



The Development of ISO 9002 Quality Management Standards for Canadian Dental Practices

David J. Kenny, B.Sc., DDS, PhD
Robin M. Conway, BDS
Douglas H. Johnston, DDS, M.Sc.

ABSTRACT

The department of dentistry of the Hospital for Sick Children has actively maintained a quality assurance system since the early 1980s. In addition, members of the department have taught courses and published articles on risk management and quality assurance for over a decade. The decision to achieve ISO 9002 registration led to an intensive 10-month process to adapt ISO systems and standards to Canadian institutional dental practice. This article describes the ISO registration system and the changes required for an existing quality assurance program to conform to ISO standards.

MeSH Key Words: dental care/standards; practice management, dental/standards; process assessment (health care).

© J Can Dent Assoc 1999; 65:105-8

Introduction

Even though dentistry is a profession, the practice of dentistry is viewed by business and government as part of the health care industry. Dental practice consists of two components, products and services, that are subject to clinical and practice standards respectively. Since health care in Canada is a provincial matter, the dental college of each province determines the clinical standards that regulate dental products such as restorations and dental surgery, as well as clinical outcomes. In the absence of specific clinical standards, disputed dental outcomes are judged against the current teachings and policies of North American faculties of dentistry. Professional colleges, whose mandate it is to pro-

tect the public from inferior products and services, have well-established systems for evaluating complaints and disciplining their members.

Practice standards, on the other hand, are not only regulated by dental colleges, but by a wide variety of governmental and legal agencies. Processes that are part of daily practice, such as infection control, record keeping, radiation protection and management of hazardous materials, are all subject to standards that have nothing to do with the success of a restoration or a dentist's surgical abilities. Furthermore, numerous practice standards come from legislation or common law, which overrides the mandate of professional colleges. In Ontario, for instance, radiation protection is determined by the

Healing Arts Radiation Protection Act (HARP).¹ This legislation stems from the Ontario government, not the Royal College of Dental Surgeons of Ontario (RCDS(O)). Within the framework of this legislation, the Ministry of Health may send inspectors to do site visits of any dental practice to determine if the specific requirements of the act are being met.

Record keeping is another area where multiple bodies are involved in the determination of practice standards. Although the RCDS(O) has been empowered by government to ensure that the record-keeping requirements of the *Dentistry Act* are met, any dental record used in a court case will be judged by the standard required for hospital record keeping, which is determined by com-



Fig. 1: Initial training session showing dental department staff completing questionnaire on material just presented by consultant.



Fig. 2: ISO 9002 logo attesting that a practice has been audited by SGS International Certification Services Canada Inc.

mon law.² Dental colleges often assist their members by interpreting and recommending changes to record keeping and passing this information on through directives.

The dental staff of teaching and research hospitals must also satisfy other regulatory bodies. For instance, hospital service and residency training programs are accredited by the Commission on Dental Accreditation of Canada, and all human research projects are reviewed and approved by the Research Ethics Board of the hospital. In addition to these multiple regulatory and reporting requirements, the RCDS(O) will implement a random Practice Review of individual dentists in Ontario, which means that dentists — whether in a group dental practice, a hospital, or a public health or university clinic — may be evaluated in their primary workplace. Salaried dentists (full- or part-time) and associate dentists now have an increased stake in ensuring that their workplace meets the standards of infection control and radiation protection, and that their personal dental records meet the standards of their regulatory body. The onus is on each and every licensed dentist in the province to meet the standards of practice described in the Practice Review documentation.

Staff of the department of dentistry of the Hospital for Sick Children have been involved in quality assurance and risk management as clinicians, authors and teachers for over a decade. The department of dentistry provides 24-hour dental emergency service as well as

ambulatory clinic treatment for patients referred by dentists and dental specialists throughout Canada. Annual clinical visits number almost 20,000. As a teaching and research centre affiliated with the University of Toronto, the department is also a clinical training site for the specialties of pediatric dentistry, orthodontics, oral and maxillofacial surgery, and endodontics. The size and diversity of this operation requires systems to help maintain consistency yet provide quality service and education. Our dental service and residency programs have consistently been rated highly when reviewed by the Commission on Dental Accreditation of Canada or by the Canadian Council on Health Services Accreditation. However, the impending Practice Review program of the RCDS(O) stimulated our desire to consolidate our core practice standards. We determined that we needed a process to ensure that our practice standards were continuously maintained and ready for review. Although much of the infrastructure was in place, we found that the organization and consolidation of records was incomplete.

First ISO Dental Practice in North America

The announcement that a private dental practice in Ontario had been the first in North America to become registered to the ISO 9002 standard provided the opportunity to pursue a similar status for our institution-based dental clinic.³⁻⁵ The ISO standard of quality management is recog-

nized and consistent throughout the world. ISO 9002 registration confirms that standards established by a dental college or by an individual dentist are continually maintained and can be proven to be so. Small service companies ranging from private pathology laboratories to real estate agencies and car dealerships have increasingly sought ISO 9002 registration.⁶ This status ensures their clients that systems are in place for providing consistent, high-quality service, and that these systems are regularly audited by external personnel.

