How Can New Technology Be Introduced, Evaluated, and Financed in Critical Care?

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We briefly review issues impacting the introduction, evaluation, and cost of technology in critical care, providing a clinician's perspective. Where appropriate, we note important distinctions between health-care systems in Canada and the United States—primarily the result of significant differences in the methods for funding health care in the two countries. Finally, we discuss what processes might be reasonably considered for evaluating technology in critical care and discuss the probability of various consequences that will significantly affect the care we provide our patients if critical-care practitioners, industry, and health planners fail to jointly undertake this responsibility.

It is time for a rigorous effort to establish what procedures produce beneficial outcomes under what conditions—and to eliminate stark instances of "over-utilization." Physicians and hospital administrators should put establishing quality standards at the top of their agendas (1).

Technology, including health-care technology, is changing at a rapid pace. New innovations are constantly flooding the market, often making current technology quickly obsolete. In the form of drugs and devices, dynamic changes in the technology of health care have become increasingly important in our treatment of patients. At the same time, health-care expenditures are consuming a substantial proportion of the gross national product, and the budgets of most health-care jurisdictions are, therefore, under constant pressures of constraint.

Because of its high cost, technology has been viewed as a major contributor to the current escalation in health-care costs (2–6). The result has been increasing conflict between health-care providers, attempting to ensure the best care for their patients, and health-care funding agencies, concerned with strategies of cost-containment. Although many have agreed that new technologies have been a major contributor to the increased costs of health care during the last two decades, few have been able to offer any easy solutions. Shortell and Kaluzny (7) and Feeny and Stoddart (5) have emphasized that future changes in the health-care system must be particular cognizant of the impact of technology.

Questions have also been raised about technology's safety and effectiveness. Indeed, the need to perform an adequate assessment before the widespread diffusion of any technology is being increasingly debated. Overall, there is concern as to whether society is making wise use of the current levels of funding devoted to health-care technology, or whether there are better uses for the same fiscal resources elsewhere in our health-care system. To answer these questions and to make informed decisions, experts from several countries have agreed that commitment to a process that includes a rigorous and objective assessment of both new and existing medical technologies is required between all players involved in the diffusion of technology to the interface with patients (5, 7, 8).

Understanding issues relating to the impact of new technology is particularly germane in critical-care medicine. The cost of providing this service far exceeds those resources usually expended at the general ward level (2, 9). However, the contribution of the cost of technology to the overall resource expenditure is largely unknown, because questions of cost-effectiveness and cost-benefit are not currently being addressed in any systematic way in critical care. The importance of evaluating the technology used in critical care, and processes for this evaluation, must be come an integral component of the teaching and practice of critical-care physicians in the 1990s. This focus for evaluating technology should encompass all of the instruments, drugs, and procedures used in the delivery of this component of health care, as well as the organizations and management models that support critical-care programs.

In this brief review of issues impacting the introduction, evaluation, and cost of technology in critical care, we will provide a clinician's perspective on those processes that have been recommended for the evaluation of this discipline's technology. Where appropriate, we will note important distinctions that may exist between Canada and the United States—primarily the result of significant differences in the methods for funding health care in the two countries. Finally, we will discuss what processes might be reasonably considered to evaluate technology in critical care and discuss the probability of various consequences that will significantly affect the care we provide our patients if critical-care practitioners, industry, and health planners fail to jointly undertake this responsibility.

Why Evaluate Technology in Critical Care?

What are the forces currently operative in requiring a more appropriate evaluation process of critical-care technology than currently exists? At the macro level, existing health-care delivery models in both Canada and the United States are under intense scrutiny. There clearly is public dissatisfaction with the current process of health-care delivery in the United States (10); meanwhile, physicians, health-care planners, and politicians simultaneously debate the benefits and performance of individual health-care delivery models. Despite a greater per capita expenditure on personal health in the United States than in Canada, the mortality rates from infant disease in certain sectors of the United States exceed those recorded in either Canada or the United Kingdom (11). Thus, the current process for determining health-care delivery in the United States as currently struggling with issues such as high cost, questionable effectiveness in some of its component parts, and the lack of universality.

