospital level or at the district level. Again the emphasis is on a capital budgeting process rather than serial review of specific proposals. A similar decentralized strategy is represented by current experiments with clinical budgeting. In this approach a clinical department within a hospital is given, prospectively, a fixed sum to pay for the care of all of its patients on an annual basis. The department is then charged for its use of ward, nursing, laboratory, radiology, etc. services. Clinicians who make clinical decisions are thus given financial responsibility as well. One implication of clinical budgeting is the need for improved cost-accounting systems, which is in part responsible for the current development in management

information systems.

Under clinical budgeting the clinical team has the incentive to identify cost-effective technologies and practice styles. New technologies may be introduced at the expense of the relatively less effective existing ones. Again, a body of evaluative evidence is essential to the success of this approach. Prospective hospital reimbursement based on case mix or other objective criteria might also achieve similar outcomes. Outside the hospital setting similar incentives exist in the prospective payment of Health Service Organizations in Ontario in which clinical and financial responsibilities are more closely aligned. (For a more complete discussion of options for rationalizing health care delivery in Ontario see Stoddart, 1985 or Feeny, Guyatt, Tugwell, 1986).

The strategies for decentralizing adoption and utilization decisions have a number of potential advantages but all rely upon the prior provision of timely evidence on effectiveness and efficiency. One advantage is that the Ministry would assume a less adversarial role, at the expense of some loss of direct control. To some officials the latter represents a disadvantage. The centralized decision-making system perpetuates the division of clinical and financial responsibility. It also places a heavy burden on the Ministry in gathering information, monitoring, enforcement, and administration. Decentralized strategies involve more indirect control with reduced administrative demands. Given that the Ministry is generally reluctant to "interfere" in the practice of medicine, decentralization strategies are consistent with important constraints in the current system. The Ministry

would still have its current prerogative to intervene when it felt that a certain hospital or agency was consistently making poor decisions. The key advantage of the decentralized approaches is the closer alignment of clinical and financial responsibility and authority.

# 7.5 DOWNSTREAM EFFECTS OF THE SYSTEMATIC USE OF EVALUATIVE EVIDENCE IN ADOPTION AND UTILIZATION DECISIONS

If decisions are increasingly made on the basis of evidence of effectiveness and efficiency, the nature of the stream of new technologies will be affected. Developers of new technologies in the private sector (especially relevant to embodied technologies for which patent protection is available) respond to profit signals. Once they become convinced that there is a small market for ineffective or marginally effective new technologies and a large market for cost-effective ones, they will respond accordingly. Drug companies are already expanding their evaluations (traditionally focused on safety and efficacy) to include cost-effectiveness and quality-of-life assessments. Similarly, clinical researchers who innovate new techniques (disembodied technical change) largely for non-pecuniary motives will discover that peer acceptance of their innovations depends upon rigorous demonstration of effectiveness. Ineffective technologies will be eliminated at an earlier stage in the development process.

#### 8. SOCIAL AND ETHICAL CONSIDERATIONS

New technologies do not just pose challenges concerning effectiveness and efficiency and the proper indications for use. Many new technologies pose troubling ethical issues. Improved information on effectiveness and

efficiency will bring one set of these issues out in the open. Imagine the situation in which a large body of information exists on the net cost per quality-adjusted life-year gained for a wide variety of alternative health care programs (hybrid combinations of cost-utility and cost-benefit analysis). How much is society willing to spend to obtain a qualityadjusted life year? The evaluation results provide clear evidence on the choices but do not make the final decision. The decision is fundamentally a value judgement and implicitly involves the politics of public representation as a means of aggregating individual preferences. public is represented on hospital boards and the Minister and, through him the Ministry, is indirectly held accountable to the electorate.

Ethical issues do not end with consideration of the level of expenditure acceptable to the community to obtain a quality-adjusted life-year. Technological capabilities to prolong life and even to manipulate its creation pose additional issues. In a sense these social ramification issues could be made part of a more complete version of technology assessment that went beyond clinical and economic evaluations. Some effort along these lines is clearly needed; making such studies a part of on-going technology assessment may, however, be premature. Although the methodologies for clinical and economic evaluation are well developed and validated, the same cannot be said for the social-analysis components of technology assessment. In addition, because these issues are ones of fundamental value judgement, it may be unwise to remove them too far from the political sphere and other mechanisms for aggregating individual preferences.

Legitimate concern is often expressed over the potential misuse of new technological capabilities. The development of enhanced diagnostic capabilities based on recombinant-DNA technologies and in vitro fertilization have raised concerns about the willful and unnatural manipulation of the composition of the next generation - - for instance giving parents the choice of gender of their offspring.

Although new technologies may enhance the capability to identify the gender of the fetus, that capability already exists. It is perhaps informative to examine the record of programs in Ontario that already provide prenatal chromosome abnormalities through amniocentesis and the diagnosis of culturing of fetal cells. Access to prenatal diagnosis is determined on the basis of a well developed set of guidelines or indications for the test. The guidelines were developed co-operatively by the Canadian College of Medical Geneticists, the Society of Obstetricians and Gynecologists of Canada, and Canadian Pediatric Society. They are based on a review of the evidence on risk of the procedure, epidemiological evidence on the risks of detectable abnormalities, and U.S. based estimates of the pecuniary costs and benefits of prenatal diagnosis. The chief indications for making the test available are late maternal age (the risk of Down Syndrome rises with maternal age) and family history (the degree of relationship provides information on the risk of abnormalities). Tests are not made available to parents who would like to choose the gender of their offspring. (An exception is that tests are made available for the determination of the sex of the fetus if there is a family history of an X-linked disorder). Thus, in at least one important case in the past, sound clinical and economic

criteria have been used and socially questionable uses of technological capabilities have been sharply curtailed.

#### 9. CONCLUSIONS

In the past the Ontario health-care system has contained excessive proliferation of expensive capital-embodied new technologies. Indirectly through the Ministry's control over the development of major facilities it has affected the adoption and utilization of major surgical procedures. These accomplishments are far from trivial. Yet the mechanisms used are adversarial and focus on containment. A strategy of cost containment is inadequate for technology policy. While the excessive costs of ineffective technologies may in large part be avoided, the realization of the benefits of highly cost-effective new technologies are delayed. As in many studies of the Canadian health-care system, the final assessment is an ironic one; the system does relatively well but there is ample room for improvement. In the area of technology policy this report has argued for:

- the need for rigorous clinical and economic evaluation prior to widespread adoption;
- 2. the creation of agencies at the provincial and national levels to organize the identification, evaluation, and dissemination of information regarding major new health-care technologies;
- 3. rationalization within the health-care system to give decision makers at multiple levels the capability, and in particular, incentives to utilize such information.

Although the tasks are formidable, they are feasible. The methodologies of technology assessment are already well developed. Ontario (and Canada in general) already has a core of highly qualified investigators upon which to build. The Ministry needs to give clear indications, verified by increased grant support for technology assessment, to draw applied researchers into these studies and younger ones into training appropriate for the expanding opportunities. Training of managers and clinicians throughout the system in critical appraisal skills so that they may be intelligent users of studies is also necessary.

Rigorous evaluation can help guide the system towards more efficient patterns both of adoption and utilization. The establishment of guidelines for the use of a technology based upon evidence of its cost-effectiveness in those uses would represent a major improvement.

Technology assessment needs to become an integral part of decision making. Because new technologies emerge frequently, it will need to be an on-going process, both in updating evaluations of existing technologies and in organizing evaluations of new ones. Assessment becomes "perpetual motion".

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