Dental technicians: regulation and quality assurance

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VERIFIABLE CPD PAPER

IN BRIEF

- Explains the background and related regulatory issues concerning GDC registration of UK-based dental technicians.
- Clarifies the various regulatory requirements demanded of overseas laboratories and the UK-based dentists they supply.
- Explains international quality assurance standards as they apply to dental laboratories and how an understanding of these can assist dentists in selecting a dental laboratory.

PRACTICE

For many years, dental technicians were largely self-regulated and left to work without any undue interference from, or legislation by, outside authorities. This situation has changed somewhat dramatically in recent years, primarily as a result of a) mandatory General Dental Council (GDC) registration of UK-based dental technicians and b) the requirement to comply with certain EC directives governing the provision of dental appliances. There seems to be some confusion, however, about these various changes and the ensuing ramifications for dental practitioners. The purpose of this paper is firstly to clarify the various regulatory issues currently surrounding technician registration and the provision of laboratory work ('Made in Britain' or otherwise) and secondly to explore the various internationally-recognised quality assurance standards that can be applied to the production of such work in order to assist dentists in gauging quality-related claims made by dental laboratories, both in the UK and overseas.

Regulation of dental technicians

Registration with the GDC for all dental technicians wishing to work in the UK became compulsory from 31 July 2008 onwards. Dental technicians comprise one of a number of groups defined as 'dental care professionals' (DCPs), which also includes clinical dental technicians, dental nurses, dental hygienists, dental therapists and orthodontic therapists. The GDC has defined the role of a dental technician in their booklet, *Scope of practice,* as follows: 'Dental technicians are registered dental professionals who make dental devices including dentures, crowns and bridges to a prescription from a dentist or clinical dental technician. They also repair dentures direct for members of the public.'[1]

The booklet goes on to list in some detail the various specific tasks undertaken by technicians. Anyone involved in the production of such dental appliances and devices within the UK must now be registered with the GDC who justify the introduction of compulsory registration as follows: 'Put very simply, we introduced compulsory registration for patient protection, so that patients can have confidence that all members of the team are properly trained and working to the same high standards set by the GDC.'[2]

Eligibility for registration is based upon the individual holding a GDC-approved qualification and at the time of writing (July 2010) a total of 7,196 dental technicians were registered with the GDC.[3] Once registered, dental technicians are responsible for maintaining their Continuing Professional Development (CPD) and for providing details of it in line with GDC regulations, that is at least 150 hours of CPD over five years of which a minimum of 50 hours must consist of verifiable CPD. The GDC also recommends that all DCPs carry out CPD in a number of recommended core subjects: medical emergencies, disinfection/decontamination and radiography/radiation protection. Dental technicians can, however, substitute radiography and radiation protection with materials and equipment as the application of radiography is not covered in the curriculum for dental technicians.

The total number of dental technicians currently working in the UK is not precisely known although a figure of 10,000 is commonly mentioned.[4] If this latter figure is correct then approximately 3,000 technicians have not yet registered. Some of these will be student dental technicians (defined as being 'in training') who are employed by a laboratory or practice and who have enrolled on a training course leading to registration. A number of technicians, however, may simply have not registered and if they continue to work as such are therefore doing so illegally. Finally, there appears to be no clarity concerning the position on dental laboratory process workers or lab assistants, who, as the law stands, do not have to be registered.[5]

For some time before 31 July 2008 the GDC was informing dentists of the imperative need for all members of the dental team to be registered with the GDC and that failure to do so would have grave and wide-ranging implications. For example, in a letter sent to UK dentists in 2007, the then Chief Executive and Registrar, Duncan Rudkin wrote:

'I am writing to you now to urge you to ensure that your DCP colleagues and team members are registered as a matter of urgency. The consequences of employing an unregistered individual are serious.'[6]

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He went on to warn that:

'Registration is not optional. After 31 July 2008, it will be a legal requirement. If you employ unregistered dental nurses or technicians after that date they will be breaking the law and you could face fitness to practice proceedings.'

The letter then drew dentists' attention specifically to dental technicians saying:

'If you are not sure whether a dental technician from whom you commission work is registered, you may wish to write to them, to remind them that they must register and to inform them that if they do not, you will not be able to commission them for work after July 2008. You will put your own registration at risk if you work with unregistered colleagues.'

