Health Policy Research Program
Summary of Research Results

Title:	**Health Technology, Governance and Patient Safety: An Overview and Synthesis of the Literature**
Investigator Name:	**Dr. Ellen Balka**
Project Completion Date:	**May 2006**
Research Category:	**Synthesis**
Institution:	**Vancouver Coastal Health Authority**
Project Number:	**6795-15-2003/5760002**

Summary

Although much attention has been focused on patient safety in recent years, little is known about the relationship between the governance of medical devices and patient safety. This reflects several factors, including variation at an international level in the classification of medical devices and a lack of consistency in how data about errors and adverse events related to medical devices are tracked at international, national, provincial and health authority levels. Interventions aimed at reducing adverse events related to the governance and use of medical devices are seldom evaluated, and when such evaluations do occur, variability in how device related adverse events are measured limits the validity of comparisons.

The governance of medical devices involves a heterogeneous network of governmental and non-governmental stakeholders. Reducing barriers to international trade are among the drivers for harmonization of regulations governing medical devices at an international level. Licensing of medical devices and post-market surveillance of medical devices—if in existence—are typically addressed at a national level. Other stakeholders involved in the governance of medical devices include manufacturers and resellers of medical devices, professional associations (e.g., the Canadian Medical Association), practitioners who use devices, the institutions that train practitioners, health care provider organizations (who make decisions about what is purchased, implement training programs, maintain equipment, and address adverse events that occur), and patients and their families. Responsibility for governance of medical devices is carried out internationally, by geographically dispersed stakeholders who often have competing interests. Governance of medical devices begins prior to the introduction of devices into

the marketplace, and continues through device implementation to post-market surveillance of devices.

Greater standardization in the means of tracking and measuring adverse events related to medical devices will need to be undertaken in order to improve the quality of data about device related adverse events, and our understanding of how the frequency of such events can be reduced.

Current governance systems place most emphasis on pre-market governance of medical devices, where governance instruments such as licensing requirements for devices are utilized. Our review of literature complemented by key informant interviews suggests that increased emphasis on non-state governance instruments aimed at health care provider agencies, and stronger post-market surveillance of medical devices could lead to reductions in device related adverse events. Governance instruments aimed at reducing error when new medical devices are introduced (e.g., through more rigorous pre-purchase assessment of devices; strengthened training of staff to use new devices; reduction in the variety of devices performing the same function in a single institution), combined with more rigorous investigation of adverse events that accommodates improved data collection about device related adverse events and strengthens post-market surveillance all hold promise.

There are several areas of medical device use in which increased regulatory attention may be warranted. These include the widespread practice of re-use of single use medical devices, and the increased use of medical devices that are integrated through software and hardware interfaces. Currently software products such as electronic patient records are not subject to regulation as medical devices, although software faults in programs or inadequate training in the use of software can have grave consequences. Increasingly medical devices are integrated through software platforms, which may expose patients to new risks.

In some instances (e.g., services provided under contract to a health authority), ambiguity exists about where responsibility for governance of medical devices is held, which may result in adverse events related to medical device use in the future.

Improving data collection about the role of medical devices in adverse events, development of governance instruments aimed at implementation and use of medical devices and a regulatory focus on software error, device integration and improved communication of policies should reduce device related adverse events (AEs).

The environmental milieu in which governance of medical devices takes place needs to change from a culture of blame to a safety culture. As a major stakeholder, Health Canada can do a lot to promote this change, together with other major stakeholders such as the Canada Patient Safety Institute. Such a change must be reflected in the language used to discuss patient safety (e.g., in the United Kingdom (UK) the term ‘patient safety incident’ is used rather than ‘adverse event’), as well as strategies for engaging stakeholders, which can include more direct communication with stakeholders aimed at

promotion of a safety culture, and more user-friendly web sites addressing issues such as medical device safety.

Target Audience

This report will be of interest to anyone concerned with patient safety and/or the governance, use and management of medical devices, as they relate to patient safety.

Extensive appendices, which include detailed reports about governance of medical devices in several countries, case studies of governance of a range of devices, and governance issues related to processes (such as device acquisition) and special cases (such as software) will be of interest to practitioners in specific areas.

