SURVEY OF DECONTAMINATION IN GENERAL DENTAL PRACTICE

CONTENTS

Executive Summary

1. Introduction and Background
   1.1 Introduction
   1.2 Primary dental care services in Scotland
   1.3 Decontamination practice
   1.4 Decontamination in primary dental care in Scotland
   1.5 Decontamination in other primary care settings

2. Review of current decontamination practice in general dental practice
   2.1 Objectives
   2.2 Methodology

3. Results
   3.1 Accuracy of general dental practitioner database
   3.2 Response rate
   3.3 Practice facilities and patient throughput
   3.4 Treatment performed
   3.5 Surgery design
   3.6 Management of decontamination
   3.7 Awareness of guidelines and sources of assistance
   3.8 Procurement of re-usable devices
   3.9 Instrument cleaning
   3.10 Instrument inspection
   3.11 Packaging prior to sterilization
   3.12 Instrument sterilization
   3.13 Packaging after sterilization
   3.14 Storage after sterilization
   3.15 Traceability
   3.16 Training
4. Discussion
   4.1 Methodology
   4.2 Results

5. Conclusions and Recommendations
   5.1 Conclusions
   5.2 Recommendations

6. Acknowledgements

Appendices
I. Authors

II. AD$^3$ Forms

III. References and technical documentation

IV. List of surveyors and other contributors
EXECUTIVE SUMMARY

Following the discovery in the UK in the 1990’s of variant CJD (vCJD), much work has been done to reduce the potential risk of person-to-person transmission of vCJD via re-usable surgical instruments that have been inadequately decontaminated. The Glennie Group (tasked with reviewing and upgrading NHSScotland sterile services provision) was formed as a result of the recommendations contained in the Old Report (2001), and produced the Glennie Framework in 2001. Whilst dental procedures are categorised as low risk for vCJD transmission, there remains a risk for transmission of bloodborne viruses (e.g. HIV, hepatitis B and C) and other bacterial, viral and fungal infections.

It is estimated that in excess of 180 million instruments are re-processed in Scottish general dental practice per annum. This volume of material represents a substantial component of the instrumentation reprocessed within the NHS, for which only scanty technical data were available. Information was required to inform the Scottish Executive Health Department as it develops a framework for change to reduce the potential risks associated with decontamination of re-usable instruments in primary care. In order to provide a more robust evidence base of current decontamination practices within the general dental services of Scotland, a large-scale observational study was designed. This has now been completed, and represents the largest survey of decontamination ever to have been undertaken in general dental practice, incorporating actual visits to individual premises to view decontamination processes. This report describes the findings from surveys of 179 practices.

The results bear a striking resemblance to those from the central sterile service departments and acute sectors published previously. Central to these has been the observation of highly motivated staff attempting, often unsuccessfully, to comply with current infection control guidelines. The survey has highlighted that the cleaning of instruments has several shortcomings and is poorly controlled. This problem is compounded by the lack of clear instructions from manufacturers/suppliers on appropriate methods for the reprocessing of many dental devices. The findings of this study are relevant to the rest of the UK.
In conclusion, the key areas identified to maximise improvements in decontamination within dental practice and to further reduce risks associated with potential onward transmission of vCJD and other pathogens are:

• Advice and training pertinent to instrument cleaning protocols.

• Access to policies and procedures, such as SHTM 2010, presented in a meaningful and relevant manner.

• Guidance on formal instrument procurement procedures.

• Guidance on surgery design, layout and separation of clinical from decontamination areas.

• Guidance on commissioning, testing and maintenance of cleaning and sterilizing equipment.

• A re-appraisal of the role of regulatory bodies overseeing the compliance of instrument manufacturers/suppliers and equipment testing and maintenance subcontractors with appropriate decontamination regulations.

• Provision of appropriate documentation from suppliers, service and maintenance agents for decontamination equipment.

• Revision of existing dental practice inspections.
SECTION 1  INTRODUCTION AND BACKGROUND

1.1  Introduction

Following the discovery of a new form of CJD, variant CJD (vCJD), in the UK during the 1990’s there is a potential risk of person-to-person transmission of this disease via re-usable surgical instruments that have been inadequately decontaminated\textsuperscript{1-6}. Decontamination is the combination of processes (including washing, disinfection and sterilization) employed to make re-usable items safe for handling by users and for use on patients. The effective decontamination of re-usable medical and dental devices is essential in reducing the risk of transmission of vCJD and a range of other infectious agents, including blood borne viruses.

This report forms one of a series of documents by a Group led by John Glennie (the ‘Glennie Group’) that has undertaken a review of sterile service provision across NHSScotland. The Group’s initial remit was:

a. to identify the nature and scope of current sterile service provision in NHSScotland (‘sterile services’ are defined as those services that reprocess invasive medical devices for reuse through decontamination);

b. to develop a framework for change with specific regard to achieving the required technical and operational standards in the most cost-effective way possible; and

c. to identify the means of achieving change.

Initial work by the Glennie Group focused on activities which carried a high level of risk relative to vCJD\textsuperscript{7}. This work has revolved around centralised sterile service departments (CSSD’s), all locally processed acute sector activity and minor procedures by general medical practitioners. Concerns about the transmission of vCJD via surgical procedures provided the initial stimulus for the review of decontamination facilities. However, the high level of healthcare associated infections and potential microbiological hazards to staff are also of significance. Obtaining data on cross-infection in primary care facilities is difficult due to the lack of surveillance data. However, there are a number of incidents of transmission of infectious agents in dental practice, for example hepatitis B\textsuperscript{8-14} and more recently
Methicillin Resistant *Staphylococcus aureus* (MRSA)\(^{15}\), which highlight the potential for cross-infection if practice is poor.

### 1.2 Primary dental care services in Scotland

Primary care dental services in Scotland are provided under both NHS and private arrangements, with many individual courses of treatment encompassing both private and NHS treatment. Many dentists offer NHS and private services independently and some under contract to a Dental Body Corporate (company). General dental services may also be provided within a salaried framework under the management of an NHS Board.

Dental practices in Scotland offering any NHS services are subject to inspection under a national practice inspection scheme. In practical terms, such practices commonly offer both private and NHS care. Dental Bodies Corporate are subject to limited regulation by the General Dental Council and those offering NHS dental services will be subject to inspection under the practice inspection scheme. Wholly private dental practices are not currently subject to inspection. However, in Scotland, draft primary care dental standards have been developed jointly by the National Care Standards Committee and NHS Quality Improvement Scotland which cover both private and NHS dental services, including those delivered wholly privately.

### 1.3 Decontamination practice

The aim of decontamination is to make re-usable medical devices safe for use on a patient and for staff to handle without presenting an infection hazard.

The processes involved in decontamination are described using the model, developed by NHS Estates, of the “life-cycle” of re-usable surgical instruments (Figure 1).
To undertake decontamination effectively requires correct implementation of all the processes illustrated in the life cycle, with appropriate controls and monitoring in place. Achieving minimum standards at each stage of the life-cycle depends on location; facilities available; equipment used; how the process is managed, and the policies and procedures employed. The basic requirements for good decontamination practice are summarised in Table 1.

### Table 1

<table>
<thead>
<tr>
<th>Basic requirements for good decontamination practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>An effective management control system is in place covering all aspects of the decontamination cycle.</td>
</tr>
<tr>
<td>Appropriate facilities are provided.</td>
</tr>
<tr>
<td>Appropriate equipment is utilised which is:</td>
</tr>
<tr>
<td>Fit for purpose,</td>
</tr>
<tr>
<td>Properly maintained and calibrated,</td>
</tr>
<tr>
<td>Properly monitored and validated.</td>
</tr>
<tr>
<td>Staff are properly trained and supervised.</td>
</tr>
<tr>
<td>Single use medical devices are not reused.</td>
</tr>
<tr>
<td>Records of decontamination are kept.</td>
</tr>
</tbody>
</table>
Guidance and specific requirements relating to decontamination practice have been published over many years. As a general principle, guidance documents, such as SHTM 2010, allow users to fulfil their legal obligations if implemented fully. There are a number of legal imperatives to ensure appropriate facilities and management processes are in place at all sites undertaking decontamination of re-usable devices. The majority of the legislation that encompasses the decontamination of medical devices is enshrined within legal documents applicable to the whole of the European Union. Examples of these documents include:

*The Consumer Protection Act (European Community Directive no. 85/37/374/EEC)*: In particular product liability, has implications for the reprocessing of devices used for patient care. It is essential to maintain adequate records that demonstrate how a particular device was processed and a description of the methods employed.

