Practice Management Forum

Quality Managing in Practice – using ISO 9002.

MS L DAVIES

Davies Associates, Practice Support Services, 33 Heathfield, Mount Pleasant, Swansea, SA1 6HD.

MR P DURNING, B.D.S., M.D.S., D.ORTH. R.C.S., F.D.S.R.C.S.,

Department of Child Dental Health, Orthodontic Division, University Dental Hospital NHS Trust, Heath Park, Cardiff, CF4 4XY.

Abstract. *The value of an International Quality Standard in Orthodontic Practice is discussed. The nature of the process is described and relevant sources presented for further exploration of the subject. The relevance of ISO 9002 to orthodontic practice is highlighted.*

Index words; Quality management. ISO 9002

Issues relating to quality and the provision of a quality service are relevant to managers of any business today, whatever the market sector. The management of the delivery of healthcare is no exception. Producing a business plan with appropriate objectives, promoting teamwork and developing leadership skills are some of the ways that quality within an organisation can be achieved. Additionally, an organisation can develop a systematic approach to quality, involving the whole team, through the development of a documented quality management system which provides a framework for achieving the organisation's goals. It is a means of working towards a total quality approach which encourages an organisation to carry out every job and every process right, first time and every time (Mortiboys and Oakland 1991).

A documented quality management system can be produced to meet the criteria of the ISO 9000 (Formerly BS5750) group of quality standards. This sets out some basic principles of management that any organisation can follow. The standard does not, as some believe, set out any special requirements which only a few organisations can comply with. It provides practical criteria which can be used by all. ISO 9000 is an internationally accepted standard which is broken down into various elements to enable an organisation to implement its management system easily and effectively. It can be used to build quality into an existing team and then one can seek external independent accreditation and certification if required. There are 20 elements or requirements to ISO9001 and 19 to ISO9002. One is no better than the other, they are just suited to different types of organisations. ISO9002 is considered applicable to general dental practice and therefore probably orthodontic practice. Figure 1 lists the 20 requirements. At first glance the requirements may appear inappropriate for an orthodontic practice as they were originally written with manufacturing firms in mind. However, on closer investigation most organisations are already complying in some form with most of the requirements.

A major route for quality improvement embodied in the International standards is the development of documentation to enshrine good practice. One of the main reasons for developing a documented quality management system is that it can save money. The intention being that written procedures are more soundly based and more efficient as quality is built in at every stage. They reduce lost time by avoiding re-working of tasks as everyone knows how they are to be achieved in advance thus ensuring patient satisfaction.

There are three tiers of documentation involved in producing a quality management system:

1. A Quality manual
2. A Procedures manual
3. Work instructions (if required)

Producing a quality manual is beneficial whether one is aiming for external assessment and certification or whether

FIG. 1 ISO9001 Requirements.

4.1	Management Responsibility
4.2	Quality system
4.3	Contract review
4.4	Design control (not applicable to 9002)
4.5	Document and Data control
4.6	Purchasing
4.7	Control of customer supplied product
4.8	Product identification and traceability
4.9	Process control
4.10	Inspection and testing
4.11	Control of inspection, measuring and test equipment
4.12	Inspection and test status
4.13	Control of non-conforming product
4.14	Corrective and preventive action
4.15	Handling, storage, packaging, preservation and delivery
4.16	Control of quality records
4.17	Internal quality audits
4.18	Training
4.19	Servicing (not applicable to an ISO9002 Dental practice)
4.20	Statistical techniques (also not applicable to a dental system)

0301-228X/97/003000+00$02.00

one simply wants to experience the advantages of developing a system within the team. The quality manual sets out the broad intention of the practice towards providing a quality service, addressing each of the standard's requirements and includes the practice's quality policy and its stated intentions towards achieving a quality service. This manual can be used as a marketing tool to demonstrate to patients, suppliers or any organisation contracted with, that the practice is aiming to provide a high quality of care.

The second level of documentation, and the one that will have most impact on the team, is the procedures manual. This sets out all the daily routines the team carry out. It is the preparation of this manual that emphasises any differences that may exist between team members in the delivery of a procedure. One of the aims of a procedures manual is to ensure consistency of performance. The procedures are written by and for experienced staff members and does not necessarily include the minute details of how a task is performed. It may, for example, state that a form is completed by a member of the team, but it does not necessarily include the exact details that are required on the form. This is left to the third level of documentation, the work instructions. These provide greater detail and support the procedure. These are very relevant to a new member of the team. In essence when preparing quality manuals, you write what you do, do what you say and then prove it through internal audit (Davies, 1993).

