

# PRACTICE DEVELOPMENT

## IS CLINIC CERTIFICATION WORTH IT?

Documenting and monitoring quality improvement programmes can be costly, but the benefits are substantial

by Howard Larkin



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In 1999, Tobias Neuhann MD invested more than €20,000 in the future of his Munich clinic. It wasn't for anything as tangible as a new laser or diagnostic device, or construction or even marketing. Instead, the money – along with a sizable chunk of his and his staff's time – went to obtain ISO 9001 certification, making Augenklinik am Marienplatz the first private ophthalmic clinic in Bavaria to do so.

Developed by the International Organisation for Standardisation, a network of 162 national standards bodies headquartered in Geneva, Switzerland, ISO 9001 is a generic set of requirements for implementing a quality management system. It requires, among other things, that an organisation: documents all of its business, production, and service processes; identifies customer needs that those processes should meet; monitors and measures process performance; and continually improves processes to serve customers better. Certification requires inspection by an ISO-accredited external auditor to verify compliance with the standards, a process that must be repeated every two years.

The cost of implementing an ISO 9001 programme has come down considerably in recent years thanks to software and other do-it-yourself materials available through third-party vendors. Dr Neuhann suggests a programme might be implemented these days for as little as €2,000, not including staff time. Still, it includes no standards specific to healthcare, and the effort involved is significant. This prompts many to question whether it's worth the cost for an ophthalmic clinic or hospital programme.

Specialised programmes, such as the LASIK-TÜV certification for laser refractive clinics available in Germany, and accreditation by global bodies such as the Joint Commission International, are also available. These programmes include detailed healthcare standards, but also require additional effort and expertise to achieve. Documenting and reworking clinic

and hospital processes to comply can take months of concerted effort.

But while the investment of financial and human resources is great, the rewards can be greater. Surgeons who have made the effort find it can reduce clinical errors, increase efficiency, and help attract quality-conscious patients. “I think there is a benefit to certification. It is quite a complex process, but it improves patient confidence as well as the efficiency of the clinic,” says Paul Rosen FRCS, FRCOphth, who chairs the ESCRS Practice Development Committee. He has not yet sought certification for his clinic outside standard government requirements, but is considering it.

In the future, certification or other proof of effective quality management may even be required as more national health plans and insurance companies move toward linking payment with outcomes and other measures of clinical quality and patient satisfaction, Dr Rosen suggests. “It's difficult to tell, but I suspect they will.”

### Effort pays off in quality and efficiency

Even Dr Neuhann, who is one of the most outspoken proponents of ophthalmic clinic certification, is uncertain if he has financially recovered his investment in quality management. Nonetheless, he believes putting his clinic through the ISO 9001 certification process – and later the LASIK-TÜV certification process – has generated substantial benefits, including improved staff accountability and patient safety, which make the effort eminently worthwhile.

“Before when I saw that my knife was not so clean and I asked ‘why?’, normally the answer I got was ‘I don't know; I just came from holiday.’ You never could find the responsible guy when things were not done right,” Dr Neuhann recalls. “Now I see everything – last week on Tuesday the process was done by this person and we saw this problem. We know what happened, so we can fix it.”

ISO standards require an organisation to compile a quality management handbook. An internal quality manager is appointed to oversee the task, but producing the handbook involves every employee. Each employee must sit down and write out every step of every practice process that he or she is involved in – from answering phones to infection control and sterilisation procedures. These process descriptions are minutely detailed. For example, Dr Neuhann's manual includes a script for what to tell patients when they are asked to place their chins on the autorefractor to get an accurate reading.

Such specificity compels practice managers and workers to think through every aspect of their jobs. “You learn everything about your clinic when installing a quality management system,” Dr Neuhann says. He estimates it took about four months of effort the first time around. Eckhard Weingärtner MD, who went through the process a few years later at his EuroEyes clinic in Stuttgart, estimates it took about 30 per cent of one staff member's time for about two months to compile the initial quality management handbook.

