Disinfection and Decontamination: The Instrument Decontamination Process

Aims: To give the participant an overview of the processes involved in dental instrument decontamination using essential quality requirements and best practice recommendations and how to comply with the requirements for HTM 01-05 (England), WHTM 01-05 (Wales), SHTM 01-05 (Scotland) and DHSSPSNI (Northern Ireland).

Objectives: On completion of this verifiable CPD article the participant will be able to demonstrate, through the completion of a questionnaire, the ability to:

- Be able to identify a definition of decontamination.
- Be able to distinguish between essential quality requirements and best practice recommendations relating to the decontamination of a dental instrument, relevant to all UK nations.
- Be able to identify the decontamination processes of an instrument.
- Be able to identify the methods of pre-cleaning and sterilisation used in general dental practice.
- Be able to identify the limitations of manual cleaning prior to sterilisation and how it is performed.
- Be able to demonstrate knowledge on the safe storage of instruments to prevent bacterial re-colonisation.
- Be able to identify where to access additional information on decontamination in primary dental care practice relevant to your area of the UK.

Introduction

Patients reserve the right to be treated in a surgery environment that is safe and clean with consistent standards of care every time they receive treatment. This includes insuring that the risk of person-person transmission of infections is minimised as much as possible.[1] Decontamination is defined as “the process by which reusable items are rendered safe for further use and for staff to handle.”[1] The decontamination of instruments is a necessary requirement to reduce the risk of cross-infection from patient to patient and also between patients and staff. As part of their registration, dental care professionals have a responsibility to demonstrate competence in all

aspects of their work[2] and take actions to protect patients[3]. This includes ensuring that the decontamination of instruments is conducted to recommended standards.

Infection control within healthcare is the subject of continued debate[4]. From April 2011, all dental practices were required to register with the Care Quality Commission (CQC). Part of the requirements for registration with the CQC is to ensure that there is the provision of a "safe, clean environment and appropriate decontamination of dental equipment[1]".

Health Technical Memorandum 01-05 is intended to progressively raise the quality of decontamination work in primary dental services by covering the decontamination of reusable instruments within dental facilities. This document should be used, or referred to, by all members of a dental team providing primary dental services.

It is designed to:

- Assist general dental practices to meet pre-existing legislative requirements.
- Define a minimum acceptable standard of decontamination (essential quality requirements or EQR).
- Provide a development path to achieve 'best practice' standard of decontamination.[1]

This article will describe the difference in instrument decontamination requirements using EQR/ Minimum levels of compliance and best practice recommendations.

Although each country in the UK has slight variations in its guidelines for good practice, they generally agree on most key issues, even if they occasionally use different terminology. The guidance for England, Northern Ireland, Scotland and Wales can be downloaded in the further reading section and should be read in conjunction with this article, which primarily focuses on HTM 01-05 (2013).

Essential Quality Requirements/Minimum Levels of Compliance

The HTM 01-05 statement for essential quality requirements is that:

“Regardless of the technology used, the cleaned instruments, prior to sterilisation, should be free of visible contaminants when inspected.” Instruments should be reprocessed using a validated decontamination cycle including:

- Cleaning/washing (this includes having a written protocol).
- A validated steam steriliser.
- At the end of the process the instruments should be in a sterilised state.
- Reprocessed dental instruments should be stored in a way that ensures the restraint of microbial recolonisation (this involves having careful controls in place).
- Practices should have in place a detailed plan on how they are moving towards best practice in the provision of their decontamination processes.[1]

In Northern Ireland, the Department of Health, Social Services and Public Safety in Northern Ireland and SHTM 01-05 in Scotland, do not accept manual cleaning as a validated process, and practices must be working at best practice standards.[5,6]

Practices should have clear standard operating procedures for how they process the instruments and staff training is essential. The decontamination process should be audited every 6 months.

Segregation of instruments

There should be a clear procedure for the management of single use and re-usable instruments. Prior to cleaning, instruments that can be sterilised should be segregated from items that are to be disposed of. The image below shows the sign used to denote instruments that are single use. Instruments that are in packaging with this symbol **must not** be reprocessed and should be segregated and disposed of in clinical waste.