ISO Dental Practices in Britain

In 1995, the British Dental Association (BDA) published an Advice Sheet describing the ISO 9002 system.⁷ ISO 9002 was identified as a means of systematically defining and verifying working methods (practice standards) to ensure quality patient care and the best use of available resources. According to the BDA Advice Sheet, getting started may involve production of an office manual by the dentist/practice personnel, utilization of a consultation service or, if already well organized, employment of a certification body to inform members of the practice where their system falls short of acceptance for registration. Certification bodies cannot provide consultation services but can identify items that are non-compliant with the ISO system. The BDA provided their members with a list of consultants with dental experience, a list of certification bodies for ISO

dental registration, and guidelines on the use of ISO 9002.

Process Development and Adaptation for an Institutional Setting

We chose to work with ISODOC, a consultation service company that includes Dr. Robin M. Conway, the pioneer in North American ISO dental registration.⁸ The authors determined that adaptation of ISO 9002 standards to dental practice was significantly different in solo, group and institutional situations. Dr. Conway had previously developed a group practice model for an ISO 9002 management system that met or exceeded the requirements of the RCDS(O) Practice Review.³ The authors subsequently developed the institutional management system so that the full range of dental practice situations are now eligible for ISO 9002 registration.

In a hospital, it is necessary to secure executive approval before proceeding with the development of standards. In our case, the project was approved and supported by the President and CEO of the Hospital for Sick Children. Departmental funds were then allocated for the project, and grant support sought.

Once the decision was made to proceed, all staff attended a training session that explained ISO 9002 and the registration process. In addition, departmental staff were identified to work directly with the consultant. Since the hospital staff consists of full- and part-time dentists, hygienists and assistants, as well as full-time secretarial staff, it was necessary to hold two training sessions, one during regular hours (**Fig. 1**) and one at the quarterly meeting of the dental staff. After the initial meeting, a training schedule and individualized plan was established and the process begun. Policies and procedures were systematically reviewed and revised, internal reviewers were trained and staff brought up to date on the changes. ISODOC consultants met monthly with staff during production of the manual, and progress was dis-

played on a staff bulletin board reserved for ISO news.

The centrepiece of the process is a control document, the ISO Manual, that contains three tiers of documentation. Tier one deals with policy, tier two with procedures and tier three with process. Some ISO requirements are surprising but make perfect sense. For instance, in addition to ensuring that dental clinic radiographic equipment meets the required standard, the company that tests the equipment must provide calibration records of its testing equipment. The company that monitors radiographic equipment must prove its ability to perform the tests accurately, or lose the contract.

Differences between private and institutional practice meant that some standards had to be adapted. For example, one of the prime features of ISO 9002 standards is that they ensure price comparison for purchasing, which is designed to reduce costs for the clinician. In hospitals, however, this function is assumed by a multi-institution purchasing consortium. In our case, departmental standards were altered to focus on early delivery, receipt of the correct order and its verification upon arrival at the clinic. Unlike private practices, the department of dentistry has portions of its equipment sterilized in a centralized hospital facility as well as in the dental clinic. This too required the development of innovative protocols. The investigation and documentation of processes in the dental clinic identified duplication of effort, reporting discrepancies between staff members, and time-consuming practices that were outdated and could be eliminated. The pre-registration process provided us with the opportunity to streamline current practices for the benefit of all staff, and ultimately, our patients. In addition, preparation for registration allowed us to implement clear guidelines identifying staff accountability. In some cases, appropriate guidelines were already in place but were either partially implemented or ignored until a system for review and

reporting of variances (infractions) was established.

Following completion of the manual, an internal review was performed to ensure all systems were operating as described. The manual was submitted for review by the non-dental external auditors, SGS International Certification Services Canada Inc., who identified some inconsistencies requiring change or clarification. Subsequently, at a predetermined date, an auditor spent one and one-half days in the dental clinic reviewing each item in the manual against a larger body of documentation that included the RCDS(O) *Dentaguide*, original documentation of the *Dentistry Act 1991*, and HARP and Workplace Hazardous Materials Information System (WHMIS) regulations.^{1,2,9,10} The auditor identified some additional areas of nonconformity with the manual, and following adjustment of those procedures, the department of dentistry received its ISO 9002 registration in December 1998, becoming the first dental clinic to achieve ISO registration in North America. Continued registration is subject to monthly internal audits that are reviewed every six months by an external auditor. This allows for early detection of incorrectly calibrated equipment, missed signatures on records, lost items, and failed maintenance schedules. It is this aspect of ISO 9002 that ensures rapid feedback to correct discrepancies and maintain standards.