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The Canadian health-care system also demonstrates significant areas of concern in issues relating to the availability-vs-needs equation of certain services, most probably due to the process of funding health care from general tax revenues, a necessary mechanism to guarantee the prerequisite universal access of this constituencies system. Thus, innovation comes slowly to the Canadian health-care system, rationing has been introduced in both implicit and explicit ways, and the cost-containment process has been diffused to the level where rationing is now the responsibility of individual health-care providers, who are held responsible for care provision at levels of the system that may not be funded to meet current societal expectations (12).

The current health-care delivery apparatus of both countries, therefore, is expensive, demonstrates little potential for growth of its funding base, and has not satisfactorily demonstrated its cost-effectiveness to either the politician or the consumer. This latter notion may not be necessarily "real" at all levels and in regards to all issues, in which case each system urgently requires improved marketing strategies by health-care professionals to describe the successes of the system and what it needs to maintain consistency in the quality of its output.

At a micro level in the hospital sector, critical care may be analyzed at two levels: the program itself (i.e., the hospital service) and the components of the program (e.g., labor, technology, management structure, and physical plant). At the program level, the primary focus is on the overall performance of this field in its mandate to provide the care required by critically ill patients. The primary goal of this hospital-based program was described by an NIH Consensus Conference in 1983 (13):

Critical Care is a multidisciplinary field concerned with patients who have sustained, or are at risk of sustaining, acutely life-threatening, single or multiple organ system failures due to disease or injury. Critical Care seeks to provide for the needs of these patients through immediate and continuous observation and intervention so as to restore health and prevent complications.

Ensuring achievement of this goal has become an expensive process during the last two decades. The proportionate growth of this particular hospital-based service has also far exceeded growth in other components of the hospital environment. It has been estimated that critical-care beds generate costs that exceed the costs of other active-treatment hospital beds by 200% to 400% (2, 14, 15), and that critical-care services impact perhaps 10% to 20% of overall hospital expenditures (15-17). Furthermore, a disproportionately small percentage of critically ill patients may be responsible for total resource consumption: some estimate that 1% of patients admitted to critical care consume 10% of the health-care program's costs and that 17% consume 50% of the program's costs (14).

Therefore, although health-care costs have generally increased in the last decade, the costs of providing critical care seem to have increased at a disproportionately greater rate. In addition, critical-care beds, which currently account for between 5% and 6% of all acute-care hospital beds in the United States, have been estimated to be increasing about 4% each year, with a majority of this growth occurring in community hospitals (18). These increases in the absolute level of critical-care resources and in the utilization of these available resources may be attributed to several factors, including an increase in the elderly patient population base, changing societal expectations, and improvements in the availability and amount of technology that can be provided, e.g., transplant and trauma programs.

Because existing critical-care programs are an expensive commitment by the hospital sector, it is important to briefly review the overall successes of this program. Although evaluations of outcome from critical care remain few, some of the recent studies that have begun to address the impact of critical care have reported on outcome that is of measurably good quality (19-22). Admittedly, several issues germane to costly admitting practices in critical care remain, such as studies prospectively demonstrating which patients admitted to critical care do not need this service by virtue of the low severity of their illness. In the broader context, however, it is important to emphasize that the high cost of critical care is generally expended on a patient population of whom 70-80% can be expected to be discharged from a critical-care unit with a quality of life that would be considered acceptable to health-care planners and patients alike.

Analyzing the components of a critical-care program establishes a focus on the individual characteristics that describe the program, e.g., technology vs staffing issues (Table 1). Because methodologies for costing-out the components of critical care remain imprecise, it has been difficult to quantify the impact of changes in any one of its technological components on the total cost of the program. However, although technology accounts for only a small proportion of the direct costs of any critical-care program, its indirect costs not only are substantial but usually define the greater issue. Thus, technology indirectly impacts staffing costs when admission rates to the critical-care unit increase by virtue of a new technology, e.g., one that allows the program to provide care to patients not previously felt to be effective consumers of its services. For example, the direct charge of a heart–lung machine and cyclosporin to the budget of a critical-care unit is negligible when compared with the more substantial costs expended by the program in the staffing required to care for a post-operative heart-transplant patient. The improved long-term quality of life emanating from some of these new, technology-dependent programs has resulted in increased consumer demand and, therefore, in a growing number of hospitalized patients who otherwise might not have been admitted to a critical-care unit.

