# Experience of 2 Dental Clinics Registered to ISO 9002

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## Abstract

*This paper describes the 3-year experience of managing 2 hospital-based dental clinics registered to ISO 9002:1994; it also examines the revision of previous quality management standards in 2 separate institutions to prepare for registration under the new ISO 9001:2000 standard. Daily equipment and process checks, combined with internal audits, were the backbone of the quality system at both locations. Corrective and protective actions had been underused, because of the partial duplication produced by 2 different institutionally mandated risk management and incident reporting systems. ISO 9002 registration provided both dental clinics with responsive quality systems, emphasizing patient satisfaction and providing measurable continuous quality improvement.*

***MeSH Key Words:*** *dental service, hospital/standards; practice management, dental/standards; quality assurance, health/standards*

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The Hospital for Sick Children (HSC) and the Bloorview MacMillan Children's Centre (BMCC) are teaching and research facilities affiliated with the University of Toronto, Toronto, Ontario. HSC is an acute care hospital. The dental clinic logs 15,000 patient visits annually and provides a 24-hour dental emergency service. BMCC is a rehabilitation centre that provides inpatient and outpatient services for disabled children and youth. The BMCC dental clinic logs more than 5,000 patient visits annually. Both institutions are part of a Child Health Network that involves 20 central Ontario hospitals. HSC and BMCC are the only hospitals with full-time facilities for dental treatment of children and are designated centres for the provincial Cleft Lip and Palate/Craniofacial Dental Program. The dental clinics share a common dentist-in-chief/director and cross-appointed staff dentists and residents. HSC has a staff turnover rate of more than one-third annually, as graduate dentists progress through their residency and training programs then leave for employment elsewhere.

Regulation of health care practices is complex and involves many stakeholders who have different priorities. Federal, provincial and municipal governments, regulatory colleges, accreditation bodies, university administration and hospital administration impose an extensive framework of standards and regulations on hospital departments and their health care professionals. Each regulatory body requires that specific quality assurance measures be implemented to satisfy its legislative or regulatory standards. Hospital-based dental clinics must demonstrate compliance with external standards through risk management or incident reporting, random compliance audits and periodic accreditation or departmental reviews. Managers who wish to optimize patient satisfaction and safety will likely introduce quality measures in addition to the measures that are mandated.

## Objectives for Registration under ISO 9002

Two objectives drove the decision to register the HSC and BMCC dental clinics under the ISO 9002:1994 quality standard: quality assurance and patient/parent satisfaction. These objectives were motivated by the desire for consistent administration of policies and procedures at each of the 2 dental clinics. A quality system that would ensure and document consistent compliance with regulatory guidelines and institutional standards was viewed as a benefit by the dentist-in-chief/director. An audited unified quality system would assure hospital management, patients and

parents that consistent practices were carried out at all times, even when the dentist-in-chief/director was not present. A second motivation was the desire to consolidate pre-existing individual quality systems and practices. A third motivation was to comply with hospital-wide strategic goals for excellence in care. Both hospitals expect that departments will ensure patient safety, provide excellent care and foster excellent relations with patients and their families.[1] The final motivation was the desire to continue to exceed the expectations of patients and parents. Information acquired from patient and parent surveys before ISO 9002 registration suggested that there was already a high level of satisfaction with the services provided by the clinic staff. It was anticipated that as services improved, patients and parents would expect these improvements as the minimum standard for subsequent visits. Continuous quality improvement would be required to exceed their expectations. ISO 9002 registration was selected as the quality system that could achieve the objectives of quality improvement and patient/parent satisfaction.