Overseas dental technicians

What much of this rather alarmist correspondence did not initially make absolutely clear was the fact that the GDC only possesses jurisdiction over technicians physically situated within the UK and does not, accordingly, have any regulatory powers over technicians located overseas. This is significant since the number of UK dentists making use of overseas laboratories, for at least a proportion of their technical work, appears to be increasing. It is not the purpose of this paper to rehearse the various arguments for and against the use of overseas laboratories but what appears undeniable is that, for a variety of reasons (including cost factors and a shortage of UK technicians), more and more laboratory work is being sent offshore, a trend which is not restricted to the UK and which appears to be commonplace in most developed countries.[7] There was some concern among dentists using overseas laboratories that this practice would no longer be possible as it might be seen to be contravening the GDC regulations in some way and therefore place their own registration at risk. The GDC were keen to clarify this matter and the current 'official' position regarding non-UK laboratory work is summarised in the following two GDC statements:

'The requirement to use registered dental technicians applies to laboratories based in the UK. Laboratories based in EU member states must be registered with the competent authority in that state (equivalent to the Medical and Healthcare Products Regulatory Agency, MHRA, in the UK) and must meet the requirements of the Medical Devices Directive. Laboratories based outside the EU must have an 'authorised representative' within the EU who takes on the same responsibilities in respect of providing dental devices as the manufacturer would in an EU state.'[8]

'When making the decision to either sub-contract the manufacture of a dental appliance, or use a dental laboratory or agent which sources dental appliances, outside the UK, your choice not to use a UK-registered dental technician puts a particular responsibility on you. You will be held professionally accountable for the safety and quality of the appliance. This is because you have chosen not to sub-contract or issue the prescription to a registered dental technician who would otherwise be accountable to him or herself. You take on the dental technician's responsibilities for the appliance and the GDC will hold you accountable for your decision. We expect you to take appropriate steps to discharge the extra responsibilities that come with this decision.'[9]

In truth, dentists must always accept the lion's share of responsibility for any restoration once placed within the patient's mouth. It would be difficult to imagine a scenario in which a patently inferior item of work was delivered to a patient only for the dentist to successfully plead, in any subsequent complaint lodged by the patient, that the blame lay with the technician. It seems reasonable to suggest that if the technical work was inferior then the dentist should be in a position to recognise this fact and not proceed. There may, of course, be a very small number of specific instances when it is almost impossible for the dentist to know that the work is of inferior quality at the time it is placed, but it would be very difficult, in the event of restoration failure, to lay the blame for that failure entirely on the technician given the wide range of clinical variables that might have contributed to that failure. It is interesting to note the stance of indemnity providers in this respect. Dental Protection Ltd, for example, include on their website the following response to a hypothetical question raised by a dental technician:

'Q. A dentist has raised a complaint against me in relation to a crown I made and indicates that the patient is not happy. Do I have to respond to the patient?

A. This very much depends on the nature of the complaint. Your responsibility, as a dental technician, does not necessarily end when the work is forwarded to the dentist. It is in fact not until the work is fitted in the patient's mouth that the responsibility passes to the dentist. The dentist should only fit the work once he or she is satisfied that it is of the appropriate standard and in the patient's best interests. You would be wise therefore to liaise with the dentist in relation to the complaint and to provide any help and assistance you can in responding. *It is unlikely that a dental technician would be asked to respond directly to a patient unless there was a good reason for doing so.*'[10] [Emphasis added]

The GDC would also have powers to penalise dental technicians should they be found guilty of a criminal offence, or deemed to be bringing the profession into disrepute. As far as dental technicians' taking out indemnity cover to protect themselves against such eventualities is concerned, paragraph 1.6 of the General Dental Council's document *Standards for dental care professionals* makes it very clear that all registrants should ensure that:

'...patients are able to claim any compensation they may be entitled to by making sure they are protected against claims at all times, including past periods of practice.'[11]

Some dental technicians may already have indemnity through their employer. Such employer indemnity (vicarious liability) is however usually limited to assistance with claims in negligence, and is unlikely to provide the individual concerned with any advice or help in the event of a complaint, an employment dispute or action against the individual at the GDC. Top-up indemnity is therefore usually required, as a failure to have appropriate indemnity could lead a technician open to allegations of professional misconduct.

Regulation of dental appliances

The Medicines and Healthcare Products Regulatory Authority (MHRA) is an

executive agency of the Department of Health and was set up in April 2003 following a merger of the Medicines Control Agency and the Medical Devices Agency. The MHRA is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. It is responsible for ensuring that relevant directives issued by the European Commission are implemented within the UK and in particular, as far as this overview is concerned, Medical Devices Directive (MDD) 93/42/EC[12] affecting the provision and manufacture of 'dental appliances'. This directive has recently been amended by the European Commission and the regulations implementing these amendments into UK law came into force on 21 March 2010. It is a legal requirement that dentists who commission, and laboratories who manufacture, dental appliances for use in the UK (wherever in the world these are made) must comply with it and failure to do so is deemed a criminal offence under sections 26B and 36M of the Dentists Act 1984.[9] At this point it might be useful to confirm just what this directive categorises as a 'dental appliance' since the term is rather wide-ranging and could mean different things to different people. In this context dental appliances are considered to be custom-made devices specifically made in accordance with a duly qualified medical or dental practitioner's written prescription with specific design characteristics and intended for the sole use of a particular patient, whether NHS, private or independent. Examples include the following appliances mainly constructed outside the mouth on a model, including:

- Laboratory-made temporary crowns and bridges
- Bleaching trays
- TMJ splints such as Michigan and Tanner appliances
- Dentures/crowns/bridges
- Removable orthodontic appliances
- CAD/CAM-produced appliances.[9]

Dentists who construct any of the above, for example bleaching trays, in their own practice may well be unaware that it is their responsibility to ensure that the production facility, that is, their practice, must also be registered with the MHRA and that MDD requirements are complied with as a manufacturer of a custom-made device, including provision to the patient of a statement of manufacture (see below).

Examples of devices not subject to MDD regulations include fillings, temporary fillings, temporary crowns and bridges, splinting teeth, etched orthodontic appliances etc provided that they are made intra-orally.

Directive 93/42/EC also includes the requirement to make available to patients a statement of manufacture showing the following:

- The name and address of the manufacturer, and if outside the EU their authorised representative
- Data allowing identification of the device in question
- A statement that the device is a custom-made dental appliance and intended for exclusive use by a particular patient, together with the name of the patient
- The name of the practitioner or other authorised person who created the prescription and, where applicable, the name of the practice concerned
- The specific characteristics of the product as indicated by the prescription
- A statement that the device in question conforms to the essential requirements set out in Medical Devices Directive 93/42/EC and, where applicable, indicating which essential requirements have not been fully met together with the grounds.

The above are open to some degree of interpretation: for example, what is meant by 'specific characteristics'? As far as dental appliances are concerned this might, for instance, include the specific composition of any alloys used. Dentists must inform patients of the existence of the statement and offer them a copy and record whether or not they choose to take it. If the patient elects not to take a copy then the dentist needs to keep it with the clinical records as the patient can request it at a later date.

Should a dentist use a dental laboratory (or agent) which sources dental appliances outside the UK then he or she will be held accountable for the safety and quality of the appliance, and for making sure that the manufacturer or their authorised representative has complied with all relevant obligations stated in Directive 93/42/EC including providing the patient with a statement of manufacture as described above. Once again though it must be stressed that these regulations do not in any way preclude dentists from using dental laboratories outside the UK or outside the EU, simply that the onus is on the prescribing dentist to ensure that the laboratory in question complies.

Quality assurance

Registration with the GDC and the associated compliance with Directive 93/42/EC may be considered relatively unreliable indicators of quality. Given that the GDC carries out no inspection of laboratory facilities and/or the work that they produce and only check up on a very small number of registered technicians to ensure that they have been fulfilling CPD requirements, how can a dentist ensure that quality claims made by laboratories are genuine? Clearly the best way is to try a laboratory and judge for oneself. Such personal experience is further reinforced if the laboratory has undergone accreditation by a respected quality assurance agency.

Quality assurance is a systematic process aimed at determining whether or not a product or service meets specified requirements. A quality assurance system is said to increase customer confidence and a company's credibility, to improve work processes and efficiency, and to enable a company to better compete with others, ensure compliance with regulations, meet environmental objectives and so on.[13] Modern quality assurance systems emphasise the need to 'catch' defects before they get into the final product. All of these attributes are clearly desirable characteristics for any provider of dental laboratory work. Quality assurance standards can be listed in the following order:

- International standards, for example, ISO standards
- Multinational standards, for example, EN standards (Comité Européen de Normalisation)
- National standards, for example, DAMAS (Dental Appliance Manufacturers' Audit Scheme); ADA standards.

ISO

ISO is a non-governmental, independent organisation and is the largest and most authoritative international standardisation body of its type. The development of ISO standards is based on product quality, management quality and the degree to which these effectively match customer requirements. Each standard is formulated by individual Technical Committees and the experts involved in policy development may be joined by representatives of government agencies, testing laboratories, consumer associations, non-governmental organisations and academic circles.

Management system standards provide a model to follow in setting up and operating a management system. The Plan-Do-Check-Act (PDCA) cycle is the basis of ISO's management system standards.

1. Plan: establish objectives and make plans (analyse the organisation's situation, establish overall objectives, set interim targets, and develop plans to achieve them)
2. Do: implement plans (do what was planned)
3. Check: measure results (measure/monitor how far the actual achievements meet planned objectives)
4. Act: correct and improve plans and how they are put into practice (correct and learn from mistakes to improve plans in order to achieve better results next time).