Concurrent with an increase in both the costs and level of service provision, revenues to critical care have not in-

| Table 1. Questions Proposed for Evaluating Diagnostic Technology [Adapted from (28)] |
|-----------------------------------|-----------------------------------|
| **Technological capability and range of use** | Does the test perform to laboratory specifications? |
| | Does the test provide clinically relevant diagnostic information? |
| **Diagnostic accuracy** | Can the critical-care worker more accurately assess the presence and severity of disease with the test? |
| **Impact on health-care providers** | Does the test impact diagnostic confidence of the critical-care worker? |
| **Therapeutic Impact** | Are therapeutic decisions altered as a result of use of the test? |
| **Patient outcome** | Does application of the test benefit the patient? |
increased proportionately; cost-containment has, therefore, become a universal feature of most critical-care programs. In the United States, pressure to reduce costs in critical care followed the introduction of prospective payment schemes; by this process, hospitals were no longer paid for individual services provided to the patient but instead were paid by a fixed allocation. Cost-outliers are common in the Diagnostic-Related Group (DRG) approach to funding of patients admitted to critical care, because this system of payment does not adequately account for the impact of wide variations in patients' severity of illness despite similar initial diagnoses (23-25). On the other hand, in the universally accessible health-care systems characteristic of countries like Canada, the global budgeting process by which hospitals are funded from government on an annual basis has not kept pace with either inflation or the apparent needs of patients (12).

Thus, the cost of providing existing critical-care programs is not only substantial, but continues to grow. Concurrently, there are increasing market pressures on the critical-care department to expand its services. With not-unexpected pressures to reduce hospital expenditures, an evolving process of decentralized management has forced the critical-care physician to become an integral part of a management system that now is consistently required to analyze the process of resource utilization. Thus, the introduction of "utilization management" to critical-care medicine has raised questions regarding the effectiveness and appropriateness of many of the technological components of this program. In analyzing the impact of new technology on critical care during this era of cost-containment, the challenge now facing this discipline is the need to understand which technology is likely to benefit the patient and to determine whether reduced costs might be anticipated from the application of new technology. If new technology introduces only marginal gain for the patient over that already available, but at a cost greater than the technology being replaced, the shrinking of critical-care budgets relative to service provided will make it impossible to justify acceptance of the new technology. It is in this area, the process of assessing technology introduced in critical care, that information remains seriously lacking.

Technology Assessment: the ideal Process

Although the last two to three decades have seen a "technological revolution" in all components of the health-care sector, nowhere has this period had such impact as in the hospital's critical-care program. In the broadest sense, a definition of technology would include the medical services available to this discipline and the systems that support their delivery (26). Therefore, technology assessment in critical care would include all drugs, machines, procedures, and management techniques used in delivering this service.

Jennett (26) lists the following proposed benefits of the technological revolution: a reduction in avoidable morbidity and mortality, the saving and prolongation of lives of good quality, and an increase in patients' well-being. Arguably, data unequivocally demonstrating these benefits in critical care do not exist. However, apparently unquestionable evidence in selected case-mix groupings indicates that improved outcome has accrued from the availability of services provided only by critical care (19, 21); individual testimony has also emphasized the strong likelihood that the technology available to critical care has had a positive impact on patients' outcomes. However, the need to justify the expenditures inherent in acquisition and utilization of new technology in this era of cost-containment requires the adoption of more precise and acceptable processes of assessment in critical care than just individual testimony and historical perspectives (13).

Disappointingly, review of current literature demonstrates little evidence that critical-care programs have responded to the need expressed by the 1983 NIH Consensus Conference for a more formalized assessment of this discipline's technology (13). Even large teaching hospitals present little evidence for programs of formal technological assessment in critical care that support its efficacy, effectiveness, and cost-efficiency. Therefore, one could argue that both current and new technologies may not be as readily available to critically ill patients in the future as they are now unless a more rigorous process of technology assessment is immediately undertaken. That is, until health-care providers and the medical industry, in partnership, develop more effective methodologies for assessing the technology of critical care, including the program and all of its component parts, the survival of this high-cost, hospital-based resource and its technologies will remain vulnerable to increasing cost-control efforts from health-care funding agencies. Also, cost-containment by third-party payers may well result in the abandonment of effective technologies, while retaining ineffective ones, unless an adequate and dynamic assessment process involving all members of the health-care delivery system is developed.