If you are unsure as to whether the item is single use you should seek advice from the manufacturer. It should be remembered that the symbol will appear on the packaging but not on the individual item. Single use items include, but are not limited to instruments such matrix bands, saliva ejectors, aspirator tips and 3 in 1 tips.[1]

HTM 01-05 states that endodontic reamers and files are designated as single patient or singe use. For singe patient use practices must have effective procedures in place

to exclude errors in identifying the instruments and associating them with the correct patient.

The Decontamination of Instruments

Once the instruments have been segregated, the decontamination of the instruments involves the following process:

- **Stage one** - Pre-sterilisation cleaning/washing
- **Stage two** - Sterilisation using a validated steam sterliser
- **Stage three** - Storage

Stage one- Pre-sterilisation Cleaning/washing

Effective cleaning of instruments before sterilisation is of the utmost importance to reduce the risk of transmission of infectious agents.[1] Manufacturers are required to provide instructions on how to decontaminate their instrument and these instructions should be adhered to. Some instruments may need to be dismantled prior to cleaning.[1] Before purchasing instruments it is recommended that consideration should be given to the methods of decontamination that are applied within the practice.[4] It is important that members of the dental team are adequately trained in all stages of the instrument decontamination process and that there are documented procedures in place.

Transportation of instruments to the decontamination area

Instruments should be transported to the decontamination room as soon as possible as instruments are easier to clean if they are decontaminated soon after use. Potable water immersion or the use of commercial gels or sprays may be considered if a delay in reprocessing is unavoidable.

All instruments on the working tray should be decontaminated even if they are not used on the patient. The dental professional should therefore consider carefully which instruments are placed on the instrument tray to reduce the number of instruments that need to go through the decontamination cycle.

The containers used to transport instruments should be designed in a way to protect both the instruments and the handler. Containers should be:

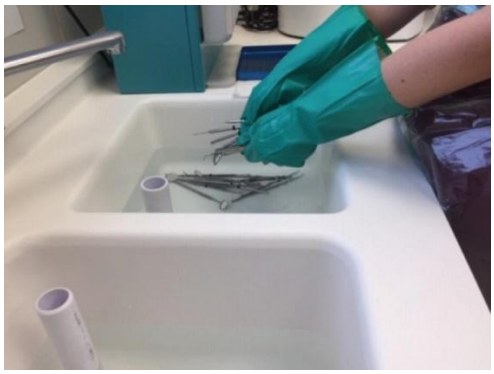
- Rigid
- Easy to clean
- Able to be closed securely (examples shown in images above)

The practice should have a policy for the safe transfer of instruments to the decontamination room [1].

The principal methods of cleaning reusable dental instruments are:

- Manual cleaning
- Manual combined with ultrasonic cleaning
- Cleaning with a washer disinfector

Manual cleaning



Although manual cleaning is acceptable when working under the essential quality requirements, under best practice recommendations, manual cleaning alone is only acceptable for those instruments that cannot be initially cleaned using an automated process.[1]

In order to achieve a validated cleaning/washing cycle, a washer disinfector must be used. In Northern Ireland and Scotland, manual cleaning following a written protocol, should be considered only where the manufacturer of the instrument specifies that the instrument is not compatible with automated processes or when the washer disinfector is temporarily unavailable (e.g., during service, validation, or repair).

When manual cleaning is necessary, the instruments should be immersed in water and detergent and scrubbed with a long-handled kitchen-type brush. Thick, waterproof household gloves, plastic disposable apron, and protective eye wear should be worn to protect against accidental injury and instruments should be inspected afterwards to validate the process.[4] Although the manual cleaning process is easier to set up, a disadvantage of the manual cleaning method is the increased risk of inoculation compared to other methods of cleaning. It is also difficult to validate the method as it is difficult to ensure that it is carried out effectively on every occasion[1].

Protocol for manual cleaning of instruments- immersion method

(This protocol is taken and adjusted from HTM 01-05[1])

All personnel involved in the decontamination of dental instruments should be trained in the content and application of this protocol and associated guidance.

To minimise the risk to personnel undertaking manual cleaning, the splashing and creation of aerosols should be avoided at all times.