ISO 9000

The ISO 9000 family of standards represents an international consensus on good quality management practices. ISO 9001:2008 is the standard that provides a set of standardised requirements for a quality management system, regardless of what the user organisation does, its size, or whether it is in the private, or public sector. It is the only standard in the ISO family against which organisations can be certified, although certification is not a compulsory requirement of the standard. ISO 13485, published in 2003, is based on ISO 9001 and represents the requirements for a comprehensive management system for the quality control of medical devices. It is this ISO standard which is therefore clearly most applicable to dental laboratory facilities.

DAMAS

The Dental Appliance Manufacturers Audit Scheme (DAMAS) is a UK-based quality management system developed by the Dental Laboratories Association based upon ISO 9000 and administered and laid out in much the same way.[14] Laboratories participating in DAMAS are audited by a third party assessor to ensure conformity to prescribed specifications.

ISO certification in practice

Since the ISO Accreditation Committee is an independent, non-governmental organisation, it is not influenced by outside third parties and follows rigid guidelines when awarding certification. Initially, the applicant is required to provide a great deal of documentation covering a wide range of topics such as company management, product safety, quality control systems, continuing improvement systems, customer service and so on. ISO also requests that the company:

- Monitors processes to ensure they are effective
- Maintains updated records
- Checks defects, with evidence of appropriate and corrective action where necessary
- Regularly reviews individual processes and the quality system itself for effectiveness
- Facilitates continual improvement
- Provides customer data on delivered product quality and dealer reports.

Once all the requirements of ISO 9001 have been met, an unbiased external audit is required. This should be carried out by a third party, accredited, certification body. The most authoritative and best-known international accreditation agencies in the world include the American Management Association; British Royal Accreditation Council; British Standards Institute; DNV (Det Norske Veritas organisation); EMC Compliance Management Group; German Technical Monitoring Association (TUV) and SGS.

All the chosen certification bodies will review the organisation's procedures, a process which involves looking at the company's evaluation of quality to ascertain if targets set for the management program are both measurable and achievable. This is followed at a later date by a full on-site audit to ensure that working practices observe the procedures and stated objectives and that appropriate records are being kept. After the successful external audit, a certificate of registration to ISO 9001 will be issued. This is not the end of the ISO process though since ISO certification is reclaimable, which means surveillance visits (usually once or twice a year) will be implemented to ensure that the quality control system is continuing to function correctly.

ISO and dental laboratories

ISO accreditation is by no means easily achieved and is a concrete recognition that a dental laboratory is doing the utmost to ensure maximum quality and fitness for purpose of its products in terms of best practice, quality of materials, as well as a commitment to keeping up to date with latest technology and techniques. It is a valuable quality marker for any laboratory wherever in the world that laboratory may be situated. ISO accreditation also requires that manufacturers are fully aware of, and comply with, all regulatory issues in those countries and regions in which it sells its products. This is particularly relevant given the discussion previously concerning the added responsibility of the growing number of dentists who send their work to laboratories outside the UK.

Dental material manufacturer accreditation

Further, tangible, evidence of quality comes from various laboratory monitoring and accreditation schemes established by leading materials manufacturers. For example only 3M-authorised Lava™ Manufacturing Centers are able to provide Lava copings and frameworks to other dental labs, which, in turn, require accreditation by 3M to ensure that the technicians are fully trained to use the materials correctly. In addition, dentists using 3M Lava™ Zirconia restorations are able to use an online verification system using barcoded labels that come with the restoration. Other manufacturers have implemented similar laboratory accreditation schemes.

Conclusion

Dentists working in the UK are confronted with a growing list of legally binding regulations, all of which have a significant

impact on how they run their practices. The relationship between dentist and technician is just about as old as dentistry itself and this too is now subject to regulation and scrutiny. It behoves every dentist to ensure that he/she is practising within the various, recently-imposed regulations. As far as dental laboratory work is concerned, this primarily means that if you are sending your work to a UK-based technician then that technician must be registered with the GDC. The regulations do not, however, compel dentists to send their work to UK-based technicians, simply that their responsibilities are different if they choose to do so. All dentists need to understand the significance of EU Directive 93/42/EC and the need to offer to provide every patient receiving a dental appliance with a comprehensive statement of manufacture. All of these regulations do not guarantee product quality and dentists should understand the meaning of quality assurance and how this can help determine technical quality. Ultimately, and in spite of GDC regulations, the final responsibility for determining that quality lies, in the vast majority of cases, with the dentist.

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