Diagnostic Technology

As previously discussed, technology in critical care can be taken to include all of the medical services available therein and the systems that support their delivery. In the remainder of this paper, however, we will be more specific with regard to technology and will henceforth use the term only to describe the equipment used in the diagnosis of critically ill patients (i.e., without regard to mode of treatment).

Technology may be regarded as a continuum, from high to medium to low "tech." "High tech" would include equipment and procedures used infrequently by critical care and having a large per-unit cost, e.g., computed tomographic scanning. In contrast, "low tech" includes equipment with wide application but relatively low cost, e.g., for measurement of arterial lactate. Indeed, the bulk of spending on technology in critical care may be accounted for not by visible big-ticket items but by the low-cost, high-volume technologies and the many small but frequently performed procedures (27).

Suggested Processes for Technology Assessment

Different methodologies have been proposed to assess technology before its diffusion into the hospital industry. The importance of this as a process has been emphasized by several published texts and journals specifically detailing the process of technology assessment.

The diffusion of a technology to critical care implies its adoption and use. New technology introduced to critical care either replaces or complements existing technology. The adoption of a technology to critical care requires an interaction of the producers, the government, and the user organizations. The implementation of technology depends on an interaction between the user professionals and their patients. Although many factors affect the speed of diffu-
sion, the current process of diffusion of a new technology to critical care usually occurs before a formal assessment of its efficacy, effectiveness, or cost-efficiency has been undertaken, despite an increasing emphasis on the importance of prior evaluation (2). Thus, the need to establish a proper assessment process for new technology before its diffusion to the critical-care environment is increasingly important, given the potential for either cost-ineffectiveness of the new technology or the fact that new technology may, in fact, be hazardous to the patient’s well-being.

Technology assessment means passing a judgement on the technology itself. In contrast, quality assurance refers to an assessment of the health-care provider’s interaction with the technology and the ultimate impact of this interaction on the patient. Jennett (26) states that the primary goals of assessment include a cataloging of its (a) feasibility, (b) efficacy, (c) effectiveness, and, finally, (d) economic impact. Guyatt et al. (3, 28) have described a multi-step process for the assessment of diagnostic technologies (Table 1), to be undertaken before an economic appraisal. Their process is as follows:

- The demonstration of technological capability and of the potential range of uses of the technology describes a developmental phase, undertaken in the laboratory, and a subsequent exploratory phase, wherein ranges of possible benefit of the technology are identified in what has been described as a hypothesis-generating stage (3).
- Subsequently, the accuracy of a diagnostic technology is described through a number of complex processes, most importantly by comparison with a “gold standard,” when available.
- The effect on the health-care provider is then established by determining whether the technology has provided information to the health-care provider that is not otherwise available and whether the technology thereby increases the physician’s confidence in diagnosis. Guyatt et al. emphasize that a diagnostic technology may have a positive effect on the health-care provider but still not influence subsequent therapy, for several reasons: the physician may ignore the results of the test or be unaware of available treatment; there may be no therapy available for the disease process identified; or the patient may have already been provided the best possible therapy.
- Subsequently, the question is asked whether the diagnostic technology has an impact on changing therapy. This component of the assessment process is most stringently evaluated by conducting a randomized, controlled trial. There are, however, substantial difficulties with undertaking such trials to assess technology, including both the feasibility and the expense of this process. Perhaps as equally important, various ethical concerns have also been expressed about the recommendation that randomized, controlled trials be used to assess all important technologies (29); e.g., the issue of premature vs delayed introduction of technology with the laboratory-defined potential for significant positive impact on a disease process, but which must undergo a lengthy assessment process by virtue of the small patient base to which it might be applied (30). Other ethical dilemmas in this approach to technology assessment include the fear that a formalized assessment process might be used by health-care-regulating agencies to cause the health-care provider to become part of the process of rationing care (30). In the rigorous application of randomized, controlled trials, serious questions also arise about selection bias, population definition, and physician bias, which make any information gained difficult to extrapolate to individual cases (31).
- Finally, one must describe the effect of the technology on patient outcome. In the final analysis, therefore, information provided by the diagnostic technology must be used to alter therapy such that outcome is better than what otherwise might have been predicted.

