The availability and content of dental instrument manufacturers' decontamination information

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IN BRIEF

- Reminds dental practitioners that manufacturers' instructions should be adhered to when reprocessing instruments.
- Highlights the difficulties that may be faced when attempting to confirm reprocessing instructions with instrument manufacturers.
- Care should be taken when following instructions since some do not comply with accepted reprocessing instructions in the United Kingdom.

RESEARCH

Objective The effective decontamination of reusable dental instruments is essential to reduce the risks from onward transmission of infectious diseases. There are therefore a number of legislative requirements placed upon manufacturers of medical devices (which includes dental instruments) to provide validated methods for the reprocessing of such devices. The aim of this study was to determine the availability and content of manufacturer's instructions for the reprocessing of reusable dental instruments. **Materials and methods** A database of reusable dental instruments with details of their manufacturers was collated from information received from three dental hospitals. A questionnaire was sent to all the manufacturers requesting information about the reprocessing instructions for their products. The response from each manufacturer was assessed for the quality of the information and compliance with the British, European and International Standard, BS EN ISO 17664 (2004). **Results** The database from the three dental hospitals included over 800 items supplied by 54 different manufacturers/suppliers. Forty protocols were available for assessing compliance with BS EN ISO 17664 (2004). These protocols accounted for 25 (46%) manufacturers covering 300 devices. The majority (90%) of the returned questionnaires did not comply with the required standard and provided insufficient information to allow for the effective decontamination of the instruments. **Conclusions** Manufacturers of medical devices are legally required to supply the user with validated instructions to enable effective decontamination of these devices. The information must be in a format as specified in BS EN ISO 17664 (2004). The information obtained in this survey demonstrated that the manufacturers' instructions fall short of the required regulatory requirements. The absence of such instructions increases the risk of cross-infection arising from inadequate cleaning, decontamination and sterilisation.

INTRODUCTION

The absolute requirement for high standards in the decontamination of medical devices has been recognised in several reports.[1-5] Over recent years, the driving force for highlighting the need to improve standards in decontamination has been the occurrence of vCJD in the UK and elsewhere,[6] although it should also be recognised that there also exists the risk of cross-infection from other pathogens, such as blood borne viruses.

The decontamination of dental instruments involves several stages which, depending on the type of instrument being reprocessed, may include disassembly, cleaning, disinfection, inspection, testing for functionality, packaging, sterilisation and storage.[3,7] The range of modern dental instruments is vast and the degree of complexity has increased with technological advances. In addition, the range of cleaning materials and equipment has increased markedly over recent years. Thus, clinicians wishing to provide the highest quality of care for their patients whilst ensuring that it is possible to clean, disinfect and sterilise re-usable instruments can be faced with a dilemma.

However, dental instruments are classified as medical devices and therefore guidance for their reprocessing is given in the Medical Devices Directive.[8] This states that manufacturers must '...provide information on the appropriate methods of cleaning, disinfecting, packaging and where appropriate, sterilisation to allow re-use of the device. Manufacturers must also supply similar information if the devices are supplied non-sterile and are required to be sterilised prior to use...' Thus it is incumbent upon the manufacturer to provide appropriate instructions for the reprocessing of their instruments. In addition, the recommended process must have been validated. Guidance on the content of these instructions has been given in the form of a British, European and International Standard BS EN ISO 17664 (2004),[9] a summary of which is provided in Table 1.

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Thus the decision to use particular cleaning processes and chemicals or sterilisation methods should not be made by the clinician, since this information must be supplied by the manufacturer of a medical device. Rather, the responsibility of the clinician is to ensure that the manufacturer's recommendations are followed. This is further emphasised in professional guidelines.[10] It is critical, therefore, that reprocessing instructions are of a high standard. Not only should they be compatible with the commonly available chemicals and equipment used, but they should also be fit for use within the different environments where instrument reprocessing takes place. In dentistry, this ranges from central decontamination units in the hospital setting to local decontamination units in general dental practice.

In the United Kingdom (UK), commonly used reprocessing conditions for reusable medical and dental instruments are:

- Washing: water at too high a temperature during the initial flushing stage may lead to the coagulation of proteins and thus serve to 'fix' proteinaceous soil to the surface of the load items. It is recommended that the initial temperature should not exceed 35°C[11]
- Thermal disinfection: an appropriate combination of time and temperature[11-13]
- Steam sterilisation: 134-137°C for three minutes.[14,15]

The aim of this study was therefore to determine the availability and quality of the reprocessing information supplied by manufacturers of dental equipment in the UK against the standard BS EN ISO 17664 (2004), to determine whether dentists were being supplied with sufficient information to safely reprocess their dental instruments.

METHOD

Selection of manufacturers

A database of all instruments currently undergoing decontamination in the three Scottish dental hospitals (Dundee, Edinburgh and Glasgow) was prepared. The categories of instruments that were being reprocessed are summarised in Table 2.