*The Medical Devices Directive (93/42/EEC) – Implemented within the UK as the Medical Devices Regulations 2002*: The European directives for medical devices were devised as part of the programme to create a single European market with the objective of enabling the free movement of goods by the removal of trade barriers. The health and safety of citizens is the responsibility of each European Union Member State. In order to allow free movement of goods the directives specify the essential requirements to be met by devices before they can be placed on the market. The CE mark means that the manufacturer is satisfied that his product complies with the essential requirements of the Medical Device Directive (MDD). The responsibility for ensuring a device complies with the requirements of the Directive falls directly on the manufacturer of that device. Manufacturers are required by the Medical Devices regulations to supply information to the user “on the appropriate processes to allow re-use, including cleaning, disinfection, packaging and where appropriate, the method of sterilisation of the device and any restriction on the number of re-uses”. The MDD also applies to devices such as benchtop steam sterilizers and washer/disinfectors.
The Health and Safety at Work etc Act 1974; Management of Health and Safety at Work Regulations 1992: Regulations enacted under this act specify the detailed requirements for ensuring Health and Safety at Work. Examples include many of the requirements for employers to ensure the health, safety and welfare at work of all their employees and others who might enter the work place, such as patients, “so far as is reasonably practical”. Specifically, employers must ensure that the work place is safe and does not pose a risk to health and that materials used do not pose a risk to health (there are additional requirements under Control Of Substances Hazardous to Health Regulations, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations. It is also incumbent that all the necessary information, instruction, training and supervision is provided. The 1992 regulations place emphasis on sound safety management and require a risk assessment to be carried out and appropriate measures taken to reduce risk.

General Dental Council Maintaining Standards, Guidance to Dentists on Professional and Personal Conduct: “There has always existed the risk of cross-infection in dental treatment. Therefore, a dentist has a duty to take appropriate precautions to protect patients and other members of the dental team from that risk. Detailed guidance on cross-infection control has been issued by the Health Departments and the British Dental Association, and is endorsed by the Council. Failure to employ adequate methods of cross-infection control would almost certainly render a dentist liable to a charge of serious professional misconduct.”

1.4 Decontamination in primary dental care in Scotland

Initial estimates of the quantity of instruments re-processed in Scottish general dental practice suggested numbers in excess of 180 million items per annum\(^7\). This volume of material represents a substantial component of the instrumentation reprocessed within the NHS, for which only scanty technical data were available. Previous studies of decontamination practice in primary dental care have either been questionnaire-based\(^16\) or limited in number, using data collection forms that were not designed specifically for dental practices, for example reviews of 15 sites in England\(^17\) and 5 sites in Scotland\(^5\). In order to provide a more robust evidence base
of current decontamination practices within the general dental services of Scotland, a large-scale observational study was designed. This has been the largest survey of decontamination ever to be undertaken in general dental practice, incorporating actual visits to individual premises to view processes. This study was limited to examining the decontamination of re-usable medical devices in general dental practice. Other infection control procedures, such as hand washing, were not reviewed.

1.5 Decontamination in other primary care settings
It is envisaged that the results from this study will also be applicable to other healthcare professionals in the primary care Independent sector, that undertake local reprocessing of devices. These include podiatry and general medical service.
SECTION 2  REVIEW OF CURRENT DECONTAMINATION PRACTICE IN GENERAL DENTAL PRACTICE

2.1 Objectives
The objectives of this survey were:

- to develop a process assessment tool for decontamination procedures used in general dental practice;
- to assess, against current standards, the procedures presently used during the decontamination cycle in primary dental care in Scotland. This encompasses all the components involved in the decontamination cycle, including the physical environment, equipment, management processes, knowledge and training undergone by the dental team; and
- to provide an evidence base for the development of future measures to ensure compliance with recognised decontamination procedures in primary dental care.

2.2 Methodology

2.2.1 Study population, sample size determination and selection of surgeries

Determination of number of sites for review
The study population comprised all general dental practitioners in Scotland with an NHS list number. Details of the number of practices in Scotland offering NHS services were obtained from NHS National Services Scotland, Practitioner Services, previously known as the Dental Practice Division of the Common Services Agency. Data generated during the inspection of the twenty dental practices reviewed as part of the original NHS Estates Decontamination Review and the Scottish audit indicated that the majority of the practices had scope for considerable improvement in their instrument decontamination processes. This information was used to determine the number of practices required to be surveyed to validate these initial findings. Assuming an expected, conservative, percentage of 75% of practices requiring improvement in the decontamination process, then from the finite population of 837 dental practices in Scotland a target sample size of 215 and a minimum of 175 surgeries was set. A target of 215 would allow the estimation of the percentage of practices requiring improvement in the decontamination process (with
a corresponding two sided 95% confidence interval) to within ± 5%. A minimum of 175 practices would allow estimation to within ± 6%.

Selection of surgeries for surveying
A list of dental practitioners and dental practices for Scotland was obtained from the NHS National Services Scotland, Practitioner Services (previously the Dental Practice Division of the Common Services Agency). This list was the basis for randomly selecting practitioners to survey.

A two-stage process was used to identify which surgeries were to be surveyed, using a proportional stratified random sampling method. First, practices were randomly selected in proportion to the distribution of practices within each of the health boards. Then, if there were more than one dentist within a selected practice, simple random sampling was used to identify a single dentist within the selected practice to be approached. The surgery that the dentist worked from and its associated decontamination facilities were the subject of the survey.

2.2.2 Liaison and support within the dental profession
Prior to implementation of the study protocol, the project group liaised closely with representatives from the dental profession, which included the Scottish Branch of the British Dental Association, regional general dental practitioner sub-committees and local dental committees.

2.2.3 Funding
Following a review of the study methodology by the Chief Scientist’s Office (CSO) for Scotland, the study was funded by the Scottish Executive Health Department. Additional financial resources were provided by the Chief Dental Officer for Scotland and the Dental Postgraduate Dean at NHS Education for Scotland. Dental practitioners were reimbursed at the Dental Guild rate for participating in the survey.

2.2.4 Survey method
The survey was a joint project between the Infection Research Group at Glasgow Dental School and the Scottish Centre for Infection and Environmental Health
(SCIEH). A project co-ordinator was appointed to oversee the running of the site surveys. Technical consultation from SCIEH provided consistent interpretation in the assessment of the decontamination standards.

Development of the data acquisition tool

The data collection forms provided questions designed to investigate compliance with extant guidance documents on decontamination, for example the BDA Advice Sheet A12 and the Glennie Technical Requirements. The data collection forms were designed on Cardiff Teleforms to permit automatic data recognition. The refinement of the data acquisition tool and corresponding guidance notes took place over several months and involved 17 pilot visits to dental surgeries. A set of 28 standardised reporting forms, referred to as AD$^3$ (automatic data acquisition documentation for assessment of decontamination), was developed to ensure a consistent approach to the data collection. The subject areas that each form covered are summarised in Appendix II.

Training of survey teams

Training of the survey team members was undertaken over three days in May 2002. The training provided an overview of decontamination guidance designed to ensure a common standard of interpretation.

Data collection

Each surgery survey was undertaken by a team of surveyors. This team comprised one infection control/decontamination expert and one experienced dental practitioner. On the morning or afternoon of the visit, the surgery was closed to patients. The survey team interviewed the dental practitioner and surgery nurse, reviewed documentation relevant to the survey and recorded the physical layout of the premises. The decontamination processes undertaken by the surgery nurse were viewed directly by a member of the survey team. All relevant data were recorded on the AD$^3$ forms. The survey visits ran from January 2003 until the end of March 2004.
Data quality, entry and analysis

All returned forms were submitted to an initial visual quality check, to ensure compliance with the instructions for surveyors contained within the guidance notes. The completed AD³ forms were scanned using an electronic scanner and downloaded to a database using a software package called Cardiff Teleforms. The forms were designed with internal verification, including a serial number on each form, multiple selection boxes, mandatory responses and range values. These checks were run automatically once the forms were scanned. In addition, the responses to a number of critical questions were required to be checked on screen. Forms could be flagged for validation when the verifier was unsure of the surveyor’s entry. Once the form had been reviewed, the data were then committed to a Standard Query Language (SQL) Server 2000 database. The practice location information was held separately from the main data to ensure secure data protection.