The Benefits of Registration

Service companies that are ISO-registered benefit from public confidence in the International Organization for Standardization. Numerous companies either seek out or require suppliers to be registered within the ISO 9000 series. In Canada, over 5,000 companies are registered, including General Motors and Quebecor; more than 3,200 are located in Ontario. Directly or indirectly, these companies involve over one million Canadians in their ISO processes. This means that a significant seg-

ment of the population has strong brand recognition for ISO and is keenly aware that a dental clinic or practice with ISO 9002 certification will provide them with the safety and security that comes with adhering to regulations and practice standards.

We undertook the development of standards for institutional dental practice to ensure consistency in a very large service, teaching and research unit with an ever-changing complement of personnel. We treat almost 20,000 outpatients annually, have a dental and support staff of 34 persons, plus six residents/fellows and numerous dental specialists in graduate training programs. ISO 9002 registration is a sign to our hospital administration, the Ministry of Health, the University of Toronto, private insurance carriers and our patients that the systems which support our dental service and teaching program are both appropriate and consistently maintained by a review process. ISO 9002 does not deal with how each staff dentist diagnoses or treats patients. However, having systems in place that are less likely to fail reduces unexpected events and complaints that directly affect patient care. An additional benefit is the maintenance of consistent staff and graduate student training in a unit with a large annual turnover, which helps reduce costs incurred through wastage or mistakes due to a lack of understanding.

Dentists in group or solo private practice will benefit from a separate set of features of ISO 9002 registration. An ISO-registered practice can display the sign of a value-added practice, the ISO 9002 registration seal from SGS International Certification Services Canada Inc. (Fig. 2). Registration can also have a direct positive effect on the sale of a practice, notify the public that ISO standards are maintained, and send a message to potential partners or associates that this practice is a leader in health care. Employees of ISO-registered companies demonstrate brand recognition through their own ISO activi-

ties and comprise a niche market of over one million potential patients who would be attracted to an ISO-registered dental practice. Patients who are wary of x-rays or concerned about cross-contamination will take comfort in the additional surveillance guaranteed by ISO standards. As for ISO-registered clinicians, in addition to the peace of mind that comes from having their office ready for Practice Review, they can practice dentistry knowing their support systems are operating as planned and are reviewed regularly to ensure consistency despite changes in staff, suppliers and materials. ■

Acknowledgment: *This project was partially funded by a grant from ISODOC and SGS International Certification Services Canada Inc. Dr. Michael J. Casas, staff pediatric dentist, Hospital for Sick Children, and assistant professor, faculty of dentistry, University of Toronto, and Leslie Brown, RN, clinic coordinator, reviewed and contributed to this manuscript.*

Dr. Kenny is director of dental research and graduate studies, Hospital for Sick Children, and professor of dentistry, University of Toronto.

Dr. Conway is in private practice in Toronto and is president of ISODOC.

Dr. Johnston is dentist-in-chief, Hospital for Sick Children, and associate professor of dentistry, University of Toronto.

Reprint requests to: Dr. David J. Kenny, Department of Dentistry, Hospital for Sick Children, 555 University Avenue, Toronto, ON M5G 1X8.

Dr. Conway is president of ISODOC. Drs. Kenny and Johnston have no declared financial interest.

References

1. Healing Arts Protection Act, R.S.O. Ch. H2 (1990).
2. Dentistry Act, R.S.O. Ch. 24 (1991).

3. ODA member first in North America to receive ISO certification. *Ont Dent* 1997; 74:4.

4. Little guys thinking big with ISO 9000. *Consensus* 1997; 24:18-20.

5. Dentist finds ISO 9000 experience painless. *Quality Systems* 1997; 7:10.

6. Church E. Service firms follow the flow to ISO. *The Globe and Mail* 1998 Aug 24; Sect. B:11.

7. Quality management using ISO 9002. *BDA Advisory Service Advice Sheet A16*. British Dental Association London 1995.

8. ISODOC. 17 Brian Cliff Drive, Don Mills, Ontario M3B 2G1, www.isodoc.com.

9. *Dentaguide A guide to the practice of dentistry in Ontario*. Royal College of Dental Surgeons of Ontario. Toronto, 1998.

10. *Occupational Health and Safety Act, Workplace Hazardous Materials Information System (WHMIS)*, R.R.O. Reg 860.

CANADA'S INTERNATIONAL IMMUNIZATION PROGRAM

HELPING CHILDREN BEAT THE ODDS



Canada is an important partner in the global effort to help children in the developing world beat the odds against six deadly, but preventable, diseases - measles, polio, tuberculosis, tetanus, whooping cough and diphtheria.

Through more than 100 million immunizations, we are saving lives and encouraging a brighter future for millions of children. For more information, please contact:

FPO
B/W
87%



Canadian Public Health Association

1565 Carling Avenue, Suite 400
Ottawa, Ontario Canada K1Z 8R1
Telephone: (613) 725-3769
Fax: (613) 725-9826