The Standards Prescription for Improving Healthcare in Canada

Quality in Healthcare
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Over the last decade, healthcare has consistently been identified as the number one social and political issue by Canadians, despite the fact that Canada is among the top five countries in the world in per capita spending on healthcare. In response to these concerns, a number of comprehensive studies have been undertaken to better understand the state of Canada’s public healthcare system. Hundreds of recommendations have been made for improving the quality of health services available to Canadians including the need for greater emphasis on standardization.

Standards have a proven reputation as an important tool in helping to improve quality and safety in many industries and sectors, and they are already playing an important role in many aspects of healthcare. Around the world, healthcare organizations are seeing encouraging results from the application of quality principles. Some of the benefits being recognized include: improved performance and productivity, increased patient satisfaction and confidence in the care they receive, and improved risk management resulting in the reduction of preventable accidents and adverse affects from treatments.

The Standards Council of Canada (SCC) has been looking at the evolving role that standards can play in improving quality and addressing the challenges of Canada’s unique healthcare system. It has identified a number of areas within the system where standardization could be effective in reducing increasing efficiency, reducing administrative costs, improving communication and information sharing and, protecting the safety of patients and professionals within the health sector.

The Canadian Healthcare System - an Overview
Canadians are guaranteed access to most healthcare services through a publicly funded healthcare system. The responsibility for public healthcare is shared between the federal government and the provinces (10) and territories (3).

The federal government is responsible for:
- setting and administering national principles or standards for the healthcare system through the Canada Health Act;
- assisting in the financing of provincial healthcare services through fiscal transfers;
- delivering direct health services to specific groups including veterans, native Canadians, military personnel, inmates and the Royal Canadian Mounted Police; and,
• other health related functions such as health protection, disease prevention and health promotion.

The provincial and territorial governments are responsible for:
• managing and delivering insured health services;
• planning, financing and evaluating the provision of hospital care, physician and related healthcare services, and
• managing some aspects of the prescription care and public health.

In order to receive federal funding, provinces and territories must demonstrate that they have met the criteria and conditions for healthcare services established in the Canada Health Act. The legislation is aimed at ensuring that all eligible residents in Canada have reasonable access to medically necessary services.

Within the different provinces and territories, regional authorities administrate publicly funded health facilities, including hospitals. Doctors in Canada are, for the most part, self-employed practitioners who work in private practices. They deliver publicly funded health services to patients and then submit a claim to the health insurance plan in their province or territory based on a pre-established fee for the service.

The private sector also plays a smaller, but significant role in Canada’s healthcare system. It provides services and products not covered under the public healthcare system, including prescription drugs and most dentistry. Coverage for services and specialties, such as optometry and physiotherapy may or may not be covered by public health insurance depending on the province or territory. Private healthcare includes any services that are either paid for directly by individuals or covered through private insurance plans or employee benefit plans.

The many organizations and individuals who work in Canada’s healthcare sector form a complex network aimed at meeting the needs of Canadians, whether they live in one of the country’s urban centres or in a remote community.

Some of the other issues that Canadians are raising with regards to sustaining quality healthcare include:
• availability of long-term funding;
• cost-effectiveness of healthcare services;
• quality and safety of new medical technologies and treatments;
• shortages of health personnel and recognition of foreign credentials; and
• balancing the benefits of implementing medical information technology with security and privacy concerns.

Standards Council of Canada
The Standards Council of Canada (SCC) is not directly involved in Canada’s healthcare system, however, it has a responsibility to help advance the social and economic well
being of Canada and to protect the health and safety of Canadians. The SCC is a federal
Crown corporation with the mandate to promote efficient and effective standardization. It
reports to Parliament through the Minister of Industry and oversees the National
Standards System, which encompasses Canadian organizations and over 15,000
individuals involved in voluntary standards development and conformity assessment
activities.

The SCC represents Canada at international standards organizations including the
International Organization for Standardization (ISO) and the International
Electrotechnical Commission (IEC) and provides accreditation services for standards
development bodies, product certification, inspection bodies, personnel certification,
testing and calibration laboratories, ISO 9000 and ISO 14000 registration organizations
and auditor course providers.

The SCC is involved indirectly in a range of healthcare-related standards activities in
Canada. The following provides a brief description of some of these activities in the area
of standards development and conformity assessment

**Healthcare Standards Development**
The development and implementation of standards for the healthcare sector has been
ongoing both in Canada and around the world for many years. Within Canada, there are
various organizations working on the development of standards for healthcare-related
issues ranging from technical specifications for various medical devices, to the adaptation
of quality management standards to meet the changing needs of the healthcare sector.