Because of the difficulties in the processes described by Guyatt et al. (3) to evaluate diagnostic technology, particularly at the level at which one undertakes randomized, controlled trials, other methods potentially applicable to an evaluation of critical-care technology have been proposed (30-35). Deber (30) has categorized some of these alternative methodologies, as detailed in Table 2 (30). In addition to using primary data acquisition to evaluate technology by randomized, controlled trials, other methods might, therefore, include evaluation based on primary data acquisition through registries and data banks, or methods of evaluation that essentially summarize existing information. In the former, i.e., evaluation from primary data acquisition, the development of a method to quantifiably compare outcome between critical-care units of different sizes and with different case-mix groupings allows an indirect assessment of the impact of technology. Thus, one can reason that the division of a network of critical-care units into those with the new technology vs those without the new technology should allow a comparison of the impact of that technology on patient outcome, if the process is simultaneously controlled for illness severity, e.g., by the use of APACHE II. Such a process for evaluating technology has been utilized within individual hospitals, by dividing the care-delivery sector into different “teams” that, broadly speaking, provide care to generally the same type of patient population; this process allows a technology to be introduced to one team, but with data being collected from both teams, thereby addressing whether patient outcome was changed by virtue of the technology’s introduction.

Methods of evaluation that summarize existing information include literature reviews, meta-analysis, group judgements, consensus conferences, and mathematical modeling approaches. Perhaps of greatest potential for evaluating technology in critical care are: meta-analysis, a statistical method for synthesizing information from collections of primary articles dealing with the same subject; group judgements, wherein experts distill available evidence and add their own informed opinion; and consensus

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Technology Assessment, Including an Economic Analysis

Once the effectiveness of a technology has been established, an economic analysis of technology entails development of a framework within which the costs of a technique can be compared with its benefits (28, 34).

Three types of economic evaluation have been used to assess health-care programs or their components:

Cost–benefit analysis is used to measure, in dollar amounts, the difference between the costs and benefits resulting from an activity. If the difference is positive, i.e., if the benefits gained from the activity outweigh the costs, the activity is deemed worth its costs; therefore, decisions should be made to allocate resources to produce the benefits. The desirability of using a cost–benefit analysis is that it allows examination of activities, i.e., programs or components with different outcomes, or of activities with more than one outcome.

A cost-effectiveness analysis compares strategies with similar outcomes. It can demonstrate the most efficient, i.e., least costly, method of achieving a particular health-care objective, by comparing the economic costs of different forms of treatment or activity. However, this type of economic evaluation does not allow one to compare two procedures that may have more than one impact, e.g., mortality vs life years saved. An example of how this might be applied to patients admitted to critical care is found in work from Susaki and Eisenberg (36), who determined the cost-effectiveness of different treatment modalities for bleeding esophageal varices; sclerotherapy had a lower cost-survivor rate ratio than did surgery. The main advantage of a cost-effective vs a cost–benefit analysis is that the former obviates placing a monetary value on benefits.

Cost-utility analysis was developed to replace money with cost utility as a measure of economic desirability. Utility of goods or services is their value to the individual, regardless of their price. Cost-utility analysis compares the cost of a program with the health improvement attributable to the program, where health improvement is measured in quality-adjusted life years gained. Quality-adjusted life years are determined by using a health profile and a health index through which individuals subjectively value their health. Thus, we can now assess the benefits of critical care within the objective of prolonging life and not merely postponing death. For example, Sage et al. (37) found that patients discharged from critical care had far less disability than did emotionally disturbed patients.

Although these techniques for evaluating components of critical care (specifically technology, in the context of this paper) appear straightforward, difficulties exist in attempting to fulfill the analytic principles required (38). Some of these difficulties include current inadequacies in costing out critical care and its interacting components; ethical issues, specifically in terms of ensuring that economic evaluations be focused on the patient’s perception of benefits rather than on the health-care provider’s or health-care funders’ perceptions; and, finally, debates over the concept of discounting costs. Notwithstanding these substantial difficulties, decision-making in health-care funding issues will probably be improved when technology can be assessed for its effectiveness; the costing component will be an important aspect of this comprehensive analysis.