This paper reports on the experience of managing the HSC and BMCC dental clinics for 3 years and 2 years, respectively, after their registration to ISO 9002. During that time, the HSC underwent 5 external audits, while the BMCC was twice audited externally. The paper also reports on the process of revising the quality management standards of the 2 clinics to register to the new ISO 9001:2000 standard. The process of developing and adapting the quality system for registration under ISO 9002 has been described previously.[2]

## Assessment of Compliance with ISO 9002 Standards

Compliance with the quality policies, operational procedures and work instructions was assessed and documented using 3 methods: preventive or corrective actions, internal audits (daily equipment and process checks and monthly audits by clinic staff) and semi-annual independent external audits. Internal and external audits are not part of usual clinical practice for Canadian dentists. Daily equipment and process checks, combined with internal audits, were the backbone of the quality system at both clinics. These daily checks provided the fastest notification of noncompliance to clinic managers, who were then able to address variances. Monthly internal audits provided feedback at a slower rate, but still reinforced the compliance of the dental assistants performing the daily equipment and process checks. Although external audits confirmed overall compliance, the fact that they occurred semi-annually limited their ability to demonstrate consistent daily compliance with standards. Other quality systems such as accreditation of the teaching program and the dental service as well as hospital-wide accreditation were also in place. Although external audits were more frequent than accreditation visits (which take place every 3 to 4 years), the possibility of staff members improving compliance in anticipation of an external audit and then reducing compliance after a successful review was perceived as a risk.

Preventive action reports (PAR) and corrective action reports (CAR) are integral methods for assessing and maintaining compliance with standards in many applications of the ISO 9002 quality system. PAR and CAR empower employees to identify a deficiency, noncompliance or potential risk and to report the finding along with the action taken to rectify the situation. At both clinics, targeted internal audits combined with CAR were effective in improving compliance. When corrective actions were reported, quality procedures or processes were modified to improve compliance. Targeted internal audits were undertaken after changes were implemented to confirm compliance with new processes. For example, a CAR identified that a weekly autoclave spore test was missed. The process for spore testing was therefore changed and a specific person was given the responsibility for spore testing and to consolidate weekly spore testing with other regular weekly tasks. Targeted internal audits confirmed compliance at 1, 2 and 3 months after the process was changed. Instituting targeted internal audits after a process was modified made it possible to verify that new changes were implemented and maintained.

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Although CAR were effective in identifying instances of noncompliance, dentists and auxiliary dental staff at both clinics were reticent to use CAR and PAR. The pre-existing systems of risk management and incident reporting that are mandatory in hospital-wide quality systems often superseded the use of PAR and CAR. It is likely that these reporting systems cover similar areas, but PAR and CAR can be applied to a broader spectrum of concerns than those covered by hospital risk management and incident reports. CAR may be used to identify a variety of management issues (e.g., vacation scheduling, clinic supervision, patient complaints) that are beyond the scope of hospital risk management and incident reports.

Encouraging dental assistants and information clerks to submit action reports empowers them at a higher level than they are accustomed to in clinical practice. CAR and PAR allow staff members to report variances from quality standards and to register direct feedback from patients and parents. This information is collected by clinic administrators and used to modify policies and standards to maximize

safety and patient/parent satisfaction. For example, at the HSC, CAR are collected for operating room and dental clinic time overruns. When a clinic session or operating room runs late, a nurse or dental assistant submits a CAR that details the length of the overrun, the reasons for the late finish and the dentist or surgeon responsible. These CAR are collected, and the data tabulated and analyzed. A semi-annual summary is submitted to the dentist-in-chief, who uses the information to discuss the issue with staff dentists or surgeons who repeatedly finish late, to respond to operating room administrators who are concerned about time overruns, or to answer parent and patient concerns about delays in the clinic and operating room. The use of CAR, in this instance, allows the clinic to meet all of its motivations for registration under ISO 9002. The tabulated CAR reports allows clinic administrators to demonstrate that the clinic is complying with hospital standards for operating room use, that consolidated quality assurance measures are in place for operating room and clinic use, that the clinic is complying with the hospital's strategic goals for optimal patient care and that it is helping to meet the expectations of parents and patients by minimizing operating room and clinic waiting times.

