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Role of a quality management system in improving patient safety — Laboratory aspects ☆

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ABSTRACT

Objectives: The aim of this study is to describe how implementation of a quality management system (QMS) based on ISO 15189 enhances patient safety.

Design and methods: A literature review showed that several European hospitals implemented a QMS based on ISO 9001 and assessed the impact on patient safety. An Internet search showed that problems affecting patient safety have occurred in a number of laboratories across Canada. The requirements of a QMS based on ISO 15189 are outlined, and the impact of the implementation of each requirement on patient safety is summarized. The Quality Management Program – Laboratory Services in Ontario is briefly described, and the experience of Ontario laboratories with Ontario Laboratory Accreditation, based on ISO 15189, is outlined.

Results: Several hospitals that implemented ISO 9001 reported either a positive impact or no impact on patient safety. Patient safety problems in Canadian laboratories are described. Implementation of each requirement of the QMS can be seen to have a positive effect on patient safety. Average laboratory conformance on Ontario Laboratory Accreditation is very high, and laboratories must address and resolve any nonconformities. Other standards, practices, and quality requirements may also contribute to patient safety.

Conclusion: Implementation of a QMS based on ISO 15189 provides a solid foundation for quality in the laboratory and enhances patient safety. It helps to prevent patient safety issues; when such issues do occur, effective processes are in place for investigation and resolution. Patient safety problems in Canadian laboratories might have been prevented had effective QMSs been in place. Ontario Laboratory Accreditation has had a positive impact on quality in Ontario laboratories.

Introduction

All laboratories in Ontario have implemented quality management systems (QMSs) that meet Ontario Laboratory Accreditation requirements, which are based on ISO 15189. This paper highlights the requirements of such a QMS based on ISO 15189 and describes how implementation of a QMS in the laboratory contributes to patient safety. It also briefly reviews how Ontario Laboratory Accreditation has improved laboratory quality in Ontario.

The mandate of ISO, the International Organization for Standardization, is to develop and publish international standards. ISO standards are developed by technical committees composed of experts from industry, consumer associations, academia, NGOs and government. Development of ISO standards is based on consensus, and comments from stakeholders are taken into account. The members of ISO are national standards bodies [1]. Canada participates in ISO through the Standards Council of Canada (SCC), which has responsibility for coordination of the National Standards System (NSS) in Canada. SCC, a full member of ISO [2], has accredited the Canadian Standards Association (CSA) as one of four nationally accredited standards development organizations. Canada participates in the development of ISO standards that are relevant to clinical laboratory testing through the CSA and specifically through a CSA Technical Committee, the CSA Z252 Technical Committee Medical Laboratory Quality Systems and SCC Mirror Committee (SMC) to ISO/TC 212, Clinical laboratory testing and in vitro diagnostic test systems [3]. The Canadian Society of Clinical Chemists is represented on this CSA Committee. Bodies

Abbreviations: A2LA, American Association for Laboratory Accreditation; APLAC, Asia Pacific Laboratory Accreditation Cooperation; CAR, corrective action report; CSA, Canadian Standards Association; EQA, External Quality Assessment; IQMH, Institute for Quality Management in Healthcare; IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; ISO, International Organization for Standardization; MOHLTC, Ontario Ministry of Health and Long-Term Care; NSS, National Standards System; OLA, Ontario Laboratory Accreditation; OMA, Ontario Medical Association; PAR, preventive action report; QC, quality control; QMP-LS, Quality Management Program — Laboratory Services; QMS, quality management system; SCC, Standards Council of Canada.

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such as the IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) are able to comment on final draft standards.

Definitions

Definitions of the most important concepts used in this paper are provided.

Quality management includes all the activities that organizations use to direct, control, and coordinate quality. These activities include formulating a quality policy and setting quality objectives. They also include *quality planning*, *quality control*, *quality assurance*, and *quality improvement* [4].

Quality management system (*QMS*) is a set of interrelated or interacting elements that organizations use to direct and control how quality policies are implemented and quality objectives are achieved. A *process-based QMS* uses a process approach to manage and control how its quality policy is implemented and quality objectives are achieved. A process-based QMS is a network of many interrelated and interconnected processes (elements). Each process uses resources to transform inputs into outputs. Since the output of one process becomes the input of another process, processes interact and are interrelated by means of such input–output relationships. These process interactions create a single process-based QMS [5].

Patient safety is a "discipline in the health care sector that applies safety science methods toward the goal of achieving a trustworthy system of health care delivery. Patient safety is also an attribute of health care systems; it minimizes the incidence and impact of, and maximizes recovery from, adverse events." [6].