Remember: Maintaining a dirty-clean workflow procedure will assist in the cleaning process.

- Wash hands (as specified in the hand hygiene policy. A full hand hygiene verifiable CPD article is available from the website).

- Wear Personal Protective Equipment (PPE) (as specified in the local infection control policy).

- Dismantle and open instruments as applicable, ready for immersion.

- Fill the clean sink (NOT the wash hand basin) with the appropriate amount of water and detergent (the detergent needs to be specified for purpose and the temperature of the water should be as recommended by the detergent manufacturer. This should be tested using a mercury-free thermometer and should be below 45^0C because a higher temperature will coagulate protein and inhibit its removal).

- Fully immerse the instruments in the solution (where manufacturer's instructions permit). The instruments should be kept under water during the cleaning process in order to prevent aerosols.

- Agitate/scrub the instruments using a long-handled brush with soft plastic bristles.

- Drain any excess cleaning solution prior to rinsing.

- Rinse in a second sink (or bowl), with satisfactory potable, distilled or RO water.

- After rinsing, drain and dry instruments if they are to be wrapped.

- Visually inspect all items under an illuminated magnifier ensuring that they are clean, functional and in good condition.

- Lubricate any relevant items prior to sterilisation. **Manufacturers guidance should be followed for care of handpieces and air/electric motors.**

- Dispose of cleaning materials safely and in accordance with local policy.

- Replace cleaning solution and the rinse water after each use.

1) <u>Ultrasonic cleaning</u>

Ultrasonic baths may be used to enhance the removal of debris and may be utilised as an optional part of the cleaning process before the instruments are placed in the washer-disinfector[1].

It is important that the ultrasonic bath is tested to manufacturer's instructions and that the water and fluid is maintained, cleaned, and changed as recommended. Cleaning instructions relating to each instrument should be followed as some instruments may need to be disassembled before being immersed in the ultrasonic bath solution. The instrument basket should not be overloaded.

2) Washer-disinfector

If working under best practice recommendations, the designated decontamination room will contain a washer-disinfector which should be used on all instruments that are able to be cleaned in this way. This is the preferred method of cleaning as it offers the best method of being able to control, reproduce and validate the cleaning process.

A typical disinfector cycle includes the following stages:

- Flush
- Wash
- Rinse
- Thermal disinfection
- Drying[1]

Washer-disinfectors must not be used as a substitute for sterilisation and the manufacturer's instructions must be followed. Staff should be appropriately trained in its use and the records of this should be maintained. Washer-disinfector logbooks and records should be kept by the operator and maintained for not less than two years [1].

In Scotland, dental decontamination records, including equipment and process records, should be held securely for the lifetime of the equipment plus 25 years afterwards.[6]

Stage two- Sterilisation

England, Wales, Scotland, and Northern Ireland all specify that, prior to sterilisation all instruments should be inspected to ensure that they are 'clean, functional and in good condition'. It is recommended that an illuminated magnifier is used to aid the process of inspection.

Whichever type of steriliser is used, the clinical parameters of them are the same. This is:

Temperature: Usually 134 to 137 ◦C.
Time: 3 minutes once 134 ◦C is reached.
Pressure: 2.2 bar.

The following sterilisers are used within health care:

Type N (fig.1 below) - Non-vacuum sterilisers designed for unwrapped, non-hollow and non-air retentive instruments. With this method of sterilisation, instruments are wrapped immediately **after** sterilisation after being dried with a disposable non-linting cloth. Instruments must **NOT** be wrapped prior to sterilising as the steam will not penetrate the bag.

Fig. 1 A type N steriliser

Air removal might be impeded if the instruments are overloaded and not loaded correctly. Therefore, instruments must be laid side to side on the tray and not overlapping. This is because the stream may not contact the surface of every instrument. Steam is essential for sterilisation to occur.

Type B (fig. 2 below) - Vacuum sterilisers used to process hollow, air-retentive and packaged loads, including handpieces. With this method instruments need to be dried with a disposable non-linting cloth **prior to wrapping**. Manufacturers prefer vacuum autoclaves to sterilise hand pieces as the steam can penetrate up through the lumen using the vacuum. However, HTM 01-05 has refrained from making this a regulation.

