

evidence | *note*

In response to an enquiry from the Scottish Dental Clinical Effectiveness Programme

Number 65 April 2017

Would the provision of benchtop vacuum sterilisers to dental practices in Scotland provide sufficient benefit in terms of increased patient safety to justify the financial outlay and ongoing revenue costs?

What is an evidence note

Evidence notes are rapid reviews of published secondary clinical and cost-effectiveness evidence on health technologies under consideration by decision makers within NHSScotland. They are intended to provide information quickly to support time-sensitive decisions. Information is available to the topic referrer within a 6 month period and the process of peer review and final publication of the associated advice is usually complete within 6-12 months. Evidence notes are not comprehensive systematic reviews. They are based on the best evidence that Healthcare Improvement Scotland could identify and retrieve within the time available. The reports are subject to peer review. Evidence notes do not make recommendations for NHSScotland, however the Scottish Health Technologies Group (SHTG) produce an Advice Statement to accompany all evidence reviews.

Key points

- Sterilisation of reusable dental instruments forms the final part of the decontamination process which includes cleaning, disinfection and drying.
- Most primary care dental practices in Scotland use non-vacuum benchtop steam sterilisers. These are not intended for sterilisation of instruments which are hollow or have a lumen.
- There is experimental evidence that dental handpieces are not reliably sterilised in non-vacuum sterilisers. The implications of this for patients' safety is unclear as there is an absence of surveillance data linking sterilisation, or any specific aspect of decontamination failure, directly to cross-contamination risk.
- Benchtop vacuum sterilisers cost more to purchase, maintain and run than non-vacuum sterilisers, have longer turnaround times and take up more space for a given capacity.

Literature search

A systematic search of the secondary literature was carried out between 29 September and 6 October 2016 to identify systematic reviews, health technology assessments and other evidence-based reports. Medline, Medline in process, Embase, Cinahl, and Web of Science databases were also searched for systematic reviews and meta-analyses.

The primary literature was systematically searched between 29 September and 6 October 2016 using the following databases: Medline, Medline in process, Embase, Cinahl and Web of Science. Results were limited to English language and 1996 onward.

Key websites were searched for guidelines, policy documents, clinical summaries, economic studies and ongoing trials. Websites of organisations related to this topic, for example the British Dental Association and the American Dental Association, were also searched.

Concepts used in all searches included: vacuum steriliser, type B steriliser, bench-top steriliser. A full list of resources searched and terms used are available on request.

Introduction

The effective decontamination of reusable medical devices is essential in reducing the risk of transmission of variant Creutzfeldt-Jakob Disease (vCJD) and a range of other infectious agents, including blood borne viruses¹.

Following cleaning and disinfection, sterilisation is a key step in the reprocessing of reusable dental instruments that have become contaminated, or are potentially contaminated with saliva, blood or other biological material. Sterilisation using a steam steriliser is the most efficient, cost-effective and safe method of sterilising dental instruments in primary care dental practices².

This evidence note updates a summary of evidence published in 2011³. The research question is whether the provision of benchtop vacuum sterilisers to dental practices in Scotland would provide sufficient benefit in terms of increased patient safety to justify the financial outlay and ongoing revenue costs. Literature reviews note the difficulties of evaluating the risk of cross-contamination within dentistry for patients, staff and others because there are no systematic records of events and acquired infections may not be reported. These reviews also note that contamination of the insides of equipment occurs and infectious agents may be expelled during subsequent use, where there has been inadequate sterilisation of dental instruments⁴⁻⁶.

In the absence of patient outcome data, the approach taken in this evidence note is to identify and examine evidence which compares the effectiveness of benchtop non-vacuum and vacuum steam sterilisation of reusable dental instruments using biological indicators (BI) as a surrogate outcome related to plausibility of cross-infection. BIs comprise live bacterial spores which are more difficult to kill than all the common disease producing microorganisms. Spores may be contained in a strip or vial, and following the sterilisation cycle, the BI is retrieved and cultured to determine if the spores were killed^{7,8}. (It should be noted that testing of steam sterilisers is generally carried out using chemical indicators or by assessment of thermometric parameters.)

