

son to lessen its criticism or reverse its position.

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Guidelines for medical technology in critical care

One of the paradoxes of contemporary medicine is the general malaise surrounding the assessment of technology at a time of unparalleled proliferation of and accomplishments in medical technology.

Much of this malaise would be diminished if users were to employ an assessment program as sophisticated as the hardware that is involved. In this respect, the recently published guidelines by the Technology Subcommittee of the Working Group on Critical Care, Ontario Ministry of Health (*Can Med Assoc J* 1991; 144: 1617-1622), are welcomed at a time when health care providers increasingly seem to feel that these new devices are not being used in a rational way.

However, the guidelines fall short in some very important respects. They do not include a review of the available information on safety-related issues and defective medical devices in the assessment process. Safety is evaluated in terms of the risk:benefit ratio; for example, a high-risk technology may be acceptable if the potential benefit is high, and a low-risk technology may not be acceptable if the potential benefit is low.

Possibly serious adverse reactions have been reported as a result of the use of faulty computer products within parent devices. A recent publication highlights these problems.¹ For example, a

cardiopulmonary function analyzer had printed erroneous results even though the computer graphic display was correct; a programmable pacemaker confirmed a program change when, in fact, the change had not been made; an infusion pump wrongly infused insulin or glucose at the maximum rate because the software package did not incorporate appropriate safeguards; and a cardiac output computer overestimated cardiac output.

The term medical technology dignifies a heterogeneous group of devices, procedures and drugs, including instruments used to perform laboratory tests on critical care patients. Such instruments are not subject to premarket assessment in Canada until they have been widely applied in practice. The appropriate use of laboratory procedures can result in greater savings than the purchase of a bedside monitor: the introduction of guidelines for blood gas estimations in two adult intensive care units led to a fall in the frequency of blood gas analysis of 44% and an estimated annual saving of \$81 000 (Canadian).²

Therefore, it would be incorrect to think that the assessment of technology alone will significantly reduce costs or ensure quality. As the Technology Subcommittee points out (*ibid*: 1613-1615) the cost increases related to the acquisition of new technology are small when compared with increases related to other major factors. Changes in physician training, experience and behaviour, admission and discharge procedures, clinical protocols and policies for the appropriate use of technologies and the elimination of ineffective ones should be of priority in correcting inefficient medicine. A study of 63 hospitals found that a significant number of physicians would not abandon old equipment when new technology was acquired, and this resulted in increased costs.³

The assessment of technology now has enthusiastic disciples, but it should not be used to control costs by delaying or limiting the availability of technology to critical care patients. Inequitable access to the technology would be a high price to pay for covering up current inefficiencies in health care.

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[The chairman of the Technology Subcommittee responds:]

The two issues that Dr. Rasaiah raises — safety and the rational use of technology — are very important.

The members of the Technology Subcommittee felt that they had neither the mandate nor the expertise to address safety and that such issues were already handled by other organizations and agencies. In Canada the Canadian Standards Associations (CSA) is the main standard-setting organization for medical devices. Performance and safety issues are addressed by this organization, and, although recommended standards are not necessarily mandatory, legislation does exist requiring compliance with particular guidelines.

Medical device regulations are covered by the Federal Food and Drug Act of 1985 and must be followed by manufacturers. The manufacturer must notify the federal government about a device