Technology Assessment: the Current Process

As has been emphasized elsewhere, the requirements for evaluations of technology are not the same as for drugs (1). Thus, diagnostic technologies are often diffused to critical care—and to the hospital environment in general—before their efficacy, effectiveness, and innocuousness have been completely demonstrated. In contrast, a rigorous and costly process culminating in the demonstration of safety and efficacy of new drugs is required of the pharmaceutical industry by regulating agencies of government in both the United States and Canada. If a similar process has not been established to evaluate technology, reasons must exist.

First, the critical-care physician has an imperfect knowledge base regarding the need and processes for undertaking technology assessment; until now, the assessment process has not been part of the educational objectives for trainees in critical-care medicine. On the other hand, health-care planners with expertise in the evaluation process also have an imperfect knowledge base of clinical practice; this limits their understanding of some of the unique forces operative in critical care, which will impact on any assessment process. The idealized processes recommended for the assessment of technology may also generate a conflict in the critical-care physician, who, in attempting to maintain advocacy for the patient, will be prepared to use any technology that might improve diagnostic accuracy and thereby improve on an otherwise unacceptable outcome. Thus, some have expressed concern that the application of a formal approach to technology assessment in critical care might slow the introduction of technology that could otherwise improve the possibility of survival (30). Remember that the emotions in the interaction between a critical-care provider and the family at the patient’s bedside are capable of interfering with the reason and logic that otherwise would insist that assessment of a technology was required before its clinical application. Such a process, that is, the description of "ethical imperatives," has contributed to the failure of randomized, controlled trials of technology in critical care.

There are other difficulties in assessing technology in critical care. Within hospitals, the process of evaluating technology is of considerable cost, both in time and money; when real budget increases are no longer the norm, the need to concurrently develop technology-assessment processes means that the costs of technology assessment, as well as other processes such as quality assurance and utilization management, must be redistributed from other components of the hospital’s budget. Thus, the growth of the administrative processes required to examine technology in critical care is usually taken away from direct patient-care activity. Health-care funding agencies must be prepared to develop the supplementary funding required to administer the new management processes applied to critical care and to other hospital programs, such as utilization management, technology assessment, and quality assurance.

Within industry, the current processes of clinical assessment of diagnostic technology must be seen as imprecise, confusing, and meddlesome, given the lack of established and agreed-upon standards by which to carry out this activity. For example, even though they are cumbersome in some instances, the requirements for getting a drug to market are known to the pharmaceutical industry. Lack of similar well-established criteria for introducing a new diagnostic technology may penalize the company that un

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dertakes such an assessment if the competition does not deem it necessary to follow the same process.

Methods Used to Control Technology Acquisition

Although there may, therefore, be valid reasons for the failure to adequately assess much of the technology found in the modern critical-care unit, the diffusion of technology to critical care without an appropriate evaluation has generated various responses from the health-care funding agencies. The common purpose of these responses is to contain costs by increasing control over the introduction of technology to critical care and to the rest of the hospital environment.

Lacking a discrete policy in the United States, current attempts to control technology acquisition have focused on the premise that technology assessment in health care can be controlled by manipulating payment mechanisms. Thus, the Medicare Program pays only for services that are “reasonable and necessary” in the patient’s diagnosis and treatment. The Health Care Financing Administration (HCFA) has historically used four criteria to determine whether a service is reasonable and necessary: general acceptance of efficacy and safety, nonexperimental status, medical necessity for the individual case, and provision according to accepted standards of medical practice in an appropriate setting. Because these criteria have not had the hoped-for significant impact on introduction of new technology to the hospital sector, it has recently been proposed that HCFA include cost-effectiveness as a criterion for funding by Medicare of a new technology or procedure (39, 40).

