



THE IMPACT OF INNOVATIVE MEDICAL DEVICE TECHNOLOGIES ON PATIENT SAFETY

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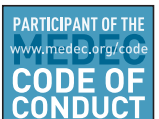
ISSUE

Patient safety must be a key focus of healthcare professionals and medical product manufacturers to ensure decreased adverse effects, decreased healthcare system costs, and improved patient outcomes. One mechanism that can help to minimize risk to patients is the appropriate use of medical devices and the adoption of innovative device technologies designed to enhance patient safety.



MEDEC

CANADA'S MEDICAL DEVICE TECHNOLOGY COMPANIES
LES SOCIÉTÉS CANADIENNES DE TECHNOLOGIE DES
DISPOSITIFS MÉDICAUX



MEDEC'S POSITION

- The adoption of innovative, patient safety enhancing medical technologies is a key factor in improving patient care. MEDEC members play an essential role in developing and promoting patient safety and risk management strategies for the safe, effective and efficient utilization of medical devices. All healthcare stakeholders, including MEDEC, have a responsibility to not only identify patient safety risks, but more importantly, to drive solutions and better outcomes; an environment that goes beyond identification and blame, to one of mutually owned solutions. To do so will require full and open collaboration among all healthcare stakeholders.
- Medical device industry stakeholders (manufacturers, government, healthcare professionals and organizations, and patients) must work together to not only ensure access to new medical technologies that enhance the patient safety profile, but to maximize the safe use of medical devices.
- Manufacturers have a responsibility to optimize patient safety by:
 - > Developing innovative technologies to enhance patient safety.
 - > Implementing appropriate risk reduction strategies during the research, design, and development process.
 - > Participating in the education and training of healthcare professionals in the appropriate use and care of medical devices. This includes reviewing, revising, and clarifying training & maintenance instructions/procedures for equipment currently in use to reflect the evolution of knowledge about the safe delivery of care.
 - > Partnering with healthcare providers and organizations to collect and communicate patient safety information and respond appropriately.
 - > Applying “best practices” to the discontinuation of older/outdated devices and the implementation of new innovative devices.
- Healthcare professionals play a critical role in this process by:
 - > Communicating appropriate risk information to patients.
 - > Partnering with manufacturers to develop safety-enhancing technologies.
 - > Collaborating with manufacturers to facilitate the education and training of hospital staff.
 - > Ensuring that appropriate incident reporting systems are in place and that the results are being shared with manufacturers and government as appropriate.
- Government & government organizations also have a responsibility to support the process by:
 - > Providing funding for innovative medical devices which improve patient safety profiles.
 - > Maintaining a regulatory environment that is geared toward ensuring the safety of new medical technologies without being burdensome towards the Canadian licensing of such new healthcare technologies. .
 - > Ensuring that appropriate data monitoring and information sharing systems are in place.

**IMPROVING PATIENT SAFETY
THROUGH THE APPLICATION OF INNOVATIVE MEDICAL DEVICE TECHNOLOGIES
IS A PRIORITY FOR MEDEC MEMBERS.**

BACKGROUND OVERVIEW

Patient safety is of paramount concern for all individuals involved in the delivery of health care. However at this time, there is not a universally agreed upon definition of patient safety. Perhaps the most elegant definition is stated in the United State's report *To Err is Human*. It defines patient safety as "freedom from accidental injury"ⁱ. The New South Wales (Australia) definition elaborates on this: "A major objective of any health care system should be the safe progress of consumers through all parts of the system. Harm from their care, by omission or commission, as well as from the environment in which it is carried out, must be avoided and risk minimized in care delivery processes."ⁱⁱ

Compromised patient safety can lead to longer duration of care, extended hospital stays, the need for further procedures, potential negative outcomes for patients, including death, and additional healthcare system costs.

