The design planning implications of HTM 01-05: decontamination in primary care dental practices

Richard Mitzman and Geoffrey L Ridgway discuss the impact that HTM 01-05 will have on the design of dental practices

The Health Technical Memorandum (HTM) series of Department of Health publications are designed to provide a distillation of current advice on various technical matters that will have an impact on the safety of both patients and healthcare workers. HTM 00 covers policy and principles, whilst HTM 01 is concerned with all aspects of decontamination. HTM 01-01 provides the background information on the decontamination of reusable medical devices, whilst other components of the 01 series deal with specific aspects, including laundry, pharmacy and endoscopy.

HTM 01-05: Decontamination in primary care dental practices was published in electronic form in November 2009. A hardback format, accompanied by an audit tool prepared by the Infection Prevention Society will be available from early 2010. Dental practitioners and their staff should already be familiar with the BDA advice sheet A12: Infection control in dentistry, which addresses amongst other aspects of infection control, the specific areas of surgery design and surface and instrument decontamination. There is no doubt that if the advice in this document is followed assiduously that the practice will be working to an acceptable standard of infection control, ensuring that the infection risk to both patients and staff is minimised. Why then was it thought necessary to produce a lengthy and detailed document dealing specifically with decontamination in primary care dentistry?

Background

In 2000, a snapshot survey of decontamination practices in healthcare premises in England was published. As part of this survey, 15 dental practices were visited. Findings were in general no different to those reported from individual clinical units in Trusts, and can be summarised by the statement at the beginning of the report:

‘The assessors found some examples of good practice, but also many instances where decontamination processes fell significantly short of current standards. In some cases, practice was unacceptably poor.’

Amongst the key findings of the report relevant to dental practice, health and safety issues were identified – including the uncontrolled use of chemicals and inappropriate use of processes for decontamination. Few organisations had an effective management control system in place to cover the equipment life-cycle, with few organisations providing appropriate facilities for decontamination. Items designated for single-use only were sometimes re-used. Manual decontamination processes were often poorly controlled, presenting hazards to staff and patients. Traceability of instruments was poor, which, along with poor record keeping, can mean that should problem arise, it would be impossible to trace patients quickly and take remedial action.

A subsequent comprehensive survey of 179 general dental practices in Scotland by NHS Scotland was published in 2004. This study noted that while staff were generally highly motivated, the cleaning of reusable instruments had several shortcomings and was, in general, poorly controlled. The authors noted that the conclusions were relevant to the whole UK. The conclusions were unsurprisingly similar to those of the more limited England study, but the need for guidance on surgery design, layout and the separation of clinical from decontamination areas was emphasised.

HTM 01-05

HTM 01-05 is designed to give not only comprehensive guidance on the whole of the instrument decontamination cycle, but also on the provision of an optimal environment where this exercise can be safely carried out. HTM 01-05 is designed for use by the dentist, the clinical staff, the servicing engineer and the surgery designer.

HTM 01-05 recognises that many practice premises in England are within buildings that were never intended for use as clinical dental units. However, there is no doubt that, in many cases, there is an urgent need to upgrade standards of instrument decontamination to at least a basic level of acceptability. It is for this reason that HTM 01-05 allows for a period of transition. Initially, all premises will be required to achieve the essential quality requirements within 12 months of publication of the hard copy version and accompanying audit tool.

The essential quality requirements require the practice to have written validated policies for infection control and instrument decontamination. Practices will also be
required to demonstrate how they intend to proceed to the requirements for achieving best practice, along with some indication of timescale.

Best practice will require the environment for decontaminating instruments to be clearly separate from the clinical treatment area. Essentially, this will require separate rooms for ‘dirty’ and ‘clean’ instruments. Use of a mechanical washer/disinfector will be necessary, and instruments will need to be stored away from the clinical treatment area. Ideally, the air direction in the decontamination suite should flow from the ‘clean’ and storage areas to the ‘dirty’ area.