The 19 requirements listed in the standard take account of the processes dealing with the product or service being provided as it is prepared and then processed through the organisation. In the case of orthodontic practice, the service being provided is the treatment of the patient. A procedure for *Contract Review*, element 4.3, for example, would need to include how the practice contracts with a patient, whether private or NHS, and what evidence there is of this together with their requirements. Element 4.6, *Purchasing*, sets out how one purchases the equipment, materials, and appliances, etc for the practice to enable delivery of the contract. Element 4.9. – *Process Control* describes how management of the process of the patient visit, from when the patient enters the practice, to the receipt of treatment to the procedures for departure.

There are two requirements of the standard that are unlikely to be adopted by a practice, yet probably hold the key to successful implementation of the system. These are 4.5. *Document and Data Control* and 4.17. *Internal Quality Audits*. Once the management system has been documented, it needs control to enable the whole team to work to the changed standard. This can be achieved by identifying the procedures by title and code and dating them to indicate when they were produced or updated. A list of all control documents is maintained to provide evidence of their current status. When a member of the team decides to change a procedure, a process for this has to be followed. This includes the signing and dating of the procedure by the member of staff previously designated as the Quality Manager, so that the team are working to the current revision and are notified of the change. Otherwise there may be the situation where some team members are working to an outdated version of the procedure whilst the remainder are working to the current version. Appropriate document and data control measures avoid such confusion. The procedures relating to document control also indicate where current documentation can be located and how a member of the team can make suggestions for changes if required. This element of the system can be flexible and dynamic and not need be bureaucratic, as is sometimes perceived.

Internal Quality Audit is another element with which most practices are unfamiliar unless they have carried out clinical audit where there are similarities. Essentially the principle is the same. Having written out procedures to an agreed standard, an internal audit is carried out at least once a year to satisfy the practice team that you are, in reality, doing what has been written. Audit involves the observation of documented evidence. As well as the documented procedures, any records used that support those procedures need to be reviewed. So if, for example, as part of a procedure on record keeping it indicates that all notes on treatment planning should be written in a particular format on the patient's record card then during the internal audit several cards should be selected at random from different practitioners where possible, to verify whether this has been done and completed correctly by the designated person.

Training for team members in performing internal audits is essential. It is preferable if a member audits a section of the manual for which they are not responsible to give the audit greater objectivity. For example a dental nurse may be involved in auditing the procedures carried out by the receptionist and vice versa. During their training, it is important to stress to the team that this is not a 'policing' exercise but a chance for the practice to learn and to develop from the experience. In this way attributing blame to an individual hopefully can be avoided. The manual and its development becomes the focus for change. If, during an audit, it is discovered that there is a mismatch between what is actually done and what is said is done, there are several options which can be taken. One can change the procedure to reflect the actual behaviour, one can agree to change behaviour to match more accurately the procedure, or one can erase the procedure altogether if it is no longer being carried out. The internal audit may also identify a training need as a result of a procedure not being carried out as required. The internal audit provides feedback to the team on performance, consistency and provides an opportunity to discuss how a procedure can be improved.

Feedback is vital to the ongoing development of the system. This can be in the form of internal audit as discussed or as part of the element 4.14 *Corrective and Preventive Action*. In complying with this element a practice needs to provide evidence that it not only corrects any problems that may occur within the practice either from a patient complaint or through problems with a supplier, but also that it actively tries to prevent problems from occurring. A patient satisfaction questionnaire could be an example of the type of exercise undertaken under this section to seek information on which to need Corrective and Preventive Action. The practice can then be seen to be taking positive steps to provide a quality service. It is taking a proactive and not reactive approach.

The process of developing a quality system is of value, in itself, even if the practice decides not to apply for external assessment. Ideally the process involves the whole team sharing ideas and producing solutions. This is truly a team

approach, everyone knowing what they are trying to achieve and how this can best be achieved. Training is required initially to convey to the team the significance of a quality system and its purpose. At this stage opposition is likely from some team members as they will not perceive the benefits and will question the purpose of writing out procedures which they perform daily and in which they feel they are competent. What can be learned through the process are the subtle, and not so subtle, differences that exist between team members on how a task is performed which can have an impact on the final outcome. Having carried out a procedure in a certain way for several years does not automatically make it the most effective way. The process of documenting the procedures provides an opportunity for staff to discuss possible improved methods or different ways of working for the practice which they may not have previously considered. A senior member of the team, either dentist, practice manager or senior nurse, should be made responsible for managing the system to ensure its smooth running and to communicate any proposed changes. Leadership and ownership of the process is commonly seen as a vital element for successful implementation.