Studies focusing specifically on other essential parameters of the decontamination process such as cleaning, disinfection, drying or storage of instruments were excluded as were studies examining sterilisation parameters associated with lubrication of mechanical devices.

The effect of steam sterilisation procedures on mechanical properties, efficiency or lifespan of dental instruments was outside the scope of this evidence note as were issues of validation and maintenance of sterilisers.

Health technology description

The UK implementation of the European standard (BS EN 13060) defines three classes of small steam sterilisers⁹. These are described in Table 1.

Type N and type B sterilisers are differentiated by the manner in which air is removed from the sterilisation chamber, air removal being essential to allow steam to contact the surfaces of the instruments.

Sterilisers that perform only type N cycles are the least complex to operate and maintain². Also termed bowl and instrument sterilisers, such machines are suitable for sterilisation of unwrapped, solid items. Following the sterilisation process, instruments are sterilised but do not remain sterile beyond the end of the sterilisation cycle. Type N cycles cannot assure sterilisation of hollow instruments or those with lumens.

Sterilisers which can deliver a type B cycle have the widest range of applications. Due to the use of a vacuum stage, this cycle can be used to produce sterile wrapped instruments and can process instruments which are hollow or which have lumens. Vacuum sterilisers are larger than non-vacuum sterilisers for a given capacity and instrument processing time is longer.

There are concerns over the use of type N cycles for dental handpieces. The Scottish Dental Clinical Effectiveness program (SDCEP) states:

“There is currently no agreed method for the effective decontamination of dental handpieces. Although the effectiveness of sterilisation of the internal structures is unclear, processing in a steriliser ensures that the external surfaces are sterilised and may also contribute to risk reduction through further thermal disinfection of the internal structures”².

Table 1: Benchtop steam steriliser cycles²

Class	Type of steriliser	Method
Type N Designed for non-wrapped solid instruments	Non-vacuum	Air removal achieved by passive displacement with steam
Type B Designed to reprocess load types such as hollow, air-retentive or wrapped/package loads	Vacuum	Incorporate a vacuum stage for air removal
Type S Designed to reprocess specific load types	Within the ‘S’ category there may be vacuum and non-vacuum devices depending on specific loads to be processed.	

Both type N and type B sterilisers are recorded on the NHSScotland National Procurement Framework NP143/13. This framework is due for re-tendering in 2017.

Type B sterilisers usually incorporate the potential to run a non-vacuum cycle meaning that unwrapped solid instruments can be processed as quickly as per type N, without having always to run the longer vacuum cycle. The Medical Devices Agency suggests that vacuum sterilisers *“should be equipped only with cycles for porous loads in order to minimise the possibility of an incorrect cycle being selected and consequent failure to sterilise the load”¹⁰.*

Health Facilities Scotland notes a similar risk issue associated with co-located vacuum and non-vacuum machines: *“Where different types of steriliser are in use within the LDU [local decontamination unit], appropriate staff training and clear identification of steriliser types are essential, to prevent device loads being processed through the wrong steriliser, resulting in failure of the sterilisation process”¹¹.*

Small type S vacuum sterilisers are available specifically for sterilisation of some dental handpieces. No devices in this class have yet been put forward by manufacturers to be considered and assessed for inclusion in the NHSScotland National Procurement Framework.

Sterilisation practice in Scotland

An observational study of the decontamination of reusable medical devices surveyed 184 dental practices across Scotland (179 providing information for analysis) and assessed, against current standards¹², the procedures presently used during the decontamination cycle in primary dental care in Scotland¹. Survey visits were conducted between January 2003 and March 2004. In 97% of the surgeries which provided information, dental handpieces were sterilised after use. In 88% of cases, the practices had type N sterilisers, whilst 11% had type B sterilisers. Deviation from current standards was identified in the use of N type sterilisers in that 28% of surgeries reported packaging instruments before sterilisation.

It is likely that sterilisation practice has changed considerably since this study was undertaken due to numerous initiatives which have been implemented to improve knowledge and adherence to best practice standards in instrument decontamination such as the Scottish Dental Clinical Effectiveness Programme.