‘Sterile’ and ‘sterilised’

The document *Sterilization, disinfection and cleaning of medical equipment: guidance on decontamination*, from the Microbiology Advisory Committee to the Department of Health (known as the MAC Manual Part 1, 2002), defines sterilisation as a process used to render an object free from viable infectious agents, including bacterial spores and viruses.

In order to maintain an article in a sterile condition, it cannot be exposed to the room air until immediately before use. In the surgical setting this means that the article must have been processed whilst wrapped, and stored in the original wrapping until required. Unwrapped instruments cease to be sterile as soon as they are exposed to the room environment. Therefore, unwrapped instruments sterilised in a type N, gravity feed autoclave cannot be maintained in a sterile state once removed from the autoclave. Pre-wrapped instruments processed in a type B autoclave, which has a pre-vacuum phase, or instruments contained within the cassette of a type S autoclave specifically programmed for dental instruments can be stored sterile if kept in the original wrapping/cassette.

An important point that underpins the guidance in HTM 01-05 is the concept of instruments having been ‘sterilised’ when available at the point of use, compared with the more usually accepted surgical standard of being ‘sterile’ at point of use. This is to acknowledge that most work in general dental practice will not take place in a sterile environment (the oral cavity). Whilst this guidance allows for the wrapping and storage of sterilised, unwrapped instruments after they have been autoclaved, such storage is for a limited period under optimised conditions. However, although these instruments are not sterile as defined above, this is not a reduction in standard of re-processing, which (with few exceptions) requires reusable instruments to be sterile at the completion of the decontamination process.

Summary of implications of HTM 01-05 to the design of dental practices

The overall aim is that the instrument should be:

- Clean and sterile at the end of the decontamination process
- Maintained in a clinically satisfactory condition up to the point of use. With a vacuum steam steriliser (types B), instruments will be pre-wrapped using purpose-designed materials that are compatible with the steriliser. Wrapping should take place with a dry product shortly after washing and disinfection. Once the wrapped instruments have been sterilised satisfactorily, the product may be stored for up to 60 days. Similarly, instruments processed in a cassette in a type S steriliser designed for re-processing dental instruments can be stored in the sealed cassette for 60 days. Instruments processed in a type N steriliser (gravity or downward displacement steriliser) should either be used in the current session, or immediately placed in suitable view packs for storage for up to 21 days.

Regardless of the choice of location used for the reprocessing facilities, a dirty to clean workflow should be maintained so that the used instruments are at a lower risk of coming into contact with decontaminated instruments. This requires a well-developed routine for surface cleaning/decontamination within the facilities:

- One room for dirty activity (cleaning instruments)
- One room for clean activity (inspection, sterilisation and wrapping instruments (pre-wrapping for processing in type B or S sterilisers and post-wrapping for instruments processed in a type N steriliser). Where possible, air movement should be from clean to dirty areas. A wash-hand basin should be provided for use by staff at the completion of each stage in the decontamination process. This guidance recognises that, because of physical limitations on space, it may take longer for some practices to meet the best practice requirements. In areas where building alterations to existing premises are restricted and/or purpose-built premises may be difficult or impossible to acquire, best practice may not be achievable.

Minimum requirements now:

| 1. Processing of contaminated instruments in a separate space from treatment areas |
| 2. Decontamination area separated into dirty and clean zones |
| 3. Dirty zone has sinks with draining for scrubbing and rinsing instruments and another designated solely for hand washing and designed for that purpose |
| 4. Dirty zone has instrument washer/disinfector (W/D) (an ultrasonic cleaner is an optional item in addition to a W/D) |
| 5. Clean zone has sink designated solely for hand washing and designed for that purpose |
| 7. No contaminated instruments or personnel pass through clean zone |
| 8. A dirty to clean workflow should be maintained |
| 9. Where possible, air movement should be from clean and storage areas to dirty area |
| 10. Adequate uncluttered worktops |
| 11. Ample clean storage |
Below is a plan (Figure 1) of the absolute minimum necessary for a decontamination area. It needs 5.25sqm (54sqft), about 11x5 feet.