Data were exported from the database into Minitab (version 13) for analysis. Data analysis comprised both tabulated and descriptive statistics.

2.2.5 Technical requirements and guidance

The findings of the survey were assessed against published technical requirements and guidelines. These are summarised under “key indicators of good practice” in the text and are based on principal references contained in Appendix III, including the BDA Advice Sheet A12 and the recommendations of NHSScotland: Sterile services provision review group: 1st Report.
SECTION 3 RESULTS

3.1 Accuracy of general dental practitioner database

An initial review of the list of general dental practitioners provided by NHS National Services Scotland, Practitioner Services (previously known as the Dental Practice Division of the Common Services Agency) revealed many inaccuracies. For example, of the initial 50 dental practitioners approached to participate, the replies from 17% claimed that the dentist had retired or no longer worked at that practice. For just under 40% of 373 dentists selected from the original list, that dentist was no longer at the practice or the practice was no longer at the given address.

3.2 Response rate

In order to recruit the 184 dentists who agreed to participate, 373 dentists’ names (from the 837 dental practices in Scotland) were selected from the original list and endeavours made to contact these dentists. Where the named dentist had moved or been replaced their named replacement was invited to participate. Seventy five of those who participated were alternatives selected in this manner.

One hundred and eighty nine practitioners either declined to participate or could not be contacted at the address supplied. Of those who declined, 102 gave reasons for non-participation. Twenty seven percent gave the reason as being a single-handed practitioner, 25% were too busy and 7% did not believe that the financial compensation for the surgery downtime was sufficient.

From the 184 surgery visits, data were available for analysis from 179 sites. Data from 5 sites were rejected because of illegibility (3) and incomplete data (2).

A summary of numbers of practices approached, participation rates and geographical coverage is provided in Table 2.
<table>
<thead>
<tr>
<th>Health Board*</th>
<th>Number of Practices</th>
<th>Target Number of Practices to be Surveyed</th>
<th>Number of Practices Selected to be Approached to Participate</th>
<th>Number of Practices Surveyed</th>
<th>Number of Practices with Available Data</th>
<th>% of Practices with Available Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argyll &amp; Clyde</td>
<td>66</td>
<td>17</td>
<td>29</td>
<td>14</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Ayrshire &amp; Arran</td>
<td>59</td>
<td>15</td>
<td>23</td>
<td>15</td>
<td>15</td>
<td>25</td>
</tr>
<tr>
<td>Borders</td>
<td>15</td>
<td>4</td>
<td>6</td>
<td>4</td>
<td>4</td>
<td>27</td>
</tr>
<tr>
<td>Dumfries &amp; Galloway</td>
<td>24</td>
<td>6</td>
<td>19</td>
<td>4</td>
<td>4</td>
<td>17</td>
</tr>
<tr>
<td>Fife</td>
<td>52</td>
<td>13</td>
<td>24</td>
<td>8</td>
<td>8</td>
<td>15</td>
</tr>
<tr>
<td>Forth Valley</td>
<td>41</td>
<td>11</td>
<td>18</td>
<td>9</td>
<td>6</td>
<td>15</td>
</tr>
<tr>
<td>Grampian</td>
<td>56</td>
<td>14</td>
<td>18</td>
<td>14</td>
<td>13</td>
<td>23</td>
</tr>
<tr>
<td>Greater Glasgow</td>
<td>181</td>
<td>46</td>
<td>82</td>
<td>45</td>
<td>45</td>
<td>25</td>
</tr>
<tr>
<td>Highland</td>
<td>34</td>
<td>9</td>
<td>13</td>
<td>6</td>
<td>6</td>
<td>18</td>
</tr>
<tr>
<td>Lanarkshire</td>
<td>76</td>
<td>20</td>
<td>40</td>
<td>15</td>
<td>15</td>
<td>20</td>
</tr>
<tr>
<td>Lothian</td>
<td>153</td>
<td>39</td>
<td>67</td>
<td>34</td>
<td>34</td>
<td>22</td>
</tr>
<tr>
<td>Orkney</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Shetland</td>
<td>3</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>33</td>
</tr>
<tr>
<td>Tayside</td>
<td>73</td>
<td>19</td>
<td>31</td>
<td>13</td>
<td>12</td>
<td>16</td>
</tr>
<tr>
<td>Western Isles</td>
<td>2</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>50</td>
</tr>
<tr>
<td>Total</td>
<td>837</td>
<td>215</td>
<td>373</td>
<td>184</td>
<td>179</td>
<td>21</td>
</tr>
</tbody>
</table>

* All health board areas in Scotland were included.
3.3 Practice facilities and patient throughput

3.3.1 Practice premises

One of the challenges facing many dental practices is the use of premises that have not been purpose built as a health care facility. This requires the provision of appropriate facilities for the surgery, waiting area, staff rooms and decontamination areas. The types of premises in which the practices were located are shown in Figure 2.

Figure 2. Type of dental practice premises

Of these practices 9% shared facilities with other healthcare providers. This included medical practitioners, podiatrists and an osteopath.

Further details relating to the practices visited are shown in Table 3.

Table 3 Practice facilities

<table>
<thead>
<tr>
<th>Practice facilities</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of rooms in practice</td>
<td>8</td>
<td>2-21</td>
</tr>
<tr>
<td>Number of surgeries in practice</td>
<td>3</td>
<td>1-6</td>
</tr>
<tr>
<td>Number of dental chairs in practice</td>
<td>3</td>
<td>1-8</td>
</tr>
</tbody>
</table>
3.3.2 Staff levels
In 25% of the sites surveyed there was only one general dental practitioner (GDP) in the practice (i.e. a single-handed practice). The staffing at each of the premises surveyed was analysed at the practice level and at the surgery level (Tables 4 & 5).

Table 4 Staffing levels at practices surveyed

<table>
<thead>
<tr>
<th>Staff working in the practice</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of GDPs in practice</td>
<td>2</td>
<td>1-9</td>
</tr>
<tr>
<td>Number of community dental officers in practice</td>
<td>0</td>
<td>0-3</td>
</tr>
<tr>
<td>Number of vocational trainees in practice</td>
<td>0</td>
<td>0-2</td>
</tr>
<tr>
<td>Number of Dental Nurses in practice</td>
<td>3</td>
<td>1-9</td>
</tr>
<tr>
<td>Number of Hygienists in practice</td>
<td>1</td>
<td>0-6</td>
</tr>
</tbody>
</table>

Table 5 Staffing levels in the individual surgeries surveyed

<table>
<thead>
<tr>
<th>Staff working in the surgery</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of GDPs who use surgery being surveyed</td>
<td>1</td>
<td>1-9</td>
</tr>
<tr>
<td>Number of community dental officers who use surgery being surveyed</td>
<td>0</td>
<td>0-1</td>
</tr>
<tr>
<td>Number of vocational trainees who use surgery being surveyed</td>
<td>0</td>
<td>0-1</td>
</tr>
<tr>
<td>Number of dental nurses who use surgery being surveyed</td>
<td>1</td>
<td>0-7</td>
</tr>
<tr>
<td>Number of dental hygienists who use surgery being surveyed</td>
<td>1</td>
<td>0-5</td>
</tr>
</tbody>
</table>

3.3.3 Number of patients
The number of patients seen in the surgery and practice were estimated by requesting figures for the number of patients attending on the same day in the previous week (Table 6).
### Table 6 Number of patients treated at the sites surveyed

<table>
<thead>
<tr>
<th>Number of patients</th>
<th>Median</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attendances for treatment per day in practice</td>
<td>54</td>
<td>7-224</td>
</tr>
<tr>
<td>Attendances for treatment per day in surgery</td>
<td>25</td>
<td>6-135</td>
</tr>
</tbody>
</table>

### 3.4 Treatment performed

The range of treatments undertaken in these surgeries is summarised in Table 7 and reflects the broad range of procedures undertaken in general dental practice.