The use of type N sterilisers to process reusable instruments which have hollow components, for example dental handpieces, is likely, in many cases, to be contrary to instructions issued by the instrument manufacturer and/or the benchtop steam steriliser manufacturer. Joint advice from the Chief Medical Officer and Chief Dental Officer for Scotland recommends ensuring that manufacturer instructions are followed¹³.

Similarly, the Health Facilities Scotland document on *Compliant Dental Local Decontamination Units in Scotland (Primary Care)*, published in 2013, notes that a technical requirement for local decontamination units is to have a decontamination process in accordance with the device manufacturer's instructions¹⁴.

Clinical effectiveness

The validity of studies on benchtop steam sterilisers may be limited by lack of information on the specification, validation and maintenance of machines.

Four studies were identified which compared the effectiveness of vacuum and non-vacuum steam sterilisation of reusable dental instruments using BI. Details of each study are summarised in Table 2.

The study most applicable to NHSScotland forms part of a Ph.D dissertation by Winter¹⁵. The study is being prepared for submission to a peer reviewed journal (S Winter, Research Assistant, Dental School, University of Glasgow, Personal Communication, and 7 October 2016). The effectiveness of seven non-vacuum and two vacuum benchtop steam sterilisers was studied in five different general dental practices. No information was provided on how the practices were selected and validation documentation for the sterilisers was not inspected. Three types of dental handpieces were used in the experiments and, the contaminant (*Bacillus stearothermophilus* on mini spore strips) was placed in different parts of the instruments. For the non-vacuum sterilisers, there were 34 BI fails out of a total of 360 valid tests (9%). Most fails were located in the chuck lever or the inside of the slow-speed motors. For the vacuum sterilisers, growth was detected from 1/108 (0.9%) of the biological indicators. The applicability of the findings to residual biological load in routine primary care practice is uncertain. The study author concludes that dental handpieces cannot be reliably sterilised in non-vacuum benchtop sterilisers commonly used in UK dental practices.

In an Iranian study published in 2013, Movahhed found that all spore strips of *Bacillus stearothermophilus* sited in dental turbines were inactivated by sterilisation both in small benchtop non-vacuum steam sterilisers and large vacuum sterilisers¹⁶. Two of each type of steriliser were tested with a total of 48

instruments. Authors suggest that the turbine chambers may not be the most challenging part of the load and that sterilisation of narrow water and air ducts be evaluated.

A study by Vickery on the sterilisation of dental syringes, after removal of all visible blood, found that duck hepatitis B could be transferred and cause infection in ducklings after high temperature short cycle sterilisation in 1/16 cases carried out in a non-vacuum steriliser compared with 0/24 in a hospital autoclave¹⁷. This provides evidence of infectious material surviving the non-vacuum sterilisation cycle. The applicability of the hospital autoclave results to benchtop vacuum sterilisers is not known.

In the study by Andersen, non-vacuum sterilisation was as effective as vacuum sterilisation as measured by inactivation of *Streptococcus salivarius* where cleaning and lubrication of high-speed dental turbines was conducted prior to sterilisation¹⁸. Although selected to be typical of the oral flora, the low heat resistance of the contaminant organism limits the generalisability of the outcome. In the same report, heat resistant spores of *Bacillus stearothermophilus* provided a robust indicator and growth was observed from 13 out of 48 (27%) cases of turbines subjected to non-vacuum sterilisation compared with 0/10 turbines undergoing vacuum procedure. The turbines were wrapped in all procedures which may have resulted in false positives for the non-vacuum test. It is unclear if the vacuum steriliser was a large hospital-type machine or suitable for benchtop use. The study was designed to detect limitations of small non-vacuum autoclaves.