Controlling the diffusion of technology to critical care in Canada has been more successful in limiting the use of high-tech items, e.g., magnetic resonance imaging, than in the United States. Because government is the single health-care funding agency in Canada, it commands a wide scope of control and regulation. Acquisition of new technology has been limited by several strategies emanating from governmental control, including legislation, regionalization of high-tech services, and the use of procedures such as “impact analysis,” which effectively reduce the size of a hospital’s staff and (or) limit the number of procedures that can be done. The most effective strategy of control in the introduction of technology in Canada is the centralized process of funding the system’s hospitals through a global budgeting process; by this mechanism, hospitals receive an annual grant, from which all operations and capital equipment must be funded. Control of the acquisition of medium- to low-tech services is best ensured by government intervention to control the methods of physician remuneration. According to this latter philosophy, the use of pulmonary artery catheters in critical care would probably be greater in a “fee-for-service” environment than when critical-care physicians receive a funding envelope from the health-care funding agency (i.e., government) through the university or hospital.

In summary, the current process of assessing technology in critical-care medicine remains unorganized and therefore is vulnerable to various cost-containment initiatives from the health-care funding agencies. Health-care funding agencies will continue to exert an increasing and unopposed control over technology diffusion and utilization to achieve cost-containment, unless suitable mechanisms for appropriate technology assessment are developed by critical care and industry, in partnership. Otherwise, data to support the timely introduction of appropriate technology will remain far behind its developmental phases; that is, diffusion of technology to the patient’s bedside in a process controlled by health-care regulatory agencies may become more of a political issue than a decision based on good medicine. Furthermore, the control currently exerted by the health-care funding agencies in the introduction of new technology may also become an issue for ethical debate if care providers fail to ensure a process that would facilitate the introduction of technological advances in a consistent and timely manner. Thus, it is ethically correct for the clinician to support a process that could save money by ensuring the introduction of only effective technologies; this is an example of the ethical principle of full beneficence, that is, a process in which decisions are maximized for the benefit of society rather than for the individual. In contrast, an assessment process that is inappropriately slow in bringing an ultimately effective technology through the assessment process would be in conflict with the concept of patient-centered beneficence, whereby the clinician should advocate on the patient’s behalf all appropriate and effective diagnostic procedures and therapies available.

Recommendations

In the preceding sections, we have argued that the lack of uniform guidelines for the assessment of technology has had several negative consequences. In this era of cost containment, regulatory activities originating from government and the health-care funding agencies may act to slow the clinical introduction of many technologies, when the purpose of this process should be only to restrict the diffusion of technologies without proven efficacy to critical care. For example, technologies with the potential to significantly alter the outcome of a critical illness may never get beyond the hypothesis-generating stage if industry becomes increasingly unwilling to begin the process of taking a technology to the bedside in the atmosphere of uncertainty inherent in broadly based and all-inclusive

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Table 3. Strategies to Control the Diffusion of Technology to Critical Care [Adapted from (35)]

**General strategies:**
- Creation of an information body (council, office, center, institute) on health-related technologies
- Gradual reorientation of the training given to health professionals
- Regulation of the number of professionals and their distribution by field of specialization

**Specific strategies:**
- High technologies
  - Allocation of global budgets
  - Central planning and direct control of equipment acquisition
  - Regionalization of specialized services, grouping of health institutions, and equipment sharing
  - Selected assignment of expensive equipment to certain institutions on condition that they participate in projects to evaluate the technologies
  - Modification of the operating methods of health institutions
- Medium and low technologies
  - Modification or adjustment of the remuneration methods for health professionals
  - Modification or adjustment of the practice environments
  - Better transmission of information on medium and low technologies to user professionals and patients

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government regulations that have as an implicit objective a reduction in the proportion of the gross national product devoted to health care. The current and proposed processes to control the diffusion of technologies in universal health-care systems characteristic of Canada (Table 3) must, therefore, be accepted as processes that do not encourage innovation. Without agreed-upon "rules," i.e., technology assessment guidelines, between industry, the care provider, and government/health-care funding agencies, progress in the care provided to critically ill patients will not continue with the same intensity as in the last decade.

To develop a reasonable process of technology assessment, Battista (35) has argued that the major players—government, industry, and the care provider—should agree on the overall objectives of the process, some of which might include (a) creating a favorable climate for research and, hence, for technological innovation and (b) establishing a framework for development that is congruent with the priorities and objectives established for the health-care system as a whole.