### Table 7 Treatment procedures undertaken in the surgeries surveyed

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of surgeries offering procedure</th>
<th>Degree of invasiveness*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine conservative dentistry</td>
<td>173</td>
<td>Semi-critical &amp; critical</td>
</tr>
<tr>
<td>Fixed / removable prosthetics</td>
<td>173</td>
<td>Semi-critical</td>
</tr>
<tr>
<td>Endodontics</td>
<td>173</td>
<td>Critical</td>
</tr>
<tr>
<td>Extractions</td>
<td>171</td>
<td>Critical</td>
</tr>
<tr>
<td>Routine periodontal treatment</td>
<td>169</td>
<td>Critical</td>
</tr>
<tr>
<td>Surgical extractions</td>
<td>158</td>
<td>Critical</td>
</tr>
<tr>
<td>Orthodontics</td>
<td>99</td>
<td>Semi-critical</td>
</tr>
<tr>
<td>Apicectomies</td>
<td>96</td>
<td>Critical</td>
</tr>
<tr>
<td>Mucosal biopsies</td>
<td>65</td>
<td>Critical</td>
</tr>
<tr>
<td>Periodontal surgery</td>
<td>50</td>
<td>Critical</td>
</tr>
<tr>
<td>Implants</td>
<td>6</td>
<td>Critical</td>
</tr>
</tbody>
</table>

*Based on a modified Spaulding (1968) classification. Critical = instruments that have contact with the blood stream (or likely to produce bleeding). Semi-critical = devices that come in contact with (intact) mucous membranes. Non-critical = devices that come into contact with the patient’s intact skin.
3.5 Surgery Design

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery Design</td>
</tr>
<tr>
<td>1. *Where possible, instruments should be decontaminated away from the surgery in a room containing the autoclave(s), ultrasonic bath(s), instrument washer(s) and sinks and a separate hand wash basin.</td>
</tr>
<tr>
<td>2. *Clean and dirty areas within the surgery should be clearly defined.</td>
</tr>
<tr>
<td>3. **The area to be used for manual cleaning should be dedicated for the purpose and not shared with other activities. This may be achieved by dedicating a zone to the cleaning process and segregating dirty from clean by appropriate workflow patterns and practices.</td>
</tr>
<tr>
<td>4. **A dedicated sink (not hand wash basin), to contain water/detergent mixture for cleaning instruments, should be provided.</td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.  
**Taken from the Glennie Framework.

Within surgeries 58% had a dedicated area for decontamination of re-usable devices, of which 80% were within the surgery itself. However, in 69% of surgeries the clean and dirty areas were not clearly defined. In 38% of surgeries, the area for decontamination was physically separated from other work areas and in 30% the decontamination area was accessed via a separate entrance. Fifty two percent of surgeries did not have a dedicated sink for the cleaning of contaminated instruments.

For the 42% of surgeries that did not have a dedicated area for decontamination, a wide variety of activities were undertaken in the same area as decontamination (Table 8).
Table 8 Examples of shared equipment and activities in decontamination areas

<table>
<thead>
<tr>
<th>Store room</th>
<th>Staff room / Office</th>
</tr>
</thead>
<tbody>
<tr>
<td>X-ray room</td>
<td>Spare surgery</td>
</tr>
<tr>
<td>Compressor room</td>
<td>Kitchen</td>
</tr>
<tr>
<td>General work surface</td>
<td>Beverage preparation</td>
</tr>
<tr>
<td>Note taking</td>
<td>Handwashing</td>
</tr>
<tr>
<td>X-ray processing</td>
<td>Orthopantomogram</td>
</tr>
<tr>
<td>Preparation of filling materials</td>
<td>Mixing impression materials</td>
</tr>
<tr>
<td>Sand blaster</td>
<td></td>
</tr>
</tbody>
</table>

3.6 Management of decontamination

3.6.1 Roles and responsibilities

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Roles and responsibilities</td>
</tr>
<tr>
<td>1. *All members of the dental team must know who is responsible for ensuring certain activities are carried out and to whom to report any accidents or incidents.</td>
</tr>
<tr>
<td>2. *The individual practitioner must ensure that all members of the dental team understand and practise these procedures routinely.</td>
</tr>
<tr>
<td>3. **Senior member of staff with responsibility for decontamination processes and capable of assessing and treating risks associated with ineffective decontamination processes.</td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.

**Taken from Glennie Framework.

The management of decontamination processes in many of the surgeries visited was based largely on ‘word of mouth’ communication between the various members of the dental team. Fifty percent of practices had no documented procedures. Whilst the ultimate legal responsibility for decontamination rests with the Practice Principal, it was unusual for these individuals or their staff to have a written job description with regard to control of infection (Figure 3).
Only 7% of practices employed an individual whose sole or principal duties were instrument re-processing. The re-processing of instruments and devices in 93% of the practices was not undertaken by a dedicated member of staff; typically this was performed by the dental nurse(s) responsible for an individual surgery.

### 3.6.2 Infection control policies and procedures

#### Key indicators of good practice

**Infection control policies and procedures**

1. *Each practice must have a written infection control policy.*

*Taken from BDA Advice Sheet A12.*

Twenty one percent of practices had no written infection control policy. For those practices which had a written policy, this was generally accessible (92%) to all the staff and was incorporated into their training (86%). An audit of infection control procedures had been undertaken in 11% of practices.
3.7 Awareness of guidelines and sources of assistance

**Key indicators of good practice**

**Awareness of guidelines**

1. *All dental staff must be aware of the procedures required to prevent the transmission of infection and should understand why these procedures are necessary.*  
   *Taken from BDA Advice Sheet A12.*

The BDA Advice Sheet A12, which deals with infection control in dental practice, was available in 79% of practices. Ninety seven percent of the practices received Safety Action Notices from the Scottish Executive Health Department. However, 98% of practices had no knowledge of, or access to, Scottish Health Technical Memoranda 2010, 2030 or 2031. Similarly, the majority of practices (80%) were unaware of the Medical Device Bulletins relevant to the purchase of benchtop steam sterilizers and the re-use of single use items.

A reflection of the low level of familiarity with guidance was the fact that 74% of dental nurses and 54% of dentists did not understand the symbol for ‘single use’ (Figure 4), whilst 75% of the dental nurses and 57% of the dentists did not understand the symbol for ‘use by date’.

**Figure 4.** Symbol for identifying single use instruments
The majority of surgeries did not have access to the use of appropriate technical advice from an Authorised Person (Sterilizers) (95%) and/or a Microbiologist (Sterilizers) (99%).

3.8 Procurement of re-usable devices

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Procurement of re-usable devices</strong></td>
</tr>
<tr>
<td>1. <em>When selecting new equipment, you should think about .... how easy it is to decontaminate .... what are the manufacturer’s recommendations?</em></td>
</tr>
<tr>
<td>2. *<em>Practices should have a written policy for the purchase of re-useable medical devices. The policy should ensure that the manufacturer supplies a device that is fit for the intended purpose, compatible with existing equipment, easy to clean, and that the processes by which decontamination is to be achieved are available within the practice.</em></td>
</tr>
<tr>
<td>3. **<em>Manufacturers must supply information to the user “on the appropriate processes to allow re-use, including cleaning, disinfection, packaging and where appropriate, the method of sterilisation of the device and any restriction on the number of re-uses”.</em></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.
**Taken from Glennie Framework.
*** Taken from Medical Device Directive (93/42/EEC), see also EN ISO 17664.

Procurement of re-usable devices is an activity that highlights the requirement for proper management of decontamination procedures. In 93% of the practices, the Principal or Partners were identified as having responsibility for the purchase of instruments and other medical devices. In a minority of cases associates (5%), dental nurses (13%) and practice managers (<1%) were identified as having, or sharing, this responsibility.

Eighty six percent of the practices did not generate a written specification prior to purchasing equipment. Similarly, 86% of practices did not review their current decontamination procedures in relation to devices purchased for the first time. The
The majority of practices (89%) purchased their instruments by placing a verbal order with a dental supply house.

Seventy-seven percent of practices did not have a documented policy on when to choose single use as opposed to re-usable instruments, if both were available. Re-use of relevant specified items is illustrated in Figure 5.