The cycle for a vacuum autoclave is considerably longer, due to the fact the machine has to generate a vacuum before and throughout the actual sterilisation cycle.

Fig 2: A type B steriliser

Type S (fig. 3 below) - Sterilisers designed to reprocess specific load types, which may include hand pieces.

Fig 3. A type S steriliser

The most frequently used sterilisers in dental practice are type N and type B.[1]

In all cases, it is important that the manufacturer's instructions are followed for the use and servicing of the steriliser used. The process should be validated, and records kept for not less than two years. If automatic records are not produced, then manual record keeping is required.[1] As previously mentioned, in Scotland, dental decontamination records, including equipment and process records, should be held securely for the lifetime of the equipment plus 25 years afterwards.[6]

The 2013 version of HTM 01-05 states that **"records are required for every sterilisation cycle".**[1]

Fig 3: Data logger

Every machine should have its own dedicated logbook. The daily tests should be completed by the operator or user and usually consist of:

A steam penetration test - Helix or Bowie Dick test (S & B vacuum only).

An automatic control test (all bench top sterilisers) in line with manufacturer's instructions. The use of automated data-loggers or interfaced computer-based recording systems is acceptable, but printouts should be photocopied as they may fade over time and the print-out should be retained or copied to a permanent record. If the steriliser does not have a printer, the user will have to manually record the following information in the process log:

- Date.
- Satisfactory completion of the cycle (absence of failure light).
- Temperature/pressure achieved.
- Signature of the operator.

If an error code occurs then this should be noted, along with the action you took and confirmation that the instruments in that cycle at that time were reprocessed. At the end of each day the reservoir should be emptied and cleaned. Door seals also need to be checked. If the surgery is not in use on a particular day you should record this on your log so that it does not appear that the log was simply not completed on that particular day.

Stage three - Storage

A re-processed dental instrument should be compliant with the Essential Requirements of the Medical Devices Regulations 2002[1,8].

This implies that the instrument should be:

- ✓ Clean and sterilised at the end of the decontamination process.

- ✓ Maintained in a clinically satisfactory condition up until the point of use.

Once sterilised, instruments need to be transported to the storage area on sterilised, covered trays. The instruments need to be stored in such a way to protect against the risk of becoming contaminated by pathogens and it is therefore recommended that there is a barrier between the instruments and the general practice environment. The instruments should be stored in a dry environment and protected from heat [1].

Unwrapped instruments in the clinical area may be stored for up to a day and HTM 01-05 states that unwrapped instruments in a non-clinical area may be stored for up to a week (the Wales Health Technical Memorandum 01-05 states that unwrapped instruments can be stored for a maximum of one day).

In Scotland, there are no set timescales and the conditions of how the instruments are stored is considered the most important factor. It is advised that the instruments are date labelled and that there is a system in place to ensure that instruments are rotated to ensure first in, first out.[6]

In England, HTM 01-05 advises that the sterilised instrument bag is date stamped with the date the instrument is due to be re processed (1 year from sterilisation).[1]

In Wales, WHTM 01-05 advises that the sterilised instrument bag is date stamped with the date the process took place (and should be re-processed after 1 year).[7]

Each instrument pack should be checked before use and should not be used if:

- The wrapping or seals are damaged.
- The pack is moist.
- The pack has labelling that is damaged or incorrect.
- The pack has a processor indicator that has not changed colour correctly (vacuum steriliser).

It is important that practices have well developed protocols and procedures in place to prevent contamination of these instruments by ensuring that those required for a particular patient are removed from their protected environment before treatment commences. In addition, practices will have a process in place to identify the date of reprocessing of wrapped instruments.

Best Practice

Although it is recognised that not all dental practices may be immediately in a position to adopt best practice recommendations, it is expected that each dental practice will assess the improvements required and demonstrate how they will move towards best practice recommendations. In addition to an infection control policy which will indicate compliance to essential quality requirements, dental practices must have a documented, clear plan as to how the dental practice is working towards best practice recommendations. This must be available for inspection as necessary.