![Minimum decontamination room to be compliant now](image1)

Figure 1: Minimum decontamination room to be compliant now

The easiest way to explain what has to be done is to describe what the decontamination areas should include to be:

a. Compliant for mandatory guidelines, now (Figure 2)

b. Compliant for ‘best practice’ in five years time (Figures 3 and 4).

![Single decontamination room compliant now](image2)

Figure 2: Single decontamination room compliant now

![Double decontamination room 'best practice'](image3)

At the moment, very few existing practices have an instrument washer/disinfector, let alone a pass-through model. The instrument washer/disinfector should always be in the dirty area; the steriliser in the clean area. The washed instruments then have to be carried through to the clean area to be inspected and packed.

The biggest difference for the ‘best practice’ decontamination areas is that the dirty and clean areas have to be divided into separate rooms each with a door and individual air supply and extraction.

It can be seen that the space requirement is of at least eight square metres (86sqft). Most existing dental practices will not have this spare space and will need to alter their layout, even possibly losing a surgery (usually a minimum of 10 square metres).

To date, one solution has been to plan a decontamination area in (or in an alcove off) a back of house staff corridor. Whilst this was far more satisfactory than found in many practices, particularly those that had the steriliser in the surgery (which has not been acceptable for several years), this no longer complies with the guidelines in HTM 01-05.
The reason for this is that it is possible for contaminated, ‘dirty’ instruments to be carried through the clean zone of the decontamination area. This now obviously has to be addressed and most dentists also find themselves in a situation where their practices do not conform to the guidelines, let alone ‘best practice’.

Many of the existing decontamination areas can be adapted to comply with the insertion of a floor to ceiling etched glass screen and possibly an etched glass sliding or pivoting door. Below are two examples of such adaptations.

Figures 5 and 6 show a decontamination area that can be adapted with the insertion of a glass screen and moving the steriliser into the clean area, to be compliant now, and then can be made ‘best practice’ with the introduction of a glass door to the clean area.

Some pointers in the design of the whole dental practice for cross infection control

1. Smaller surgeries make room for a decontamination area. A standard surgery need not be any bigger than 3.4m x 2.75m (11ft x 9ft). Anything more makes it less efficient.

2. Twin surgeries make time for cleaning. Start working on the next patient in a clean surgery, allowing time to clean the vacated surgery properly. This also removes much of the stress from a busy practice and, unbelievably, can save up to six working weeks a year, just cleaning the surgery (five minutes/patient = one hour/day = approx five hours/week = 20 hours/month = 240 hours/year).

3. Multiple doors to surgeries ease direction of flow of contaminated instruments, separate staff from patients and help nurture a calm environment.

Some pointers in the design in the dental surgery for cross infection control

To maximise ease of cleaning/disinfection of surgeries:

1. Minimise worktops. The less worktop, the less to clutter and the less to clean.

2. No clutter. The less that is kept out, the less there is to clean between every patient. Everything, if possible, should be put away.
3. Glass work surfaces. Glass work surfaces can be seen to be clean. Patients can see immediately that the surgery is clean and gleaming.

4. Ample clean storage. It is most important to have easily accessible clean storage so that sterilised instruments stay in good condition for as long as possible without contamination.

5. ‘Steri-Walls’. The system of ‘Steri-Walls’ has been developed over several years to efficiently house everything that is needed during dental surgery.

The views expressed in this article are of the authors, and not necessarily those of the Department of Health.

Comments to pd@fmc.co.uk

Richard Mitzman DDS, BDS, RIBA, DipArch, BA is an architect and dentist. For further information please visit the website at www.richardmitzman.com. Geoffrey L Ridgway OBE, MD, BSc, FRCP, FRCPath is a clinical microbiologist and a contributor to HTM 01-05.