## The Evolution of Quality Standards

Staff specialists and clinic managers together set the quality policies, operational procedures and work instructions in the quality manuals. The HSC and BMCC manuals have evolved since initial registration to ISO 9002. In addition to externally mandated changes, administrative practices also changed within the clinics. A requirement that staff specialists request holidays and meetings 6 weeks in advance proved unworkable. The process was subsequently changed so that a specific coordinator was assigned to keep track of the off-service requests of all clinicians. In direct consultation with the service directors, the coordinator was able to shorten the lead-time for such requests, yet ensure that clinical coverage was not compromised.

The most recent modifications to the quality system were the result of procedural alterations mandated by the hospitals, professional colleges or government legislation. The quality manual was updated to incorporate these new processes and to eliminate redundancies. Changes that occurred between semi-annual external audits were monitored internally and the relevant documentation was presented to auditors at the time of the next external audit. Both clinics have numerous part-time dental staff and residents who are not on site every day. The requirement that clinic administrators ensure that part-time clinic members were informed of procedural changes and modifications was significant. Information dissemination was identified as inadequate during the review process in preparation for the initial ISO 9002 registration. A number of procedures were therefore instituted to ensure that a pre-existing system of mail slots, e-mails, fan-out lists and a communication book were integrated. The procedures supporting this new process were included in the revised HSC manual.

The ISO 9001:2000 standard was itself revised from the ISO 9002:1994 standard to which both clinics were originally registered. The revised 2000 standards emphasize customer satisfaction and process-oriented objectives. The designation ISO 9002 was deleted in the 2000 reorganization of standards. Organizations that revise their standards for registration to the new standard are now registered as ISO 9001. The process-based standards of ISO 9001:2000 were designed to allow organizations to measure and demonstrate continuous quality improvement, and not simply to demonstrate compliance with quality standards.[3] The HSC dental clinic achieved registration to the ISO 9001:2000 standard in February 2002. The BMCC clinic achieved ISO 9001:2000 registration in December 2002. They are the first and only North American dental clinics to achieve the original ISO 9002:1994 and the current ISO 9001:2000 registration. The HSC and BMCC dental clinics are also the only departments within their institutions to pursue ISO 9001 registration.

## Limitations of ISO 9002 Registration

Not all staff members have expressed positive opinions about the ISO 9002 quality system. Some members have reported that the quality system occupies an excessive amount of their time and effort for the perceived benefits of a unified quality system. A strong emphasis on quality assurance and patient satisfaction before ISO registration may minimize the perception, among staff, of the benefits of registration. Concerns about increased workload associated with managing the quality system have been reported in other health care practices[4] registered to ISO 9002. Furthermore, the quality policies, operational procedures and work instructions for registration to the ISO 9002 standard have been of limited assistance in preparing for accreditation reviews. Each accreditation body has its own unique and evolving method of assessment, so documentation requirements change with each survey. The documentation required for ISO 9002 registration is differently focused and more extensive in scope than that required for accreditation assessments. Also, accreditation and regulatory reviews determine compliance with a minimum standard, not a proficiency standard that may be higher than the minimum standard. ISO 9002 registration allowed both clinics to set and monitor compliance with standards before the standards were included in regulatory guidelines. For example, standards for mercury discharge in wastewater were in place in both clinics before they became a requirement under City of Toronto bylaws. Also, standards for waterline biofilm testing, which are not required under regulatory guidelines, have been incorporated in the quality systems at both clinics.

ISO 9002 registration has provided the dental clinics at HSC and BMCC with centralized and responsive quality systems. Corrective and preventive actions, internal audits and external audits have allowed the clinics to document compliance with institutional, regulatory and departmental requirements. Departmental quality manuals were modified when original standards were unworkable or to reflect the introduction of new external regulatory guidelines. In the future, use of CAR and PAR as risk analysis and problem-solving tools for quality issues will be emphasized. The successful move to the ISO 9001:2000 quality standard will allow detailed measurement of continuous quality improvement and improved documentation of patient satisfaction. ➧

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