In Canada, researchers found that in 2000–2001 adverse events occurred in 7.5% of medical/surgical admissions in non-specialized acute care hospitals.ⁱⁱⁱ Expert reviewers considered 37% of adverse events to be highly preventable.^{iv} Most patients recovered from adverse events within six months, but about 21% (or between 9,250 and 23,750 people across the country) died, possibly as a result of the event. That's more than the number who die from breast cancer, motor vehicle and other transport accidents, and HIV combined. In 2003, 5.2 million Canadians (about 24%) reported that they or a family member had ever experienced a preventable adverse event related to their care. Of those who had experienced an event, about half (52%) said that the most recent event had had serious consequences.^v

These adverse events also lead to significant costs for the healthcare system. For example, researchers

estimate that the 255 patients with adverse events detected in the study (Baker, et al) stayed about 1,521 extra days in hospital because of the event. If similar rates prevail across Canada, more than 1.1 million days could be attributed to adverse events. That's close to the number of days used each year by all women hospitalized



during pregnancy and childbirth.^{vi} The U.S. report, *To Err is Human* estimated the annual cost of medical errors in the U.S. as \$37.6 billion U.S.D., with about \$17 billion U.S.D. deemed preventable with half - \$8.5 billion U.S.D. - being for direct healthcare costs.^{vii}

Patient safety should be a primary focus for medical device manufacturers in the medical device design and development process. Addressing medical device use-related hazards should be undertaken within the context of a thorough understanding of how a device will be used. Essential components of this understanding include:

- Device users, (e.g., patient, family member, physician, nurse, professional caregiver)
- Typical and atypical device use
- Device characteristics
- Characteristics of the environments in which the device will be used
- The interaction between users, devices, and use environments.^{viii}

CONCLUSION



Improving patient safety through the application of innovative medical device technologies is a priority for MEDEC members. Collaboration with healthcare professionals, organizations and government to ensure access to, and adoption of, new safer medical technologies, is essential to developing an enhanced patient safety environment. By creating an environment in which patient safety is a top priority, stakeholders can maximize the benefits available through the use of innovative technologies, reduce the safety burden on patients and the healthcare system, and improve the delivery of healthcare in Canada.

ABOUT MEDEC

- MEDEC is the national industry association representing medical device and diagnostic companies. Our members are dedicated to serving the healthcare community through research and development and the provision of high quality medical products and services that benefit Canadians. – safely and efficaciously.
- MEDEC members are committed to advancing healthcare in Canada by ensuring patients have access to safe medical device technologies.
- Member companies represent a range of medical devices such as operating room devices and hospital equipment, as well as medical specialties such as cardiovascular, orthopaedic, ophthalmic, diabetes, and in-vitro diagnostics.
- MEDEC's mission is to strengthen and grow the industry in Canada by working closely with governments, medical associations and the public to establish an environment that supports the adoption of new technology from both regulatory and reimbursement perspectives.
- MEDEC members are committed to the highest standards of professional conduct. MEDEC has designed and adopted a Code of Conduct to promote ethical business practices and socially responsible industry conduct to govern interactions with healthcare professionals.



ⁱ To Err Is Human: Building a Safer Health System (2000) Institute of Medicine. National Academy of Sciences.

ⁱⁱ Governments and Patient Safety in Australia, the United Kingdom and the United States: A Review of Policies, Institutional and Funding Frameworks, and Current Initiatives: Final Report. J. Paul Gardner, G. Ross Baker, Peter Norton and Adalsteinn D. Brown. Advisory Committee on Health Services, Working Group on Quality of Health Care Services. August 2002.

ⁱⁱⁱ Health Care in Canada, 2004. Canadian Institute for Health Information.

^{iv} The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. G. Ross Baker GR, et al. CMAJ • May 25, 2004; 170 (11).

^v Health Care in Canada, 2004. Canadian Institute for Health Information.

^{vi} Health Care in Canada, 2004. Canadian Institute for Health Information.

^{vii} To Err Is Human: Building a Safer Health System (2000) Institute of Medicine. National Academy of Sciences.

^{viii} Guidance for Industry and FDA Premarket and Design Control Reviewers - Medical Device Use-Safety: Incorporating Human Factors, Engineering into Risk Management. July 2000. U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health.

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