Table 1 Guidance for the requirements of manufacturers' instructions (BS EN ISO 17664 (2004))[9]

Parameter	Criteria
Reprocessing instructions	At least one validated method for reprocessing the medical device shall be specified
Preparation at the point of use prior to reprocessing	Description of the maximum period of time that may elapse between use and cleaning Description of the pre-cleaning techniques critical to further processing
Preparation before cleaning	Description of the soaking/brushing technique required, ultrasonic treatment of device, disassembly of the device
Cleaning	A validated method of manual cleaning shall be specified. At least one validated automated method using a washer-disinfector shall also be specified unless the medical device cannot withstand any such process, in which case a warning should be issued Identification and concentration of chemicals required for cleaning
Inspection, maintenance and testing	When methods are required at any stage of processing to confirm the cleanliness or performance or both of the medical device, these should be stated
Packaging	If a specified method for packaging or containing the medical device during and after sterilisation is required, it shall be stated and be compatible with the sterilisation process and the medical device
Sterilisation	A validated method of sterilisation shall be specified (wherever possible, moist heat sterilisation is recommended)
Storage	Any specific limitations for the time or conditions of storage of the reprocessed medical device prior to use shall be stated
Presentation of the information	The information required shall accompany the device in the instructions for use supplied with the medical device, on the medical device label or packaging
Validation of the reprocessing information provided	The manufacturer shall validate that any process identified in the information provided is capable of reprocessing the medical device for its intended use

Information requested from manufacturers

Manufacturer's websites were viewed, but the inclusion of reprocessing information was rare. Instrument suppliers and manufacturers were therefore contacted by letter and asked to provide details about:

i) Cleaning and disinfection (the use of thermal washer disinfectors, restrictions on chemicals, the use of ultrasonic cleaners)
ii) Sterilisation (the process and conditions).

The letter also highlighted the requirements for written reprocessing instructions placed on manufacturers by the BS EN ISO 17664 (2004)[9] standard (Table 1).

Analysis of returned forms

Returns were assessed for compliance by one reviewer (RS). The information was assessed for the level of information supplied by the manufacturers to enable decontamination to be performed using the facilities readily available either at a central sterile service department or a typical general practice setting. The information supplied was graded into one of two categories:

a) Full details supplied to enable decontamination of devices and fully compliant with BS EN ISO 17664 (2004)
b) Information supplied was not compliant with BS EN ISO 17664 (2004) and insufficient details were supplied to enable decontamination of devices.

The assessment was focused on the instructions for cleaning, disinfection and sterilisation of the dental instrument concerned.

RESULTS

The database of reusable dental instruments contained over 800 items supplied by 54 different manufacturers.

Table 2 Groups of instruments undergoing reprocessing at the three Scottish dental hospitals

Instrument group
Handpieces (turbines, air rotors, motors and ultrasonic scalers)
Hand instruments (conservation, perio, prostho)
Surgical instruments (extraction forceps, elevators)
Non-surgical burs
Surgical burs
Endodontic instruments (for example rotary instruments, ie excluding single-use)
Miscellaneous (matrix band holders etc)

Table 3 Analysis of returned protocols for decontamination of dental devices

Process	Information compliant with ISO 17664 (2004)	Information not compliant with ISO 17664 (2004)*
Cleaning	4 (10%)	36 (90%)
Sterilisation	17 (42%)	23 (58%)

*Includes missing information, procedures that cannot be easily followed.

Twenty-five (46%) manufacturers/suppliers responded to the questionnaire. Forty reprocessing protocols for the reprocessing of 300 items were available for assessing compliance with BS EN ISO 17664 (2004).

Of the 40 protocols reviewed, only 12 (30%) were in the format recommended by BS EN ISO 17664 (2004). These protocols were supplied by six (24%) of the 25 manufacturers.

On reviewing the instructions relating to cleaning of the devices (Table 3), 36 (90%) of the returned questionnaires either had no information on the type of detergent to use for cleaning, had a complete absence of cleaning information, or gave inappropriate information, for example 'The minimum water temperature shall be 80°C'.

When the sterilisation instructions were reviewed, 23 (58%) gave incomplete or in appropriate parameters. These fell into three categories:

- Sterilisation time was not specified
- Inappropriate times were recommended, for example cycle times which were not readily available on UK sterilisers, or failed to specify whether this related to cycle time or holding time, for example 'sterilise for five minutes' and 'sterilise for 30 minutes'
- Recommended temperatures were not readily available on UK sterilisers, for example 275°F.

When the advice for both stages was reviewed, the four (10%) appropriate protocols for cleaning also complied with instructions for sterilising.

DISCUSSION

A number of standards and guidelines highlight the importance of cleaning prior to sterilisation, for example the BDA Advice Sheet A12[10] recommends that all instruments contaminated with oral fluids must be thoroughly cleaned and sterilised after use, and identifies three stages to the decontamination process: pre-sterilisation cleaning, sterilisation and storage. In Scotland the preferred method for cleaning instruments is the use of automated washer-disinfectors.[16,17]. In addition to the cross infection risks, sub-optimal cleaning resulting in residual debris in instrument lumens, joints or on cutting edges will also be detrimental to the clinical effectiveness of the device.