Impediments to achieving these goals are numerous, including a lack of apparent societal focus for issues relating to the interaction of technology, the patient, and the health-care funding agency. Battista has, therefore, recommended the creation of information bodies to advise health-care funding agencies on the priorities of technology assessment, to assist in developing a consistent approach to technology assessment, to act as an expert panel to interpret existing information on health-care technologies, and to disseminate information to everyone involved in the diffusion of technology. Representatives of the funding agency, industry, care providers, and the consumer should be involved in the process at all levels.

For critical-care providers, significant improvements are required in the current attitude towards technology assessment and in the processes utilized. Failure to meet the needs of funding agencies in understanding the impact of technology on the critically ill will lead to the development of more regulation of care provision.

In the remainder of this section, we will deal with specific objectives that could improve the current disorganization in technology evaluation in critical care.

1. Improve the ability of critical care to evaluate its own technology. There has been little educational focus, to date, on the processes of assessing technology in critical care. If critical-care physicians and nurses do not accept the premise that they should become leaders in technology evaluation, that process will be assumed by individuals without the clinical expertise in critical care required to prioritize and design the specific questions. Therefore, critical-care residents and nurses-in-training should insist that one of the objectives of their training be proficiency in managerial issues such as technology assessment and utilization review. Continuing medical education programs of the many societies with representation in critical-care units should concurrently highlight the need and processes for technology evaluation.

2. Encourage the development of national and international bodies with a specific mandate to advise on technology assessment. These groups might have a number of functions and should include health-care workers, industry, hospitals, and government. Perhaps the most important early role of such a group would be to act as a data bank relating to the evaluation of technology. Another important objective would be development of consensus on the methods of assessment that could be applied or utilized in the many different technologies of critical care.

3. Undertake research on methods for assessing technology. We previously mentioned that difficulties exist in both the time and the cost of performing randomized, controlled trials in all instances of assessing technology that impacts critical care. Other methods (Table 2) must, therefore, be researched, to define their role vs that of a randomized, controlled trial in technology assessment. Presumably, new, less costly, and less time-consuming techniques for evaluating technology in critical care would follow. Research is particularly needed on methods of economic evaluation and on how best to quantify outcome in specific technology assessments.

4. Agree on funding sources of the assessment process. Undertaking an assessment of technology and other utilization management issues is particularly expensive in critical care; hospital budgets, therefore, require added funding from the funding agency to carry out the technology assessment. Government cannot realistically expect a physician–manager to redirect funds from the clinical budget to an assessment component of the budget. In this era of cost containment, the further rationing of care that this principle would cause is ethically incorrect until the evaluation process identifies areas of savings that will not reduce the current level of care efficacy in the particular unit.

To maintain a degree of independence, industry could contribute to the costing of assessments in the form of contracts to groups willing to undertake such assessment in critical care. Alternatively, industry might form partnerships with government in assessing technology, such as currently is the case in Canada through the Medical Research Council/Industry joint programs to fund technology-based research.

5. Encourage industry to develop stronger liaisons with the hospital sector. The issue behind this concept is the possibility that innovation in the development of a technology has a greater need to be developed out of ideas generated at the bedside than in the considerable work currently undertaken in industry's laboratories, most frequently at an area significantly remote from the hub of clinical activity. If industry could be convinced to establish some of their "idea" people in strong clinical programs, the early innovation process of a new technology assessment might become more cost efficient. We need to develop a cooperative system between the care provider and industry that will constantly interact on ideas for the future with a better understanding of each party's limits and needs than has heretofore existed.

In summary, the current lack of accepted guidelines for the assessment and documentation of efficacy of new technologies before their diffusion to critical care has resulted in actions that aim to contain costs, in part by restricting the introduction of new technology to the critical-care bedside. The escalating cost of providing care to the critically ill has resulted in different anxieties among the health-care funding agencies, the hospitals, and the critical-care programs. Although the direct cost of technology acquisition in critical care is small relative to other operational costs, the indirect effect of technology, especially new technology, on costs cannot be overemphasized. The current cost-containment era in health care necessitates that critical-care providers attempt to improve the efficiency of
care provision and to establish mechanisms for prospective evaluation of new and existing technology, including drugs, equipment, management, and the care process itself. The control over health-care expenditures exerted by funding agencies requires that those in the critical-care process strive to develop the information required to provide meaningful technological advances to our constituency.

References