Table 2: Studies comparing the effectiveness of vacuum and non-vacuum steam sterilisation of reusable dental instruments using biological indicators

Study	Type of dental instrument	Contaminant	Sterilisation interventions	Outcome assessment	Findings
Winter 2016 ¹⁵ (Ph.D dissertation)	Dental handpieces – three types – turbine, surgical, slow speed Handpieces used were new and were only used for one treatment before assessment	Biological indicator mini spore strips (2.2×10^5 of <i>Bacillus stearothermophilus</i>) placed in three positions in the turbine (turbine head, drive air channel center, drive air channel back), in two positions in the surgical handpiece (chuck lever, handpiece back) and in one position in the slow speed (inside sleeve)	Compared 7 non-vacuum bench top steam sterilisers and 2 vacuum bench top steam sterilisers in Scottish general dental practices. Handpieces for vacuum sterilisation were placed in sealable sterilisation pouches (Steris) before sterilisation Non-vacuum cycle times 16 – 25 min, with plateau periods of 3.5-4.5 min at 134°C Vacuum cycle times 60 - 70 min, with a holding time of 4-4.5 min at 134°C	Growth of <i>Bacillus stearothermophilus</i> In 2ml of tryptic soy broth with incubation for up to 8 days at 56 °C	A total of 34 biological indicator fails were detected out of a total of 360 valid tests (9%). Most fails were located in the chuck lever or the inside of the slow-speed motors. Three of the non-vacuum sterilisers were associated with 1/54 BI fail each, in each instance location was the chuck lever. The number of fails in the remaining sterilisers ranged from 3/54 to 11/54 Growth was detected in one out of 108 (0.9%) biological indicators used in the handpieces processed in two vacuum sterilisers

Movahhed 2013 ¹⁶	Dental turbines	Biological indicator strip (2.2 x 10 ⁵ of <i>Bacillus stearothermophilus</i>)	<p>Non-vacuum small steam steriliser x2 (n=24) Large vacuum steriliser x2 (n=24)</p> <p>Sterilization process was performed according to the manufacturer's instructions</p> <p>Control strips in each steriliser (n=4)</p>	Positive cell culture assessed colorimetrically	<p>For both steriliser types, results of cell culture were negative in all cases</p> <p>All control strips were positive</p>
Vickery 2000 ¹⁷	Auto aspirating cartridge dental syringes	Duck hepatitis B virus contaminated blood	<p>Control = washing to remove all visible blood (n=8)</p> <p>Washing followed by 121 °C at 103.4KPa for 15 minutes then 20 minute drying time (n=24)[hospital autoclave – [cycle type not provided]</p> <p>Washing followed by 134°C at 200KPa for 3 minutes holding time then 20 minute drying time in downward displacement autoclave (n=16)</p>	Infection of day-old ducklings as confirmed by DNA extraction and analysis of liver tissue at 2.5 weeks of age	<p>Control failure rate 100% (n=8)</p> <p>Hospital autoclave failure rate 0% (n=0/24)</p> <p>High temperature short cycle autoclave failure rate 6.25% (n=1/16)</p>

Andersen 1999 ¹⁸	High-speed dental turbines	Contamination of turbine wheels with <i>Streptococcus salivarius</i> culture	<p>Sterilisation in four different small non-vacuum autoclaves (n=24 following cleaning and lubrication, n=24 without prior cleaning and lubrication)</p> <p>Sterilisation in one vacuum autoclave, following cleaning and lubrication (n=6)</p>	Bacterial growth from fluid into which the turbine wheel was transferred post sterilisation procedure	Where cleaning and lubricating were conducted there was no bacterial growth related to any of the autoclaves tested
	High-speed dental turbines	Cotton carrier inoculated with spores of <i>Bacillus stearothermophilus</i>	<p>Sterilisation in four different small non-vacuum autoclaves (n=48)</p> <p>Sterilisation in one vacuum autoclave, (n=10)</p> <p>Each autoclave was operated at 121°C for 15 to 20 minutes</p>	Growth from aerobic culture of cotton carrier – number of observations with growth	<p>Growth observed from 13/48 of the turbines which had been subjected to the non-vacuum procedure compared with 0/10 of the devices undergoing the vacuum procedure. Failures ranged from 1 to 6 per machine</p> <p>All of the handpieces were autoclaved in autoclaving bags which may have led to false positive results for the non-vacuum machines</p>

Safety

No evidence was identified relating to safety around the use of benchtop steam sterilisers.