**Figure 5.** Percentage of surgeries re-using specified devices

![Graph showing percentage of surgeries re-using specified devices](image)

Forty-seven percent of practices had a policy on the use of devices labelled as ‘single use’, of which 35% permitted their re-use, i.e. at least 15% of practices overall re-used single use devices.
3.9 Instrument cleaning

### Key indicators of good practice

**Instrument cleaning**

1. *Ultrasonic cleaners and washer/disinfectors are preferred over hand cleaning instruments.

2. **Automated cleaning is preferred to manual cleaning due to the reproducibility and control of the process. This type of process is also more readily validated than manual cleaning. The process used should be appropriate to the equipment being cleaned and the type of contamination being removed.*

*Taken from BDA Advice Sheet A12.

**Taken from Glennie Framework.

### 3.9.1 Methods of instrument cleaning

Table 9 summarises the methods used by the surgeries to clean their re-usable instruments. Most surgeries used a combination of manual washing and ultrasonic cleaning, although not all instruments within a surgery were re-processed this way. Some devices, such as handpieces, are not recommended by the manufacturer to be cleaned in an ultrasonic bath.

**Table 9 Methods of cleaning instruments**

<table>
<thead>
<tr>
<th>Method</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual washing only</td>
<td>10</td>
</tr>
<tr>
<td>Ultrasonic cleaning only</td>
<td>5</td>
</tr>
<tr>
<td>Manual washing (+/- ultrasonic cleaning)</td>
<td>164*</td>
</tr>
<tr>
<td>Washer/disinfector</td>
<td>0</td>
</tr>
</tbody>
</table>

*Many surgeries used different combinations of cleaning methods for different instruments.
### 3.9.2 Manual washing

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manual washing</td>
</tr>
<tr>
<td>1. <em>Instruments should be fully immersed in a sink pre-filled with warm water and detergent.</em></td>
</tr>
<tr>
<td>2. <strong>Manual cleaning would normally be undertaken either by employing immersion or non-immersion techniques depending on the construction of the device.</strong></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.**

**Taken from Glennie Framework.

Virtually all (96%) of the surgeries used manual washing as either the sole method or as part of the cleaning process. Forty-three percent of the surgeries had a designated sink which was used only for instrument cleaning, but the remainder also used the sink for hand washing (84%), beverage preparation (16%) or environmental cleaning (34%). The manual washing process was generally poorly controlled with 41% of practices not using any cleaning agent other than water. A range of cleaning agents was used (Figure 6) but there was no standardisation of concentration of cleaning agents, nor of the temperature of water used for cleaning. Only 2% of surgeries used a detergent formulated for manual washing of surgical instruments, with 37% using surgical handwash. Miscellaneous agents used for cleaning included bars of soap, disinfectants and kitchen cleaning agents.
Eighty six percent did not perform manual cleaning with the instruments entirely immersed to prevent aerosol generation whilst 60% carried out manual washing entirely under running water. Rinsing of washed instruments was undertaken in 84% of surgeries. Only 1% of surgeries used a separate sink for rinsing and 2% rinsed in a bowl. In most cases, water from a holding tank or from the mains supply was used for rinsing. One percent of surgeries rinsed instruments with softened water and less than 1% rinsed instruments with sterile water for irrigation. Eighty five percent of the surgeries never dried instruments after manual cleaning. Less than 1% of surgeries kept records of which instruments had been washed and by whom.

### 3.9.3 Personal protective equipment (PPE) used during manual washing

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>PPE</td>
<td></td>
</tr>
<tr>
<td>1. <em>Thick waterproof house hold gloves must be worn to protect against accidental injury and protective eyewear to shield against splashing.</em></td>
<td></td>
</tr>
<tr>
<td><em>Taken from BDA Advice Sheet A12.</em></td>
<td></td>
</tr>
</tbody>
</table>

In relation to staff safety, the majority of those undertaking the manual washing wore gloves (99%). However, 51% of staff did not use eye protection and 93% did not use waterproof overalls.
3.9.4 Ultrasonic baths

### Key indicators of good practice

#### Ultrasonic cleaners

1. *Ultrasonic cleaners should contain a detergent not a disinfectant.
2. *The liquid in the ultrasonic cleaner should be disposed of at the end of each clinical session and more often if it appears heavily contaminated.
3. *At the end of each day, the ultrasonic cleaner must be emptied.
4. **There must be a procedure to ensure change of water at not more than 4 hourly intervals.
5. **Ultrasonic cleaners must be tested on installation, and weekly, using the aluminium foil erosion test to ensure continued ultrasonic activity.

*Taken from BDA Advice Sheet A12.
**Taken from Glennie report.

Ultrasonic baths were present in 92% of surgeries. The age of the ultrasonic baths ranged from $<1$ – 14 years (median of 3 years old). The features of the ultrasonic baths are summarised in Table 10. The majority of surgeries (92%) operated the ultrasonic with the lid in the closed position.

#### Table 10 Ultrasonic cleaner features

<table>
<thead>
<tr>
<th>Features present in the ultrasonic cleaner</th>
<th>Number (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Removable lid</td>
<td>157 (96%)</td>
</tr>
<tr>
<td>Chamber drain</td>
<td>29 (18%)</td>
</tr>
<tr>
<td>Thermostatic control</td>
<td>10 (6%)</td>
</tr>
<tr>
<td>Disinfection stage</td>
<td>3 (2%)</td>
</tr>
<tr>
<td>Cannulated instrument irrigation</td>
<td>2 (1%)</td>
</tr>
<tr>
<td>Rinsing stage</td>
<td>1 (&lt;1%)</td>
</tr>
<tr>
<td>Lid interlock</td>
<td>1 (&lt;1%)</td>
</tr>
</tbody>
</table>

The range of cleaning agents used in the ultrasonic baths is shown in Figure 7.
Figure 7. Agents used in ultrasonic cleaning baths


The interval between changing the solution in the ultrasonic bath ranged from 2 to 504 hours (median of 9 hours) and 63% emptied the ultrasonic bath at the end of the working day. Eighty percent of surgeries did not change the ultrasonic cleaning fluid at 4 hourly intervals or more frequently. In 11% of surgeries the interval was 5 days or more. However, 83% of surgeries changed the ultrasonic bath solution when visibly soiled.

Ninety six percent of the surgeries did not check the efficacy of the ultrasonic generator by means of the aluminium foil ablation test. One surgery (<1%) undertook periodic tests of the cleaning efficacy of the bath.

Eighty six percent of surgeries rinsed instruments after immersion in the ultrasonic bath.
### 3.10 Instrument inspection

#### Key indicators of good practice

<table>
<thead>
<tr>
<th>Instrument inspection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <em>After cleaning, all instruments must be examined thoroughly and, if there is residual debris, recleaned.</em></td>
</tr>
<tr>
<td>2. *<em>Following cleaning, all instruments should be carefully examined for organic material and/or damage (under magnification where appropriate). Where practicable the inspection and functional testing of surgical instruments should be carried out by a person not responsible for cleaning the item. Those persons carrying out these tasks have a responsibility for ensuring that the items are fit for reuse. Records of all work performed, including functional testing, should be maintained.</em></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.

**Taken from Glennie Framework.

Eighty five percent of surgeries routinely inspected all instruments for cleanliness after the cleaning process. One percent of surgeries had a magnifier available for inspection of small or intricate devices and 3% had task lighting for cleanliness inspections. In 52% of surgeries cleaned instruments were checked or tested for functionality prior to use on patients.
### Key indicators of good practice

<table>
<thead>
<tr>
<th>Packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <em>Clean and dirty areas within the surgery should be clearly defined.</em></td>
</tr>
<tr>
<td>2. <em>Processing wrapped instruments in a conventional downward displacement autoclave (also known as a Bowl &amp; Instrument or Unwrapped Instrument &amp; Utensil Sterilizer) may result in inadequate air removal and failure to sterilize. Wrapped instruments and instruments in pouches must be sterilized using a vacuum-phase autoclave.</em></td>
</tr>
<tr>
<td>3. *<em>Where products are to be packaged, the materials used should be compliant with the relevant European Standards (BS EN 868). The methodology employed for packaging within the surgery should be documented.</em></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.