**Canadian Standards Association**
The Canadian Standards Association (CSA) is an SCC-accredited standards development
organization. Its work in the area of healthcare falls under its Health Care Technology
Program (HCT), which currently maintains approximately 200 standards in 18 subject
areas including: laser safety, medical and laboratory quality systems, blood and blood
components, application of electricity in healthcare, and implantable medical devices.
The goal of HCT is to develop standards that respond to the specific needs of Canadian
health care providers and manufacturers while supporting their harmonization with
international standards wherever possible.

**International Standards Bodies**
The SCC supports the work of Canadians participating on the country’s behalf in
international healthcare standards development. At the International Organization for
Standardization (ISO), Canada sits on numerous technical committees and related
subcommittees responsible for the development of both technical and performance-based
healthcare standards.

Canada has been actively involved at ISO with the creation of an international workshop
agreement on healthcare (known as: IWA 1 Improvement of Healthcare Providers). The
goal of the workshop has been to aid in the development or improvement of a
fundamental quality system for healthcare organizations that provides for continuous
improvement, emphasizes error prevention, and reduces variation and organizational waste. In 2004, the SCC and CSA initiated a three-year review of the agreement.

Also of note is the work of the Canadian Advisory Committee to the ISO Technical Committee on Health Informatics (CAC/ISO/TC215), and the Canadian Advisory Committee to ISO Technical Committee on Quality management and corresponding general aspects for medical devices (CAC/ISO/TC 210).

Some of the other ISO Technical committees Canada participates in include: ISO/TC 106 (Dentistry), ISO/TC 150 (Implantable Medical Devices), ISO/TC 194 (Biological Evaluation of Medical Devices), ISO/TC 121 (Anaesthesia) and, ISO/TC 173 (Technologies for Persons with Disabilities). Canadians are also active in the International Electrotechnical Commission (IEC) Technical Committee on Electrical Equipment in Medical Practice (IEC TC 62) and its four subcommittees.

**Electronic Health Record (EHR) Standards**

Canada is one of several countries around the world moving towards the online management of health records as part of efforts to improve patient care. Electronic health records (EHR)\(^\text{iii}\) are already being successfully used in some health jurisdictions in Canada.

The province of Alberta was the first health region in Canada to implement an EHR system on a large scale. In order to address concerns about protecting patient information that was being converted to online records, and to meet the requirements of the province’s privacy legislation, it has applied ISO/IEC 17999:2001 *Information Technology, Code of practice for information security and policy*. The management system standard provides a framework for managing risk, developing organizational security requirements and implementing effective security management practices.

ISO/IEC 17999 was not developed specifically for the healthcare sector, but as a result of significant international interest, a working group of the ISO Technical Committee on Health Informatics (TC 215) is currently developing a standard based on ISO/IEC 17999 that will address healthcare security needs. The working group is being led by a Canadian.

One of the biggest challenges Canada faces in making EHR a national reality is ensuring that the various systems being developed for information exchange within the provinces can be connected. Two organizations are spearheading these efforts at the national level: the Canadian Institute for Health Information (CIHI)\(^\text{iii}\) and the Canada Health Infoway (CHI)\(^\text{iv}\). They have recently completed a study on the need for EHR standards. As a result, they have identified the gaps in existing standards and developed a plan for addressing them. The SCC will be involved in this work as a member of the EHR Standards Steering Committee, which was established to lead and endorse the establishment of EHR standards for Canada.
Healthcare-related Accreditation
The following are examples of SCC’s involvement in healthcare-related accreditation activities.

Canadian Medical Devices Conformity Assessment System
Since January 1, 2003, Canadian regulation has required that medical devices used in Canada be designed and manufactured under a registered quality management system that meets the criteria of ISO 13485 or ISO 13488. These standards outline sector specific requirements for the application of the ISO 9000 series of standards in the manufacturing of medical devices.

The Canadian Medical Devices Conformity Assessment System (CMDCAS) program was developed by Health Canada and the Standards Council to support Canadian regulations. Under the program, the Standards Council’s qualifies QMS registration bodies to register the quality management systems of medical device manufacturers that have demonstrated conformity to the appropriate standards.

