Summary of: The availability and content of dental instrument manufacturers' decontamination information

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FULL PAPER DETAILS

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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.

EDITOR'S SUMMARY

With cross infection control and instrument decontamination currently such an important concern in dentistry, dental practitioners will increasingly be seeking up-to-date, definitive information on how to reprocess their dental instruments safely and in accordance with legislation. It is reasonable to assume that one of the first places to look for this information would be the instrument manufacturer's instructions: after all, when looking for information about the correct use and re-use of any piece of equipment, the instruction booklet that accompanies the device is for most people at least, the obvious choice. In addition, the Medical Devices Directive states that manufacturers must provide appropriate, validated methods for reprocessing dental instruments, so the manufacturer's instructions should be all a dentist requires by way of information in this regard.

This paper by Roebuck *et al.* casts doubt on the wisdom of relying on manufacturer's instructions for instrument reprocessing. The authors set out to investigate the availability and quality of reprocessing information supplied by dental instrument manufacturers. The results make worrying reading: less than half the manufacturers surveyed responded to the questionnaire. Those that did reply submitted a total of 40 reprocessing protocols for assessment of compliance with the British, European and International Standard covering the content of reprocessing instructions. Only 12 of these were in the recommended format, 36 (90%) did not comply with the standard for instrument cleaning instructions and 23 (58%) did not comply with the standard for sterilisation instructions.

It seems clear that the majority of dental instrument manufacturers are contravening medical devices regulations and not supplying sufficient or correct instructions for reprocessing their instruments. It is therefore vital that all parties and authorities concerned with regulations, standards and guidance on instrument reprocessing address this issue as a matter of urgency. If dental practitioners cannot rely on the instructions they are obliged to follow, then despite their best efforts, the problem of instrument contamination will persist and may even increase.

The full paper can be accessed from the *BDJ* website (www.bdj.co.uk), under 'Research' in the table of contents for Volume 204 issue 8.

Rowena Milan,
Journal Editor

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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

COMMENT

This paper seeks to quantify the difficulties dentists face when they need to decontaminate reuseable instruments. It appears that only a very small minority (10%) of instruments of the 800 examined in this paper are supplied with appropriate validated decontamination instructions. They are sold, however, as medical devices and yet fail to comply with the Medical Devices Directive, which requires them to be supplied with reprocessing instructions. This therefore calls into question the credibility of the CE marking system!

The question is asked about the effectiveness of the regulatory system, or rather the enforcement of it, that allows the manufacturers to sell such equipment. It is incumbent on the user to ensure that all the equipment they purchase is CE marked as appropriate for their intended use but surely not their responsibility to ensure that this marking is compliant with all the regulations. If this system is not regulated then one needs to ask the question 'why bother?'

The suggestion is made in the paper, that purchasers boycott that equipment that is not supplied with adequate reprocessing instructions. This seems to be impractical advice bearing in mind the very small number of items that are compliant!

The findings presented here make the standard advice issued by many professional and other organisations that issue guidelines, to follow manufacturers instructions with regards to decontamination protocols, somewhat irrelevant. It would seem sensible for all parties involved in this issue to formulate an action plan to address the shortcomings highlighted here, as a matter of urgency. This is especially important as the matter of instrument decontamination is currently at the top of the dental agenda.

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AUTHOR QUESTIONS AND ANSWERS

1. Why did you undertake this research?

The Medical Devices Directive is quite clear in its guidance for the reprocessing of medical devices. When attempting to source the manufacturer's instructions for a small number of instruments, it became apparent that there were difficulties in accessing accurate information. This study was therefore undertaken to establish the extent of the non-compliance of manufacturers supplying dental instruments in the UK.

2. What would you like to do next in this area to follow on from this work?

The next step in this project is to encourage the regulatory bodies such as the Medicines and Healthcare Regulatory Authority to take appropriate action to ensure that manufacturers produce reprocessing instructions for their instruments which are appropriate, compliant and easily accessible.