No incidents attributable to benchtop sterilisers as used in dental practices have been recorded by the Incident Reporting & Investigation Centre (IRIC) database since August 2014 (C Campbell, IRIC. Personal Communication, 20 Dec 2016).

Cost effectiveness

No cost-effectiveness analyses were identified. In order to undertake cost-effectiveness analyses, data are required to link the impact of the intervention to relevant outcomes or health effects. There are currently no baseline data relating to cross-infections caused in UK primary care dental practices, so it is not possible to conduct a robust cost-effectiveness assessment of infection control interventions⁶.

A comparison of some of the costs related to type B and type N sterilisers is outlined in Table 3 (K Lindsay, Commodity Manager, NHS National Procurement, Personal Communication, 27 October 2016). Manufacturers' instructions for running, checking and maintaining sterilisers differ widely so it is challenging to accurately compare costs. Vacuum sterilisers are more expensive both to purchase and to run.

Table 3: Cost of benchtop sterilisers, data from NHS National Procurement Framework NP143/13

Vacuum steriliser – type B		Non-vacuum steriliser – type N	
16/17L capacity	22L capacity	17L capacity	22L capacity
purchase cost		purchase cost	
£3,500-£4,810	£4,750-£5,300	£2,500	£2,700-£2,995
Installation /commissioning /initial validation		Installation /commissioning /initial validation	
£800	£800	£325	£325
Annual cost (maintenance + revalidation)		Annual cost (maintenance + revalidation)	
£1050	£798-£1050	£504	£504
Cost per cycle		Cost per cycle	
£0.22-£0.29	£0.22-£0.29	£0.15	£0.15-£0.17
Additional requirements		Additional requirements	
Printer rolls Chemical indicator tests Pressure vessel insurance Daily steam penetration tests** Potential requirement for more instruments due to longer turnaround time		Printer rolls Chemical indicator tests Pressure vessel insurance	
** Tests are available via NP 187/15 Helix test £77.50 for 25, Bowie Dick test strips £29.50 for 20 (K Lindsay, Commodity Manager, NHS National Procurement, Personal Communication, 1 November 2016)			

Conclusion

It is not clear, from the information available, whether the provision of benchtop vacuum sterilisers to dental practices in Scotland would provide sufficient benefit in terms of increased patient safety to justify the financial outlay and ongoing revenue costs.

Local decontamination units in Scottish primary care dental practices use primarily non-vacuum steam sterilisers as part of the decontamination process for reusable dental instruments. These devices are not designed to sterilise instruments which have hollow components such as dental handpieces. Adherence to regulations is compromised where instructions set out by device manufacturers are not followed.

Although it is not possible to link sterilisation failure directly to patient safety outcomes, there is experimental evidence that dental handpieces are not reliably sterilised using non-vacuum sterilisers.

Whilst vacuum sterilisers offer the advantage of delivering wrapped instruments sterile at the point of use, their provision presents challenges around sterilisation capacity and instrument turnaround time, as well as processing cost.

Equality and diversity

Healthcare Improvement Scotland is committed to equality and diversity in respect of the nine equality groups defined by age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion, sex, and sexual orientation.

The process for producing evidence notes has been assessed and no adverse impact across any of these groups is expected. The completed equality and diversity checklist is available on www.healthcareimprovementscotland.org

About evidence notes

This evidence note will be considered for review 2 years post-publication, and at 2-yearly intervals thereafter. For further information about the evidence note process see http://www.healthcareimprovementscotland.org/our_work/clinical_cost_effectiveness/shtg/standard_operating_procedures.aspx

To propose a topic for an evidence note, email shtg.hcis@nhs.net

References can be accessed via the internet (where addresses are provided), via the NHS Knowledge Network <http://www.knowledge.scot.nhs.uk>, or by contacting your local library and information service.

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Healthcare Improvement Scotland development team:

- Lorna Thompson, Health Services Researcher
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- Members of the SHTG evidence review committee

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