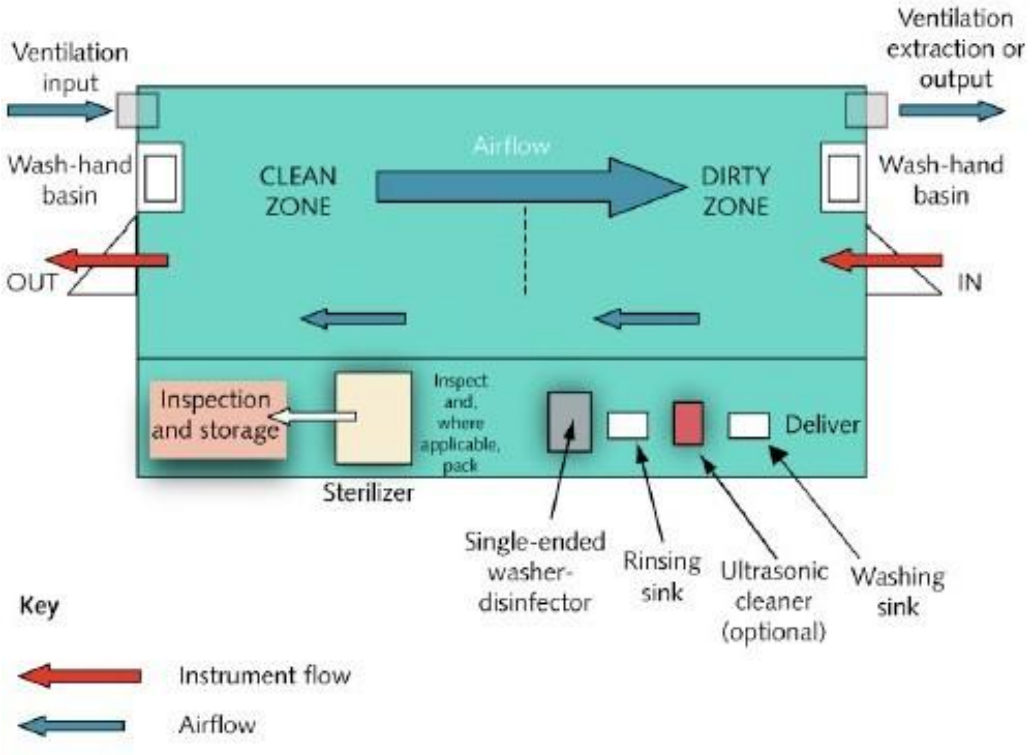
Best practice recommendations include:

- The use of an automated washer-disinfector.
- Decontamination facilities that are separate from clinical areas. This is ideally carried out in a separate room which has restricted access to only those staff trained to carry out the decontamination process.
- Appropriate storage of reprocessed instruments to prevent microbiological re-colonisation. This includes ensuring that storage dates are logged.[1]

Dental practices in Northern Ireland and Scotland are required to have separate decontamination room and washer disinfector. In Wales and England, this is required if the practice is to attain 'best practice' status.