Beyond clearly establishing what precisely is expected of each staff member, the exercise also proved very good for staff morale and building teamwork, Dr Neuhann says. “Everyone is involved, so it helps everyone know that what they do is valuable.” Detailed instructions for practice processes also help in training new employees, Dr Weingärtner adds. “They know exactly what they are supposed to do.”

ISO 9001 standards also call for keeping records of the execution of key processes and outcomes. While the processes and outcomes are not specified, they must be related to customer needs and satisfaction. So steps like double-checking the power of an IOL before implanting it and outcomes such as how close post-op refraction came to the target would be considered relevant for purposes of meeting the standards,

though the clinic is under no obligation to adopt any specific standard.

Under ISO, an organisation is also required to maintain a quality improvement programme in which customer-focused process and outcome measures are used to identify opportunities for improving processes, and to measure the results of process changes. These principles originate in industrial quality management theory propounded by the likes of W Edwards Deming and Joseph Juran and are consistent with modern statistical quality improvement systems such as Lean and Six-Sigma.

The structured process improvement programme Dr Neuhann's clinic adopted has helped strengthen patient identification and avoid performing procedures on the wrong patient or the wrong eye, he says. In the past, mistakes were made because staff would ask a patient about which eye was to be operated on – and sometimes, the patient got it wrong. The clinic developed a more robust process that requires the head nurse and anaesthesia nurse to confirm the right or left eye in the chart.

Also, sometimes patients who are hard of hearing may respond when a similar name is called in the waiting room, Dr Neuhann notes. To avoid such mistakes, patients are given name tags at registration and nurses ask a patient's first and last names before proceeding.

A better controlled process for handling and sterilising diamond knives also has paid off, Dr Neuhann adds. "If you aren't nice to a diamond knife, it becomes blunt immediately and is very expensive to replace. I now have knives that last several months. The money I spent on process improvement is now coming back."

Of course, any clinic could adopt a quality improvement programme, even one that fully meets ISO standards, without seeking external certification. However, Dr Neuhann believes there are several advantages to going through a third-party audit.

One is that it keeps the staff honest. "This kind of control I cannot do myself; it is an independent look at the clinic. I don't have to say anything."

A second advantage is credibility with patients. Dr Neuhann estimates that 20 per cent to 30 per cent of his patients are aware of the ISO and look for it as a confirmation of quality. The TÜV-SÜD and TÜV-NORD ISO certifications are especially well known, and are also sought by hospitals and clinics outside of Germany. These certifications are prominently featured as assurances of quality in advertisements for clinics involved in medical tourism. Certification may also be helpful in defending lawsuits because sticking to documented practice guidelines helps show that care was taken to reduce the chance of human error.

Perhaps most valuable is the peace of mind that comes from knowing the mistakes are being avoided, Dr Neuhann says. "It makes you sleep much better."

These certifications also help satisfy insurance requirements for a quality improvement programme. Starting this year, German public insurers now require that a quality improvement programme be in place as a condition of payment, though Dr Neuhann says it will likely be a couple

of years before the requirement can be fully enforced. He estimates that about 80 per cent of eye clinics in Germany have a quality improvement programme in place and about 30 per cent are ISO certified.

Similar requirements are emerging in other European countries. From this year, the UK Care Quality Commission will require all public and private clinics to measure patient outcomes and have quality and safety assurance programmes in place to be registered. While the commission does not prescribe specific approaches to quality assurance or record keeping, it does consider an organisation's adoption of recognised standards developed by medical specialty societies and other qualified experts, says Maureen Campbell, provider registration manager at the UK commission. Accreditation or certification "is indicative to us that they are more likely to comply with regulations that we are likely to assess, but there is no list we follow," she explains.

**A more clinical approach** As helpful as ISO 9001 can be for guiding an effective quality management programme, its lack of healthcare-specific requirements limits its utility in many clinic and hospital settings. Most countries maintain strict national accreditation standards for medical facilities. In the wake of outbreaks of mad cow disease, MRSA and other treatment-resistant organisms, many have adopted extremely strict infection control and hygiene requirements. Dr Neuhann credits the standards developed for Germany by the Robert Koch Institute for preventing outbreaks of toxic anterior segment syndrome in the country. On the other hand, he believes the initial requirement that all instruments be disposable, similar to current UK practice, was wasteful and unnecessarily strict. Along with the German ophthalmological society and refractive surgery commission, he campaigned for sterilisation standards that would allow diamond knives, a process that took two years.

