LITIGATION, LEGISLATION, AND ETHICS

ISO 9002 Certification

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The Institute of Medicine (IOM) recently announced a national plan called the International Standards Organization (ISO) 9002. The primary goal of the plan is the adoption of measures to reduce medical mistakes. It is already in effect in most of the industrially developed European countries. Originating from the IOM, an organization that believes accurate reporting to be essential to hold health care systems accountable for delivering quality care, the plan will result in mistakes being reported and analyzed in the same way airline accidents and safety risks are tallied. As a result, not only will the public be alerted to safety issues in our health care delivery system, but they will also be able to analyze what is effective and what is not. It is claimed that the plan is critical to uncovering weaknesses and widespread problems inherent in our health care system.

Product standardization in the United States dates back to the Civil War when identical parts facilitated the mass production of rifles. In 1878, Dr J. N. Farrar, a pioneer in orthodontics, prophesied that a time would come when our armamentarium would be standardized to the point that "parts will be kept in stock in dental depots or offices; catalogued, and as such [will be] predictably suitable for any case."[1] First attempts at international industrial standardization date from the early 1900s, but real progress came only after World War II. Today, there are numerous standards for both products and services. Usually, the product standards are highly specific, whereas service standards are more general. In the medical field, for instance, the ISO for heart catheterization is very specific in terms of catheter manufacturing, sterilization, shelf life, and so on; however, the ISO is rather nonspecific and provides only "accepted guidelines" vis à vis the procedure itself.

Historically, after manufacturers embraced standardization of their products, they then extended this trend to processes, eventually focusing on quality management. First addressed by Frederick Winslow Taylor, this sort of standardization was improved upon and applied in its full measure in post-WWII Japan by W. Edwards Deming. Numerous products previously considered "junk" became not only acceptable, but even respectable. Deming's methods (dubbed *kaizen*) were applied all over the world and are known today as total quality management (TQM). They eventually led to the establishment of the ISO, headquartered in Geneva, Switzerland.

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The ISO contrasts sharply with both the Malcolm Baldridge National Quality Award, established in the United States in 1987, and the European Quality Award, first given in 1992. Despite some controversies with the American-formulated National Institute of Standards (NIST) and other quality management organizations, ISO 9000 systems are slowly being adopted in the United States. NASA became the first governmental agency in the world to have each one of its sites certified by the ISO.

By 1996, 90 countries had adopted ISO 9000 as their national standards. Today, more than 130 countries participate in the ISO 9000, with the United States, Italy, and Australia showing the highest growth of ISO 9000 compliance certifications. Africa and West Asia are following suit, with annual growth rates of 40%, 3 to 4 times higher than the growth rates of their respective national economies.

Four ISO 9000 quality management systems are now in use. The systems pertaining to medicine and dentistry are found in ISO 9002. To date, the American Medical Association (AMA) and other large lobbies have opposed the mandatory reporting required by the ISO. They contend that such reporting could leave hospitals and physicians open to lawsuits. The White House counters this argument by citing studies showing that between 44,000 and 98,000 hospitalized Americans die each year as a result of medical mistakes. The AMA's attitude seems to prevail for now, but there are voices of dissent. Some medical organizations proudly state that they have met the exacting requirements of the ISO 9002 standards.

Most dentists are either ignorant of, eschew, or carefully avoid ISO involvement. Some journals, such as *Dental Economics,* promote the less stringent TQM and Deming's 14 points, urging their readers to try for the Malcolm Baldridge Award. In other countries, however, the ISO movement has caught on. The editor of the *Journal of the Israeli Dental Association*, while noting that the creation of bodies to govern or monitor dentistry does harbor some difficulties, nonetheless accepts them as a primary tool for screening new materials and technologies.

Unlike medicine, where most work is performed in hospitals, dental services are mostly provided by the private sector, which makes obtaining relevant data difficult. Another concern is whether a national body is capable of monitoring the private sector without infringing on private initiatives or prerogatives. In the United Kingdom, the British Dental Association advises its members to apply the ISO 9002 quality management system. One problem is that such standards, useful in larger practices, require more management time than smaller practices are normally able to afford. An analy-

sis from the practitioner's point of view can be found in the *British Journal of Orthodontics* (1997;24:271-5).

Closer to home, the Royal College of Dental Surgeons in Ontario is introducing an ISO-related program for random reviews of dentists in their primary work site. For the first time, dentists, whether in a group dental practice, a hospital, public health, or a university clinic, will be reviewed. These dentists will be charged with ensuring that their workplaces meet the standards for infection control and radiation protection and that their dental records meet the standards of their regulatory body. The scope of ISO registration also covers the management of the office; however, it excludes clinical procedures, which are covered by legal, ethical, and medical guidelines. The trend toward increased certification may have been prompted by the success of Dr Robin M. Conway, the first dentist in North America to gain ISO 9002 registration.