In Scotland alone, over 180 million instruments are reprocessed in general dental practices per year.[18] To ensure the appropriate reprocessing of these, the Medical Device Directive (93/42/EEC) places a regulatory requirement on device manufacturers to supply the end user with reprocessing instructions.[8] The BS EN ISO 17664 (2004) standard outlines the format of those requirements in more detail.[9] In this study, only 40 protocols were available for assessment and the majority of manufacturers (54%) who were contacted failed to respond to the request for details on reprocessing instructions. This poor response rate highlights difficulties that practitioners in primary care experience in attempting to comply with good practice guidance. It is also alarming given the regulatory requirements on the manufacturers and the risks associated with inadequate reprocessing.

The solution to this problem may lie in increased vigilance by purchasers of dental equipment to ensure adequate instructions for reprocessing are available prior to purchase, and restricting procurement to those devices that come with the required device reprocessing instructions. However, the widespread failure of manufacturers to supply validated and appropriate processes for reprocessing found in this study will make this a difficult task in the short term. The findings of this study also raise questions concerning the effectiveness of the regulatory authorities in the UK, such as the Medicines and Healthcare Regulatory Agency (MHRA).

In conclusion, with over 90% of the responding manufacturers providing insufficient information for the cleaning of dental instruments and 58% providing insufficient or incorrect instructions for sterilisation, it is clear that the majority of manufacturers of dental devices are in contravention of the Medical Devices Regulations and are thus failing to observe current regulatory requirements. The absence of validated instructions from instrument manufacturers and suppliers is compounding efforts by practitioners and institutions to comply with current regulatory standards and good practice guidance. These shortcomings should be addressed as a matter of urgency.

1. Pineau L, Roques C, Luc J, Michel G. Automatic washer disinfector for flexible endoscopes: a new evaluation process. *Endoscopy* 1997; **29:** 372-379.
2. Rutala W A, Weber D J. Infection control: the role of disinfection and sterilization. *J Hosp Infect* 1999; **43 (Suppl):** S43-S55.
3. Smith A, Dickson M, Aitken J, Bagg J. Contaminated dental instruments. *J Hosp Infect* 2002; **51:** 233-235.

4. Walker J T, Bradshaw D J, Fulford M R, Marsh P D. Control of biofilms and microbial contamination in dental unit water systems in general dental practice. *In* Walker J, McBain A, Allison D, Brading M, Rickard A, Verran J (eds) *Biofilm communities: order from chaos?* pp 227-235. Cardiff: BioLine, 2003.
5. Zuhlsdorf B, Floss H, Martiny H. Efficacy of 10 different cleaning processes in a washer-disinfector for flexible endoscopes. *J Hosp Infect* 2004; **56:** 305-311.
6. Department of Health Economics and Operational Research Division. Risk assessment for vCJD and dentistry. London: The Stationery Office, 2003.
7. Whitworth C L. Variant Creutzfeldt-Jakob disease - a problem for general dental practitioners? *Primary Dent Care* 2002; **9:** 95-99.
8. The Council of the European Communities. Council directive 93/42/EEC of 14 June 1993 concerning medical devices. Council of the European Communities, 1993.
9. BS EN ISO 17664 (2004). Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices. 2004.
10. British Dental Association. Infection control in dentistry: BDA advice sheet A12. London: British Dental Association, 2003.
11. European Standard EN ISO 15883-1:2006. Washer-disinfection - part 1: general requirements, terms and definitions and tests. 2006.
12. NHS Estates (Scotland). Scottish health technical memorandum 2030 (washer disinfectors). Edinburgh: The Stationery Office, 2001.
13. NHS Estates (England). Health technical memorandum 2030 (washer disinfectors). London: The Stationery Office, 1997.
14. NHS Estates. Health Technical Memorandum 2010 (sterilisation) part 1: management policy. London: HMSO, 1994.
15. NHS Estates (England). Health Technical Memorandum 2010. Good practice guide: sterilisation. London: The Stationery Office, 1995.
16. Health Protection Scotland. Local decontamination units: guidance on the requirements for equipment, facilities and management. Glasgow: Health Protection Scotland, 2005. http://www.hps.scot.nhs.uk/haiic/decontamination/guidelinedetail.aspx?id=31262
17. Scottish Executive Health Department Performance Management and Finance Directorate. Decontamination - compliance in primary care. NHS HDL(2005) 01. Edinburgh: Scottish Executive Health Department, 2005.
18. NHS Scotland Sterile Services Provision Review Group. Survey of decontamination in general dental practice. Edinburgh: NHS Scotland, 2004. http://www.scotland.gov.uk/Publications/2004/11/20093/45208