**Taken from Glennie Framework.

In eighty percent of surgeries which packaged instruments prior to sterilization, the packaging area was not clearly segregated from the area where cleaning and disinfection took place. Of the surgeries with a B&I sterilizer, 28% were packaging instruments before sterilization. The type of packaging used before sterilization in a B & I sterilizer is shown in Figure 8.
Figure 8. Type of packaging used when wrapping instruments before sterilization in a B & I Sterilizer


Of the surgeries with a vacuum sterilizer 60% were packing instruments before sterilization. Of these, 17% were using a double layer of packaging, although the manufacturers of most vacuum benchtop sterilizers recommend that only a single layer of packaging should be used.

Seventy nine percent of the surgeries used packaging materials purchased against British or European standards. The pre-sterilization packaging was reused by 9% of surgeries.

3.12 Instrument sterilization
3.12.1 Types of Sterilizer
There are two types of sterilizer in common use in dental surgeries. The majority of the surgeries used benchtop bowl and instrument (B&I) sterilizers (also known as downward displacement sterilizers or unwrapped instrument & utensil sterilizers) (Table 11).
### Table 11 Types of sterilizer

<table>
<thead>
<tr>
<th>Type</th>
<th>Number (percent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bowl &amp; instrument</td>
<td>160 (88%)</td>
</tr>
<tr>
<td>Vacuum benchtop</td>
<td>20 (11%)</td>
</tr>
<tr>
<td>Hot air</td>
<td>1 (&lt;1%)</td>
</tr>
</tbody>
</table>

The B&I sterilizers were aged between 1 and 19 years (median of 5 years old), whilst the vacuum benchtop steam sterilizers were between <1 and 5 years old (median of 2 years old).

#### 3.12.2 Installation, commissioning, validation and testing of sterilizers

**Key indicators of good practice**

**Installation, commissioning, validation and testing of sterilizers**

1. **The sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010.**

**Taken from Glennie Framework.**

Fifty one percent of the sterilizers were tested on installation and 26% were commissioned, of which 38% were commissioned to SHTM 2010 standard. Sterilizers were installed by manufacturers (39%), suppliers (30%), Primary Care Trust or Health Board (3%) and by others (27%). Other agents installing sterilizers were generally the dentist or dental nurse.

In most cases it was difficult to determine, from the documentation available, whether daily, weekly, quarterly and annual testing was undertaken in accordance with SHTM 2010. Documentation available indicated that 15% of B&I sterilizers and 13% of vacuum benchtop sterilizers were tested in accordance with SHTM 2010.

Sixty five percent of surgeries did not undertake testing of the sterilizer at the beginning of each day. Integrating chemical indicators were used in 39% of sterilizers; 17% used these for every load. Biological indicators were used in 1% of sterilizers. Fifteen percent of surgeries with a vacuum benchtop sterilizer were...
performing a daily Bowie Dick test (used to demonstrate adequacy of air removal from a challenge load).

### 3.12.3 Servicing and maintenance of sterilizers

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Servicing and maintenance of sterilizers</strong></td>
</tr>
<tr>
<td>1. <em>All autoclaves must be regularly serviced and maintained according to the manufacturer’s recommendations and periodically inspected.</em></td>
</tr>
<tr>
<td>2. <strong>The sterilizer must be subject to documented planned maintenance (SHTM 2010 Part 3).</strong></td>
</tr>
</tbody>
</table>

* *Taken from BDA Advice Sheet A12.*

**Taken from Glennie Framework.

Ninety percent of sterilizers had a maintenance contract. Ninety two percent of the B&I sterilizers were serviced regularly, 88% annually and 63% quarterly.

### 3.12.4 Operation of Sterilizers

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Operation of Sterilizers</strong></td>
</tr>
<tr>
<td>1. <em>Correct operation of the autoclave must be checked whenever the autoclave is used by recording the readings (physical parameters) on the autoclave’s instruments or printouts at the beginning of each clinical session.</em></td>
</tr>
<tr>
<td>2. <em>Autoclave logs and printouts should be retained for inspection and monitoring.</em></td>
</tr>
<tr>
<td>3. *<em>A documented procedure requiring operator to observe and record attainment of required temperature on independent temperature gauge or the sterilizer must be fitted with chart recorder or data logger as per SHTM 2010 Part 2.</em></td>
</tr>
</tbody>
</table>

* *Taken from BDA Advice Sheet A12.*

**Taken from Glennie Framework.*
Written instructions for operation of the sterilizer were not available in 61% of practices. Thirty three percent of surgeries kept records of user checks undertaken of the sterilizer. Sixty percent of the vacuum benchtop steam sterilizers were fitted with a chart recorder or datalogger and 23% of the B&I sterilizers were fitted with dataloggers.

### 3.12.5 Paperwork associated with pressure vessel

#### Key indicators of good practice

<table>
<thead>
<tr>
<th>Paperwork associated with pressure vessels</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <em>All autoclaves must be regularly serviced and maintained according to the manufacturer’s recommendations and periodically inspected.</em></td>
</tr>
<tr>
<td>2. <strong>The sterilizer must be commissioned, validated and tested annually, quarterly, weekly and daily as per SHTM 2010.</strong></td>
</tr>
<tr>
<td>3. <em><strong>Users should have third party liability insurance to cover the particular risks associated with pressurized equipment and steam (also known as <em>pressure vessel insurance</em>).</strong></em></td>
</tr>
<tr>
<td>4. <em><strong>Periodic examination of the pressure system by a Competent Person (Pressure Vessels) is required.</strong></em></td>
</tr>
<tr>
<td>5. <em><strong>A ‘written scheme of examination’ for the pressure system is required to be drawn up in conjunction with a Competent Person (Pressure Vessels).</strong></em></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.  
**Taken from Glennie Framework.  
***Taken from MDA DB2000(05) October 2000.

According to paperwork made available to the survey team members, insurance cover for the pressure vessels was available in 79% of surgeries with a B&I sterilizer and 60% of surgeries with a vacuum benchtop sterilizer; a written scheme of examination approved by a Competent Person (Pressure Vessels) was available for 61% of surgeries with a B&I sterilizer and 65% of surgeries with a vacuum benchtop sterilizer; an annual visit from a Competent Person (Pressure Vessels) was made to 63% and 55% of surgeries with B&I and vacuum benchtop sterilizers respectively.
3.12.6 Sterilizer water

Key indicators of good practice

Sterilizer water

1. *It is important that the water used in the autoclave should contain no minerals ..... it should be free of pathogens and endotoxins (pyrogen free).
2. *At the end of each day, the residual water should be drained from the autoclave chamber and reservoir.
3. **There must be records demonstrating that reservoir and chamber are drained daily and refilled with sterile water for irrigation.

*Taken from BDA Advice Sheet A12.
**Taken from Glennie Framework.

Figure 9 summarises the types of water that were being used to replenish the reservoirs of the sterilizers.

Figure 9. Water used in sterilizers
The frequency of draining and replenishing the sterilizer reservoir is shown in Figure 10.

**Figure 10.** Frequency of draining sterilizer reservoir

If the sterilizer was unavailable, for example on account of a mechanical breakdown, then the surgery took the actions shown in Figure 11.
Figure 11. Action taken by surgery when sterilizer out of service

3.13 Packaging after sterilization

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packaging</td>
</tr>
<tr>
<td>1. *Processing wrapped instruments in a conventional downward displacement autoclave (B&amp;I) may result in inadequate air removal and failure to sterilize. Wrapped instruments and instruments in pouches must be sterilized using a vacuum-phase autoclave.</td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.

Seventy percent of surgeries packaged goods for storage after sterilization. Fifty five per cent of the surgeries packaged some of their instruments after sterilization in a B&I sterilizer. Fifty percent of surgeries were packaging after sterilization in a vacuum autoclave. In 63% of surgeries post sterilization packaging did not take place in a dedicated area.
### 3.14 Storage after sterilization

**Key indicators of good practice**

<table>
<thead>
<tr>
<th>Storage</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <em>Sterilized instruments should be stored in dry, covered conditions.</em></td>
</tr>
<tr>
<td>2. <strong>The environmental conditions of the areas designated for storage and distribution should ensure the integrity of all materials and products, i.e. clean, dry, well ventilated and secure. The accommodation should afford adequate protection to prevent contamination or deterioration of the product. Items with damaged packaging should not be used. Stock rotation should be used for storage, i.e. FIFO (First in, First out).</strong></td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.*  
**Taken from Glennie Framework.*

Sterilized items were stored in cupboards (51%), drawers (86%), on shelves (32%) and on work surfaces (34%). In 91% of the surgeries this storage was in the same area as patient treatment and in 48% of surgeries it was in the same area as decontamination was undertaken. Eighty nine percent of the storage areas were visibly tidy and well organised. Nineteen percent of surgeries issued sterile packs and sterilized instruments in strict rotation (FIFO).