Recommendations

A full set of recommendations from all reviews undertaken are contained in Appendix A.
Monitoring, Measuring, Tracking of Medical Device Adverse Events

- Support development of a national system for measuring and monitoring device related adverse events which reflects a systems understanding of adverse events and captures data about medical devices. Such a system should also address issues related to the reuse of single use devices (SUDs), (e.g., problems with sterilization and disinfectants).
- Encourage interaction between provider agencies and the medico-legal community with the aim of fostering greater systematic learning from adverse events.
- Support additional research that will be required to develop measures that can better capture the numerous factors that come to bear on patient safety incidents involving medical devices.

Strengthen Existing Governance Instruments and Introduce New Instruments in Areas to Address Regulatory Loopholes and Ambiguities

- Increase the capacity within Health Canada to conduct investigations for enforcement of compliance with regulations relating to medical devices.
- Work with stakeholders including the medico-legal community to develop governance instruments to address areas of emergent concern, such as the integration of multiple stand-alone medical devices and testing of software embedded in medical devices and software used to integrate multiple medical devices.
- Improve communication with smaller agencies that lack in house departments dedicated to management of medical devices, about medical device governance and safety.
- In instances where medical services are provided on a contractual basis (e.g., by a non-profit community based agency), clarify the responsibilities of payers and contractors concerning safe use of medical devices.

- Address ambiguities relating to off-market use of medical devices, as well as devices that may not be classified as medical devices but may be used as such.

Support Infrastructure that can Contribute to Improved Device Usability

Facilitate the development of national mechanisms for

- sharing of information about existing device usability;
- working with the Canadian medical device community to improve usability of medical devices prior to their introduction on the market;
- sharing information about device usability within the acquisitions community in the Canadian health care system.

Acquisition

- Work with professional associations to develop materials to support best practices in medical device acquisition, such as pre-purchase checklists and acquisition planning and evaluation committees;
- Support the development and sharing of protocols to guide pre-purchase decision making about new medical device acquisitions;
- Contribute to the development of performance standards for medical devices (e.g., such as the UK Device Evaluation Service (DES), and the NHS PASA Centre for Evidence-based Purchasing), which support procurement decisions and the uptake of useful, safe, innovative products and related procedures in health and social care.

Implementation

- Support multi-stakeholder initiatives (e.g., with professional associations, educational institutions and facilities) aimed at strengthening education about the safe operation of medical devices. Educational initiatives should also stress the responsibility of practitioners to report devices in need of maintenance. Such initiatives might include fostering partnerships aimed at:

    $ Supporting the development of mechanisms within complex health authorities and provider agencies to improve communication about medical devices to those staff using them.
    $ Developing specialized programs about safe device use aimed at new practitioners, across practitioner groups.
    $ Encourage professional training programs (medicine, nursing etc.) to promote a culture of safety and to develop approaches for addressing device related patient safety incidents.

Re-Use of Single Use Devices (SUDs)

Continue to support the development of national standards about the re-use of single use devices.

- Use the government's purchasing power to exert pressure on device manufacturers to set appropriate thresholds indicating to what extent devices can be safely re-used. This may be facilitated through tax credits to device manufacturers or re-processors who undertake scientifically sound research aimed at establishing safe re-use thresholds.
- Share information about safety procedures related to SUDs and reusable devices with hospitals that provide in-house re-processing in order to promote a more consistent level of safety and to ensure workers are knowledgeable about the processing risks.

The views expressed herein do not necessarily represent the views of Health Canada

---

In addition to the above summary, the full report can be accessed in the following ways:

- A print version of the full report in the language of submission can be borrowed from the Departmental Library; requests may be sent to HCLibrary_BibliothequeSC@hc-sc.gc.ca.
- An electronic version of the full report in the language of submission is available upon request from Health Canada by e-mailing the Research Management and Dissemination Division.

This research has been conducted with a financial contribution from Health Canada's Health Policy Research Program. For permission to reproduce all or part of the research report, please contact the Principal Investigator directly at the following address: ellenb@sfu.ca..

Health Canada's Health Policy Research Program (HPRP) was created to increase the quantity of academic research that is directly relevant to current and future health policy issues. The Program supports research and/or policy research workshops.