While it may make life simpler, the amount of supervision and documentation that ISO certification requires is very high. Within the ISO, voluntary technical standards have been designed to make the development, manufacture, and supply of products and services more efficient, safer, and environmentally cleaner. While the vast majority of ISO standards are highly specific to a particular product or abstract, the ISO 9000 also establishes system standards for quality management. These generic technical standards are applied evenly to all organizations, regardless of their size, product, or service. Quality management standards ensure that the organization's products or services conform to the customer's (the patient's) requirements. While ISO 9000 certification is not a guarantee of quality, independent auditors check that the quality controls conform to the standard's strict requirements. Cases of nonconformance or noncompliance can result in the withdrawal of ISO certification.

Concerned with standardizing numerous products, tests, specifications, and even terms, the ISO has established a multitude of technical committees. The committee dedicated to dental products includes 8 subcommittees that focus on subjects such as restorative materials, dental terminology, dental instruments and equipment, oral hygiene products, and, the latest addition, dental implants. There are standards for some orthodontic materials, such as stainless steel and brazing compounds, but no specific standards yet for others, such as brackets, bands, and wires.

Here is an example of how the ISO works in an orthodontic office. Orthodontic treatment is viewed as a contract in which the clinician is the supplier and the patient is the customer. The clinician completes standardized forms that inform each patient in detail of the work to be performed. The forms cover details such as diagnostic records, appliances to be used, techniques for application, and fees. The patient cosigns the form. Thereafter, any change in the treatment plan would have to be discussed with the patient and new consent obtained and documented. The performance of an ISO 9002-accredited orthodontist can be constantly or randomly checked for quality—something that is not done now.

The first step in becoming ISO certified involves performing a self-audit, followed by an independent review. The audit addresses 19 elements, including management, quality, treatment planning, document and data control, purchasing, control of customer-supplied products, process control, inspection and testing, control of inspections, measuring and test equipment, and statistical analysis.

All in all, certification is complex and rigorous. The question becomes, Is it worth obtaining? Issues such as infection control and protection from ionizing radiation have little to do with the success of your treatment or with your skills as an orthodontist, yet these relevant practice standards arise from legislation that override any recommendations from professional associations. Having your practice certified means that it maintains high standards that are regularly controlled and reviewed—a fact that sends a powerful message to potential patients as well as to professional colleagues and the community at large. ISO-certified practitioners are encouraged to display the ISO registration seal. Strong brand recognition of this type can provide patients with the security of knowing they will not be overexposed to radiation, cross-contaminated, or otherwise improperly treated.

Eventually, an important factor in becoming ISO certified may be governmental pressure, although this did not play a part in Dr Conway's decision to become registered. His motivation was to gain better control of and more consistently apply quality assurance. Ten years ago, few of us had heard of ISO systems or product standards. Today, ISO 9002 certification not only acknowledges our profession's high quality standards, but also proves that we can provide methods for self-policing. Voluntary self-regulation via ISO certification and registration may keep governmental agencies at a distance. If the present trend continues, the public, the authorities, and the profession will demand such quality guarantees. Can we afford not to provide them?

REFERENCES

1. Farrar JN. A treatise on the irregularity of teeth. New York: Appleton;1878.

COMMENTARY

Drs Kuftinec and Matasa provide the reader with a good overview of the current status of ISO 9002 and its role in the future of dentistry. Should we become certified? Look at it this way: Why do many of us undertake the rigors of becoming ABO certified? The answer is, because it is meaningful for those who did it. Diplomates have chosen to undergo self-scrutiny and examination by others to attest to our professional skills and commitment. ISO represents the same thing. Practitioners today should jump at the chance to become certified. Think about it. Professionally, you are showing the world

that you provide the highest level of self-scrutiny regarding the rendering of orthodontic services. Practically, you are telling the public that you care enough to be the best you can be. Talk about internal marketing, this is the cat's meow!

When (some may read, *if*) ISO certification becomes synonymous with quality, you will have the competitive edge among your colleagues. I know, it shouldn't be like that. But the sad fact is, it *is* like that. A sadder fact is that Drs Kuftinec and Matasa are right in pointing out that governments and oversight agencies will indeed continue to dictate quality control mechanisms to health care providers in the name of public safety. If it were up to me, I'd want to beat them to the punch any way I could. If we follow the rest of the world, ISO registration will either be the next step or possibly an exemption from certain regulatory edicts. If none of this happens, is it all for naught? Heck no! At worst... I'm the best.

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