### 3.15 Traceability

**Key indicators of good practice**

<table>
<thead>
<tr>
<th>Traceability</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>The Consumer Protection Act, in particular product liability, has implications for the reprocessing of devices used for patient care. In particular it is essential to maintain adequate records that demonstrate how a particular device was processed and a description of the methods employed. The practice should have the ability to demonstrate how instruments have been processed, for example, a log of personnel involved in the cleaning and operation of the decontamination equipment.</strong></td>
</tr>
</tbody>
</table>

**Taken from Glennie Framework.**
None of the surgeries had any form of traceability systems for their re-usable devices. For one percent of sterilizers, records were kept of all items sterilized. Documentation for sterile product release was recorded for one sterilizer (<1%). Eleven percent of sterilizer cycles were examined before instruments were released as sterile.

3.16 Training

<table>
<thead>
<tr>
<th>Key indicators of good practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Training</td>
</tr>
<tr>
<td>1. *All new staff must be appropriately trained in infection control procedures. Training should equip staff to understand how infections are transmitted, the practice policy on decontamination and infection control, what personal protection is required and when to use it, what to do in the event of accidents or personal injury.</td>
</tr>
<tr>
<td>2. *It is useful for each member of staff to receive a copy of the infection control policy and to sign a declaration that the policy has been received and the training provided.</td>
</tr>
<tr>
<td>3. **All personnel carrying out decontamination processes have documented training needs assessment and record of training received.</td>
</tr>
</tbody>
</table>

*Taken from BDA Advice Sheet A12.

**Taken from Glennie Framework.

Staff training in decontamination was provided mainly by demonstration (97%) and observed practice (88%). There was little documentation associated with training (10%). There were no records available for staff training in 69% of surgeries.

There was no documentation of staff training in the use of sterilizers in 90% of surgeries. The training was generally provided by observed practice (88%) and demonstration (93%). Twenty seven percent of the surgeries provided training on the limitations of the type of load which may be processed and 33% on correct loading procedures.
SECTION 4  DISCUSSION

4.1  Methodology
This is the largest study ever completed which has surveyed, by direct observation, decontamination procedures in general dental practices. The methodology of this survey, which employed direct interviews with dental surgeons and dental nurses in the workplace, and observed the decontamination processes first hand, has provided high quality data. The robustness and accuracy is significantly greater than that gathered through postal questionnaires, which to date have been the main source of such information\textsuperscript{16}.

Anecdotally, all the survey teams reported the enthusiasm and willingness of the staff in the participating practices to co-operate fully during each visit and their requests for guidance on appropriate decontamination protocols.

4.2  Results
We would like to draw attention to the deficiencies in centrally held databases of activity in general dental practice. Incomplete and inaccurate data have seriously hindered recruitment of dentists into the survey and have implications for other studies into delivery of dental care to the Scottish population.

The overall findings of this survey bear striking similarities to those from the central sterile departments and acute sectors\textsuperscript{5,17}. Central to these has been the observation of highly motivated staff attempting to comply with infection control guidelines available to them and according to their own interpretation. However, the need for more detailed practical guidance to dental personnel on implementation of the technical requirements implicit in high quality decontamination cannot be overstressed.

The results reported here support the earlier findings from a smaller number of practices surveyed in Scotland\textsuperscript{5}, England and Wales\textsuperscript{17}. Therefore the recommendations of this study are relevant to the whole of the UK.
Re-use of single use devices
This topic highlights key issues over labelling of devices, manufacturers’ instructions and users’ knowledge. Some devices, such as impression trays, are clearly labelled as single use. Other devices, such as endodontic files, are labelled as single use by some manufacturers whilst other manufacturers supply decontamination instructions that are incompatible with common practices in the UK. In addition there is evidence that some devices, such as Siveland matrix bands, can be especially problematic\textsuperscript{18,19}. Although guidance has been issued\textsuperscript{20} recommending that the matrix bands must not be re-used there are a number of practitioners who continue to decontaminate and re-use assembled bands for treatment of multiple patients.

Premises
During the course of the survey, many types of premises were visited, but only a very small proportion were purpose-built as dental surgeries and the majority were remote from other healthcare providers. This potentially complicates the separation of decontamination from clinical areas, a fundamental problem identified in many practices visited and one which must be overcome if dental surgeries are to continue acting as local decontamination units (LDUs).

Management and quality assurance
There was little evidence of clear management processes underlying decontamination procedures in most practices and audit of instrument decontamination was virtually non-existent. Whilst cumbersome management procedures are clearly inappropriate for busy dental practices, guidance for dental staff on the various elements of process control is essential and required urgently, since ensuring and recording the quality of the process of decontamination is the only safeguard for the supply of adequately sterilized dental instruments.

Instrument procurement
The concept of instrument procurement as an element of the decontamination cycle must be stressed to dental staff. Currently most instrumentation is ordered by phone from a dental supplier, with little consideration for the compatibility of
decontamination instructions as supplied by the manufacturer, in relation to the practice’s current procedures. This process could be improved dramatically if dentists were provided with recommended specifications for particular items, which they could then use as a guide during purchasing.

**Equipment manufacturers and suppliers**
The safe and efficient decontamination of dental instruments by dental practitioners is seriously hindered by the lack of clear information from the majority of manufacturers / suppliers. Appropriate instructions for reprocessing many dental devices are either absent or incompatible with common processes in use in the UK, for example, “operate at a sterilizing temperature and pressure of 134°C for 12 minutes, followed by a 20-30 minute drying time.” Another example recommends sterilizing with an autoclave at 134°C “during 5 min at 3 bars.” This in turn raises questions over the effectiveness of the appropriate regulatory bodies in the UK.

**Equipment installation, testing and maintenance**
The majority of items of dental equipment essential to the decontamination process, such as ultrasonic baths and benchtop steam sterilizers, are not commissioned on installation or tested at appropriate intervals as recommended in a number of technical publications. The nature of the sterilization process requires validation of equipment, confirmed at regular intervals by appropriate testing. Many practices subscribing to third party testing and maintenance schedules had insufficient paper work to support the efficacy of these visits. Guidance is required to provide appropriate value for money and assurance for dental practitioners that relevant testing and maintenance is undertaken by appropriately trained engineers.

**Instrument cleaning**
Previous risk assessments of the potential transmission of vCJD via surgical instruments\(^3,6\) have stressed the importance of cleaning of instruments prior to the sterilization phase. Instrument cleaning has emerged from this survey as an area where significant improvement is required urgently. Manual cleaning, alone or in
combination with other cleaning processes, is the most common method and is carried out in the virtual absence of any form of quality control. Many practices use only tap water, in the total absence of a cleaning agent, and those who use a cleaning agent often choose one that is entirely inappropriate, for example surgical hand wash. Rinsing is typically with tap water in the same sink as the manual cleaning and most practices do not dry instruments after cleaning. Most practices used ultrasonic cleaners in addition to, or instead of, manual cleaning. The frequency with which the ultrasonic bath liquid was cleaned was variable and virtually no practices undertook any testing of the efficacy of the ultrasonic cleaner.

**Instrument sterilization**

In relation to instrument sterilization, most practices used bowl and instrument sterilizers. Although most practices had a maintenance contract, the majority of practices were unaware of the existence of SHTM 2010 and it was difficult on most visits to ascertain from the paperwork made available whether regular testing of the autoclaves was undertaken in accordance with that document. Many autoclaves had not been tested or commissioned on installation. Some practices had failed to obtain pressure vessel insurance which is in breach of Health and Safety Laws. The quality of water used in the autoclave reservoirs ranged from tap water to sterile water and the frequency of draining the reservoir was also variable, though some were following the recommendation of daily drainage and replacement. Some practices were still packaging instruments before loading them into a bowl and instrument sterilizer, though significantly more were packaging after sterilization.