Recognising a need to reassure patients of the safety of LASIK and other refractive surgeries, Dr Neuhann and colleagues, including Michael Knorz MD, PhD, also worked with TÜV-SÜD to develop LASIK-TÜV certification. To achieve this higher level of certification, laser clinics must be ISO certified and be listed by the refractive surgery commission. In addition, they must meet minimum volume requirements including more than 1,000 LASIK procedures in the preceding five years, provide proof of staff training and qualification, operate only within accepted refractive limits, maintain equipment to specified standards and keep complication rates below certain ranges.

"LASIK-TÜV certification prioritises the quality of the treatment and results. The certification is the result of combining the ISO 9001:2008 quality management system, an additional hygiene inspection and the specialist LASIK section," says Michael Zimmer, who directs the programme. However, because hygiene standards and other regulations vary so much from country to country, TÜV-SÜD does not offer the certification outside Germany, though it plans to develop an international version.

Dr Neuhann would like to see not only the LASIK standard internationalised, but also development of international certification standards for cataract surgery. "Cataract surgery is highly standardised and it is the same all over the world. It doesn't make sense to have different standards in Belgium and France and Germany." He notes that there are three or four different certification standards in Germany alone.

One major obstacle to standardising guidelines is European Union law, notes Carlo Ramponi MD, managing director of European operations for Joint Commission International, which accredits hospitals, including specialised eye hospitals, around the world. Most experience improvements in both clinical outcomes and customer service measures, such as waits for service in emergency rooms, after going through the comprehensive accreditation process, which can take from 12 to 40 months. Yet uniform requirements for healthcare are not allowed in the EU because they could have the effect of freezing standards in place in more developed countries, he notes.



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Eckhard Weingärtner MD

However, Dr Ramponi believes that international standards are the future. Joint Commission International already accredits hospitals in 15 European countries and throughout the Middle East, Africa, Asia and South America. Many consider international accreditation as a key to their success in what has become a global healthcare services market. The clinical benefits could also be significant. "It would be great if hospitals in Singapore knew what was being done in Italy," he says. "Better care and quality is a worldwide idea."

## ISO 9001

### What it is:

Generic quality management system requirements developed by the International Organisation for Standardisation, a network of 162 national standards bodies headquartered in Geneva, Switzerland.

### What it requires:

- Establish a process-based quality management system;
- Document all practice processes in a quality manual;
- Establish management structures to support quality improvement;
- Establish quality goals related to customer/patient needs;
- Plan and implement a quality improvement programme;
- Track quality measures and adjust practice processes to improve quality;
- Monitor and measure customer/patient satisfaction and other customer-focused outcomes;
- Audit results regularly.

Organisations meeting all ISO 9001 requirements may be certified by undergoing an audit by an accredited ISO vendor to ensure compliance with all standards. Audits must be repeated every two years to maintain certification.

## Joint Commission International

### What it is:

International hospital accreditation and programme certification organisation that currently accredits healthcare organisations in 39 countries around the world.

### What it requires:

- Adherence with detailed management structure, leadership and organisational standards designed to support quality patient care and continuous quality improvement;
- Patient safety, including procedures to correctly identify patients and reduce medication and other care errors, and reduce infection risk;
- Access to care, including registration, record keeping and follow-up requirements;
- Patient family rights upheld;
- Patient assessment standards, including requirements for staff seeing patients, conducting lab tests, etc;
- Patient care, including procedures for emergency, end-of-life and other special circumstances;
- Anaesthesia and medication administration requirements;
- Quality improvement programmes in place throughout organisation;
- Infection control and prevention;
- Facility management and safety.

Accreditation is a rigorous process that typically takes a year or more for a hospital to prepare for. Hospitals must be re-accredited every three years.

**Don't miss** EUREQUO update, see page 28