Impact of QMS in hospitals on patient safety

Hospitals in several countries have embarked on implementation of QMSs and have reported on the impact on patient safety. Only a few hospitals appear to have sought certification to ISO 9001.

The Red Cross Hospital in The Netherlands achieved such certification in 2000. They assessed the impact of this certification on patient safety using an insurance company tool before and after implementing ISO 9001. This involved 29 questionnaires, one for each group of employees, and there were over 700 questions. Patient safety was scored in 5 areas: care process, policy and management, prevention of incidents, client orientation, and complaints and claims. Their comparison was to 10 other hospitals that did not implement a QMS. Their overall patient safety score showed an improvement of 80% compared to 50% for 10 hospitals with no QMS, and their policy and management score showed an improvement of 58% compared to 5%. They concluded that a document control system reduced bureaucracy (duplication of SOPs was resolved), the experience was positive, a focus on patients was re-established, all processes were identified and subject to continuous improvement, and performance measurements were introduced [7].

Lithuanian complex continuing care hospitals ($N = 58$) started implementation of a QMS in 1998. In 2005 they assessed the current stage of implementation from the perspective of managers. The methodology involved completion of questionnaires by the managers (they recognized the subjectivity of this approach). They found that QMSs were operating, and being implemented in, 40% and 47% of hospitals, respectively. Critical issues were the development of procedures and the lack of financial resources and information. They concluded that the benefits of a QMS included improved responsibility and power sharing, better service quality, and higher patient satisfaction [8].

Most hospitals in Hungary implemented QMSs based on ISO or the Hungarian Hospital Care Standards. The study indicated that 79% of hospitals were ISO certified, but they did not have a patient safety policy. Emphasis on patient safety increased after some fatal medical errors. One objective of their study was to answer the policy question, can patient safety be expected to emerge from the QMS, or is a separate patient safety policy required? Hospitals were surveyed on the implementation of a QMS and patient safety activities using questionnaires completed by quality managers. A weak but significant relationship was found between the development stage of the QMS and the number of patient safety activities, no relationship was observed between certification status and the number of patient safety activities, and the development of the QMS was not strongly related to patient safety. They concluded that separate patient safety policies were required [9].

Problems experienced by Canadian laboratories

Laboratories in nearly every province in Canada have experienced patient safety issues. The most serious of these was in Newfoundland, where in 2005, 425 (39%) of 1088 "ER (estrogen-receptor) negative" patients (696 living and 392 deceased) had positive results upon retesting. Among many investigations was a task force on adverse health events. Findings of the inquiry demonstrated that the primary causes of the changes in test results were methodological, and that the absence of a good quality assurance program was problematic. Their conclusion was that national standards and quality assurance programs for hormone receptor testing together with laboratory accreditation may have prevented the debacle [10].

In New Brunswick in 2008, a commission of inquiry was appointed to review pathology services at Miramichi Health Authority [11]. In 2009, in British Columbia, breast cancer lab tests were reviewed after the former clinical director of the Okanagan Health Service Area Laboratories voiced concerns that a lack of uniform practices for conducting tests may have put them at risk of misinterpretation [12]. In that same year, the Health and Social Services Minister in Quebec announced that 2100 pathology tests would be reviewed [13]. In Ontario in 2010, a report on the investigation of pathology errors in a Windsor hospital highlighted the need for quality pathology services across the province [14].

In 2012, in Alberta, the Alberta Health Minister called for a province-wide review of diagnostic imaging and pathology test procedures after errors were discovered in three different cities in less than two months [15]. In Manitoba, the review of pathology cases found five critical incidents out of 137 cases reported [16]. In Nova Scotia, medical staff encouraged more than 350 people to have their blood retested after laboratory equipment malfunctioned at a hospital in Truro; the results from tests run over 3 days may have been inaccurate after one of its two chemistry analyzers broke down [17].

Table 1
Section headings in ISO 15189.

Management requirements	Technical requirements
Organization and management	Personnel
Quality management system	Accommodation and environmental conditions
Document control	Laboratory equipment
Review of contracts	Pre-examination procedures
Examination by referral laboratories	Examination procedures
External services and supplies	Assuring quality of examination procedures
Advisory services	Post-examination procedures
Resolution of complaints	Reporting of results
Identification and control of nonconformities	
Corrective action	
Preventive action	
Continual improvement	
Quality and technical records	
Internal audits	
Management review	