**Staff training**

An urgent requirement for staff training has emerged from this survey. At present, much of the training in procedures such as autoclave use is provided by word of mouth and demonstration within the practice and there is only scanty documentation of training. It was the view of many of the surveyors who took part in this study that the dental staff were very keen to be given practical, pragmatic guidance on the procedures necessary to improve the standards of instrument decontamination being practised.
SECTION 5 CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

This survey has revealed that most staff in general dental practice are keen to deliver an efficient and safe supply of sterilized, re-usable instruments, but that in many cases their efforts are misdirected. There is a clear requirement for changes to the way in which the decontamination cycle is applied in the general dental services, if current key indicators of good practice are to be achieved across the sector.

Instrument decontamination requires a considerable level of technical knowledge and it is the role of experts in the field to provide this in a format which is accessible to those in primary care. Given appropriate guidance and support, including financial resources, the continued operation of LDUs within dental practices is practicable. The data generated from this survey of general dental practices will also be relevant to the other providers of primary care services in the United Kingdom, notably Community Dental Service clinics, podiatry and general medical practice.

5.2 Recommendations

The key areas identified by this survey to maximise improvements in decontamination within dental practice and to reduce risks associated with potential onward transmission of vCJD and other pathogens are:

1. Advice and training pertinent to instrument cleaning protocols.

2. Access to policies and procedures, such as SHTM 2010, presented in a meaningful and relevant manner.


4. Guidance on surgery design, layout and separation of clinical from decontamination areas.
5. Guidance on commissioning, testing and maintenance of cleaning and sterilizing equipment.

6. A re-appraisal of the role of regulatory bodies overseeing the compliance of instrument manufacturers/suppliers and equipment testing and maintenance sub-contractors with appropriate decontamination regulations.

7. Provision of appropriate documentation from suppliers, service and maintenance agents for decontamination equipment.

8. Revision of existing dental practice inspections.
SECTION 6 ACKNOWLEDGEMENTS

Much credit must be given to the individual members of the survey teams (Appendix IV) and to the Scottish general dental practitioners for agreeing to participate in this survey. The survey was also supported by the Scottish Branch of the British Dental Association, regional general dental practitioner sub-committees and local dental committees.
Appendix I: Authors

Andrew Smith
*Infection Research Group, Glasgow Dental Hospital and School, 378 Sauchiehall Street, Glasgow, G2 3JZ.*

Jeremy Bagg
*Infection Research Group, Glasgow Dental Hospital and School, 378 Sauchiehall Street, Glasgow, G2 3JZ.*

Siobhan McHugh
*Infection Research Group, Glasgow Dental Hospital and School, 378 Sauchiehall Street, Glasgow, G2 3JZ.*

David Hurrell
*Healthcare Science Ltd, Unit 4 Northend Industrial Estate, Burymead Road, Hitchin, Hertfordshire, SG5 1RT.*

Hew Mathewson
*General Dental Practitioner, 176, St Johns Road, Edinburgh.*

Mary Henry
*Scottish Centre for Infection and Environmental Health, Clifton House, Clifton Place, Glasgow, G3 7LN.*
Appendix II: AD³ Forms

Dental surgery – administrative information: this form collects details of the dentist, practice and surveyors. These data are stored securely and separately from the main database.

Dental practice – summary: data on this form provide a summary overview of the practice infrastructure, staffing, clinical service provision and decontamination procedures.

Management of infection control: data on this form provide details of infection control policies, staff communication and staff training in decontamination.

Procurement: this form gathers information which describes the methods of procurement and the control over the acquisition of reusable medical devices.

Environment and work flow: this form gathers information which describes the facilities available for the decontamination of instruments and examines the movement of both used and sterilized instruments within the surgery and practice.

Summary of decontamination: this form summarises the equipment and chemicals used in the decontamination process.

Manual cleaning: this form gathers information on the extent to which manual cleaning is employed and how manual cleaning is carried out.

Automatic washer disinfectors: this form gathers information concerning automatic washer disinfectors.

Ultrasonic cleaner: this form gathers information concerning ultrasonic cleaners.

Chemical disinfection: this form gathers information about the chemical disinfectants used in the surgery.

Post cleaning inspection: this form collects data about the procedures used for inspecting cleaned instruments prior to their being sterilized.

Packing and tray assembly: this form gathers information about packaging of cleaned devices, before and after sterilization.

B&I benchtop sterilizers: this form gathers information about bowl and instrument benchtop sterilizers, including testing.

Vacuum benchtop sterilizers: this form gathers information about vacuum benchtop sterilizers, including testing.

Hot air sterilizers: this form gathers information about hot air (dry heat) sterilizers, including testing.
Sterilization process control: this form collects information about the procedures in place to ensure appropriate monitoring and quality control of sterilization of instruments used in the surgery.

Storage: this form collects information on the storage sites available for sterile and sterilized items.

Transit – on site: this form collects information on the methods for movement of contaminated and sterilized items both within the surgery and within the practice.

Transit – off site: this form collects information on the methods for movement of contaminated and sterilized items between the surgery / practice and an external decontamination facility.

Instruments and devices: this form collects information on the types and numbers of instruments in the surgery.

Staff and health & safety: this form collects data relating to the measures taken to protect the health and safety of staff undertaking decontamination and the training received by staff in respect of decontamination.

Dental handpieces: this form collects data on dental handpiece purchase, decontamination and servicing.

Loan equipment: this form examines policies and procedures linked to the borrowing and lending of equipment associated with the surgery.

Subcontractors and maintenance: this form collects information about contractors employed to carry out maintenance and testing on decontamination equipment.

Validation and testing of washer disinfectors: this form examines the validation studies and periodic testing carried out on an automatic washer disinfector.

Domiciliary care: this form records information linked to decontamination of instruments used for domiciliary visits.

Reference documents: this form collects information on the availability of reference documents on decontamination to the staff within the surgery.

Surgery layout: this form collects information on the physical layout of the dental surgery and decontamination areas being surveyed.
Appendix III: References

14. Rimland D, Parkin WE, Miller GB Jr, Schrack WD. Hepatitis B outbreak


20. Scottish Executive Health Department, Primary Care Unit. Letter to Dentists, General Dental Service, Community Dental Service, Hospital Dental Service. Re-use of Dental Matrix Bands. 21st December 2001.

**Technical Documentation**

- Sterilization, disinfection and cleaning of medical equipment: Guidance on decontamination from the microbiology advisory committee to Department of Health, Medical Devices Agency.
- SHTM 2010 Sterilizers.
- SHTM 2030 Washer Disinfectors.
Appendix IV: List of surveyors and other contributors

Irene Black  General dental practitioner
Elaine Humphreys General dental practitioner
John Jamieson General dental practitioner
Robert Lambert General dental practitioner
Maggie Leggate General dental practitioner
Sharon Letters General dental practitioner
Sandra Lowe General dental practitioner
Alex Matthewson General dental practitioner
Olive Melvin General dental practitioner
David Mcletchie General dental practitioner
James McCafferty General dental practitioner
Ken Scoular General dental practitioner
John Simpson General dental practitioner
Lindsey Smith General dental practitioner
George Taylor General dental practitioner
George Taylor General dental practitioner
Robin Thompson General dental practitioner
Andrew Yuill General dental practitioner
Irene Aitkin Dental nurse/infection control link nurse
Iris Green Dental nurse manager
Margaret Watson Dental nurse
Rosemary Waters Dental nurse
Jeremy Bagg Microbiologist
Chris Fox Principal Clinical Scientist
Paul Howard Authorised Person (Sterilizers)
Andrew Hay Microbiologist
David Hurrell Microbiologist
Ken Liddell Microbiologist
Gabby Phillips Microbiologist
Andrew Smith Microbiologist
Alan Stewart Sterile Services Manager
David Taylor Microbiologist
Carol Fraser Senior Public Health Infection Control Nurse
Maggie McCowan Infection control nurse / HDL(2001)10 Manager
Gill McEwan Theatre Manager / Decontamination Project Co-ordinator
Carole Reed Infection control nurse
Sue McLeod Theatre Manager
Eric Wiseman Infection control advisor
Jackie Riley Infection control nurse
Maureen Stride Infection control nurse
Gillian Irvine Infection control Nurse
Jim White Infection control Nurse

Information technology support: Steven Renton, Robert Giles and Abi Fisher.