Design of decontamination room

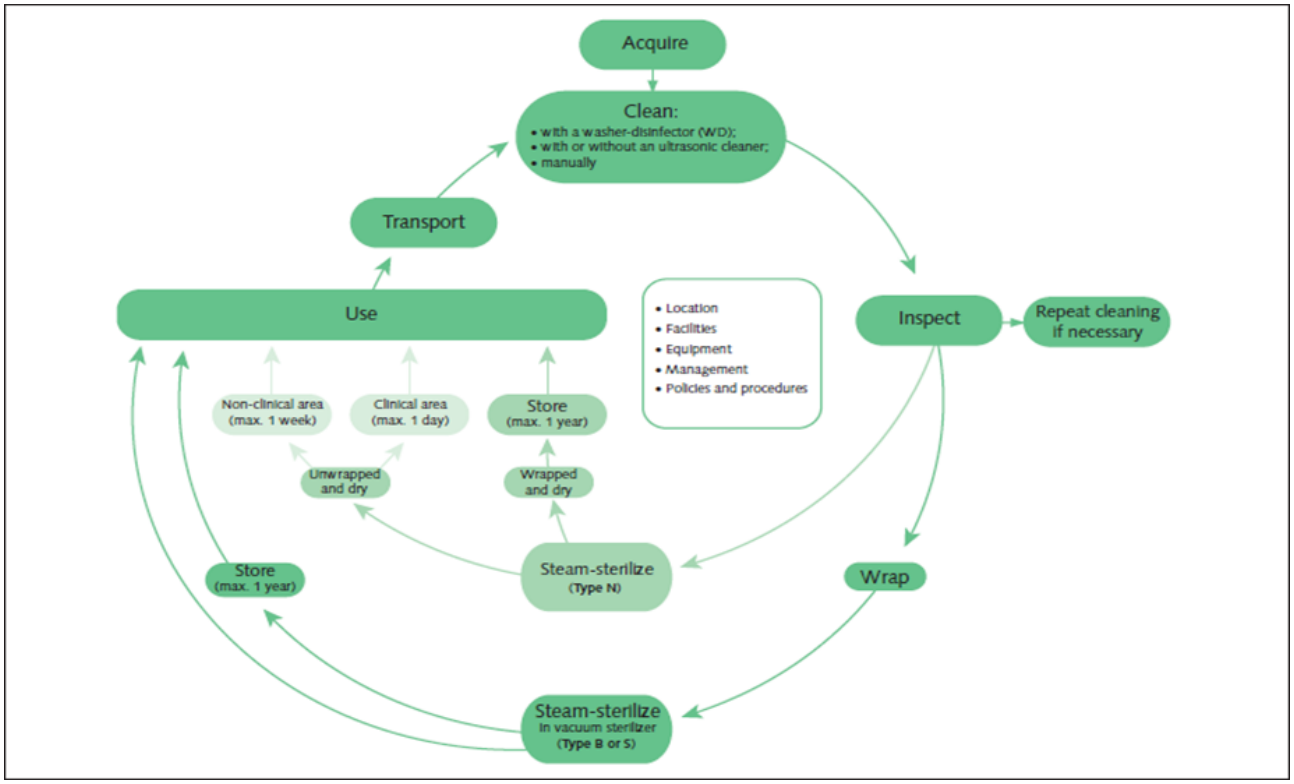
The image below shows a possible design for a single decontamination room. Ventilation should be considered as shown in the diagram.



Example diagram of a single decontamination room[1]

The Journey of instruments through the decontamination process

Throughout the decontamination process, a systematic approach should be followed. The following flow diagram shows a possible approach that could be taken.[4]



Conclusion

Patients reserve the right to be treated in a surgery environment that is clean and sterile[1]. Dental professionals need to ensure that instruments are decontaminated in a way that meets essential quality requirements as a minimum standard. As part of the registration with the CQC, dental practices need to demonstrate that they are working towards best practice recommendations contained within the HTM 01-05 document.

This article has described the process of decontaminating instruments using best practice recommendations. The process is discussed in more detail in the relevant documents below for England, Northern Ireland, Scotland, and Wales.

Personal Development Plan and Reflective Learning

This CPD is linked to the following GDC Enhanced CPD Development Outcome:

C. Maintenance and development of knowledge and skill within your field of practice. Reflective learning is now a requirement of the GDC Enhanced Professional Development Scheme. As such, you will now need to answer some reflective learning questions, before your certificate is generated. These will be:

1) What did you learn (or confirm) from the activity that was helpful or relevant to your daily work and patients?
2) Comment on any changes/updates needed in your daily work
3) How has completion of this CPD article benefitted your work as a DCP?

Examples will be provided. Please remember that you need to fill this in on completion of the exam but you can also update this at any time from your CPD log. If you take a few moments to write your reflection on completion, you will have fulfilled the Enhanced CPD requirements.

Further Reading

We recommend that you review the decontamination guidelines for your area of the UK

England: The Department of Health (2013) Health Technical Memorandum 01-05: Decontamination in primary dental care practice.

Northern Ireland : Northern Ireland Guidance on Decontamination in Primary Dental Care Practices (HTM 01-05 Amendments)

Wales: WHTM 01-05 (2014)

Scotland: SHTM 01-05 (2024)

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