In order for a manufacturer to receive a new license to sell medical devices in Canada, or to renew an existing one, it must present a certificate to Health Canada confirming that it has been found to meet the requirements of these standards by an SCC accredited and CMDCAS qualified registration body. Under the program, registration bodies also have a responsibility to notify Health Canada if a client’s certification has been suspended or not renewed.

Medical Laboratories
Medical testing is another area where quality management standards can play a role in improving the efficiency and effectiveness of healthcare. The SCC is currently discussing a partnership arrangement with the Ontario Medical Association to deliver accreditation services to medical laboratories in the province of Ontario. To be accredited, laboratories would need to demonstrate that they meet the requirements as set out in the international standard ISO 15189 – Medical Laboratories – Particular Requirements for Quality and Competence.

Canadian Council on Health Services Accreditation (CCHSA)
The SCC has recently signed a memorandum of understanding with the Canadian Council on Health Services Accreditation (CCHSA). The CCHSA is a national body that is committed to integrating quality principals into the healthcare system. It accredits the services that are provided by health care organizations across Canada through the development of standards, a review process and the sharing of accreditation results. Its accreditation program has approximately 1,500 health service organizations as members and covers a wide range of healthcare disciplines. The CCHSA is a member of the International Society for Quality in Health Care (ISQua), an international organization of national healthcare accrediting organizations.
The agreement between CCHSA and the SCC signals a desire to increase cooperation with the organization in the area of health services accreditation. The SCC is also in discussions with CCHSA about its accreditation as a Standards Development Organization (SDO).

**Future Directions**

Although there is already a range of standards-related activity being undertaken to improve the quality of healthcare in Canada, the Standards Council of Canada sees room for further expansion and greater collaboration.

These healthcare-related objectives are documented not only in the SCC’s internal business plans but also in the Canadian Standards Strategy – the roadmap for the National Standards System, which recently underwent its first update since being launched in 2000. During consultations on the CSS renewal, healthcare was identified as a key area of focus in terms of using standardization to best advance the social and economic well-being of Canadians in the global economy.

Educating decision makers about the National Standards System is crucial to maximizing the role for standardization in improving the quality of healthcare. In particular, the financial and administrative benefits of employing standards and conformity assessment, either directly or by reference, into statutes or regulations, needs to be articulated to political leaders and regulators at both the federal and provincial/territorial levels.

The CMDCAS program is one example of how quality standards have been integrated into medical regulations. Another is the Health Canada’s regulation for safety of organs and tissues used in transplantation, which references standards as a means of providing flexibility and greater guarantees of safety and security. Regulators need to be reminded to consider the benefits of existing domestic, foreign or international standards to effectively address regulatory issues, and where this is not possible, they should be encouraged to consider the advantages of initiating the development of a new standard.

Using standards-based conformity assessment processes to promote or monitor compliance with a regulation can also provide numerous benefits for Canadian regulators working with a limited budget. In most cases, use of third-party verification is preferred because the individuals overseeing the compliance process have greater expertise and understanding of the latest industry processes.

Healthcare professionals also need to be better informed about how quality standards can improve their ability to ensure the safety and efficiency of the system and the overall quality of patient care. One way this has already been achieved is through partnerships with organizations like the Canadian Council on Health Services Accreditation and the Canadian Institute of Health Information. While building upon the relationships it has already cemented, the SCC is interested in creating additional linkages with other organizations working in the Canadian healthcare system.
Finally, the SCC will continue to monitor the healthcare sector to identify new areas where standardization can offer solutions that contribute to improving the quality of care. This work will be especially important as the sector continues to evolve to reflect the changing health needs of Canadians.

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i Average per capita spending on healthcare for 2003 was forecast at $3,839. In 2001, Canada’s per capita spending on healthcare ranked fifth in the OECD (Organisation for Economic Co-operation and Development), behind the U.S., Switzerland, Norway and Germany.

ii An electronic health record provides each individual Canadian with a secure and private lifetime record of their key health history and care within the health system. The record is available electronically to authorized health care providers anywhere, anytime in support of high quality care.

iii The Canadian Institute for Health Information is an independent, not-for-profit organization working to improve the health of Canadians and the healthcare system by providing quality, reliable and timely health information. [http://secure.cihi.ca/](http://secure.cihi.ca/)

iv Canada Health Infoway was created by Canada’s First Ministers (Premiers of the provinces and territories) to support the development and adoption of compatible electronic health information systems. [http://www.infoway-inforoute.ca/](http://www.infoway-inforoute.ca/)