There are several ways a practice may choose to document the system. One or two senior members of the team may receive training on how to document a system and set about doing this whilst training the team at the same time. Alternatively, a practice may employ a consultant who, with the help of the team, will document the practice system for them, providing the necessary training. 'Off the shelf' packs on how to develop systems can be purchased which help a practice to work through the different stages. As an example, the British Dental Association produces a 'ISO Kit for Dental Practice' (fig. 2)* which focuses the quality standards with direct relevance for a practice environment.

Therefore costs can vary when setting up a quality management system depending on the method used to install it. It is worth contacting a local Training and Enterprise Council (TEC) as they may be able to provide some financial assistance particularly if a business benefit to the practice can be demonstrated. The British Dental Association also produces a list of practitioners in General Dental Practice who have had experience of ISO 9002. This list is available for members of the association to benefit from colleagues who have had experience of the systems involved in ISO 9002.

What are the benefits of developing a quality management system? If there is already a good system in place, by documenting and auditing it can be confirmed to the team. If there is not a documented system in place it can help re-assess the practice and consolidate methods of working. This enhances a team approach which means everyone pulling together rather than working to their own agendas. If people are clear on what they are supposed to be doing and to what standard there should be less need to repeat tasks, less errors and a culture is fostered in which the patient is placed first. All these advantages are significant in terms of the cost effectiveness of the service being provided. In terms of time and money, the costs of implementing the standard may be significant. However, the benefits accrued can easily repay the effort and resource expenditure.

*British Dental Association, 64 Wimpole St, London, W1M 8AL. £65.00. BDA & FGDP members, £95.00 Non-members.

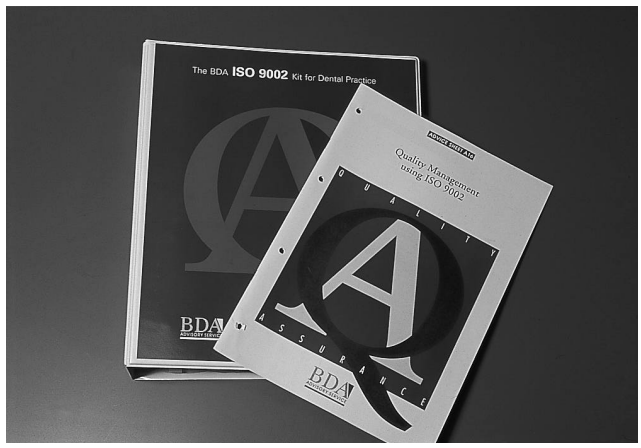

FIG. 2 BDA ISO 9002 Kit for Dental Practice

FIG. 3 Certification bodies for ISO 9002.

1. SGS Yardley
2. British Standards Institute
3. DNV Quality Assurance Limited
4. Lloyds

Once the system is up and running, the practice may feel confident enough to apply for certification to the ISO9002 standard. There are many certification bodies that provide this service (Figure 3). However, it is important to approach an organisation that has already been involved in the assessment of dental practices and who have themselves been accredited to assess practice through their own accrediting body. To date the authors do not know of any orthodontic practice having achieved the standard, although several dental practices have been successful.

An external assessment and certification process provides an opportunity for a practice to confirm that it is achieving what it has set out to achieve against a recognised quality assured standard. A good assessment body can also be enormously helpful to the practice. During assessment it confirms whether or not a practice is doing what it says it is doing and can issue corrective action requests if it finds to the contrary. These can be viewed as a learning opportunity and not as a fault finding exercise. The certificate and logo of achievement may also prove valuable marketing tools by demonstrating that you are in a practice working to a recognised quality management standard.

Conclusion

ISO9002 is a standard that if obtained can help a practice to achieve its full potential. It enables a practice to identify weak areas of management and provides an opportunity to develop systems to a quality assured standard. The development of management systems is only one way of helping an organisation move closer towards a *total quality management approach*, but one that can have a significant effect on the performance and attitudes of the whole team.

References

Mortiboys, R. and Oakland, J. (1991)
Total Quality Management and Effective Leadership. DTI Managing in the '90s, HMSO, October 1991.

Davies, L. (1993)
What is BS5750? British Dental Journal, 1993:**174**(8).

Lee Davies is Development Manager for Davies Associates Practice Support Services Ltd, a company providing training and management development to the dental profession. If you are interested in implementing ISO9002 or require any information on training or management issues, she can be contacted at 3 Heathfield, Mt. Pleasant, Swansea SA1 6HD or by telephone 01792 470060.