



SCOTTISH EXECUTIVE

Health Department
Performance Management and Finance Directorate

Dear Colleague

DECONTAMINATION – COMPLIANCE IN PRIMARY CARE

Purpose

1. Ross Scott's letter of 21st September 2004 to Chief Executives advised that a Glennie sub-group had been working on a Decontamination Strategy for Primary Care which would take into account the preliminary findings of a survey of dental decontamination practice.

2. This report, Survey of Decontamination in General Dental Practice was published on Friday 26th November 2004 and is available on the Scottish Executive website at <http://www.show.scot.nhs.uk/sehd/publications/DC20041202Dental.pdf>.

3. This letter now provides an update on:

- The work of the Primary Care Strategy Group;
- Revised deadlines for achieving compliance in Primary Care;
- Clarification on the roles and responsibilities of NHS Boards; and
- How to get practical help and advice.

Background

4. The Sterile Services Provision Review Group Report was published in August 2001. The report was two fold: firstly it addressed the acute sector, the area considered to have the highest level of risk relative to vCJD and covers activity for all centralised sterile service departments, all locally processed acute sector activity, dental hospital activity and minor procedures by general medical practitioners. The second stage

11th January 2005

Addresses

For action

Chief Executives: NHS Boards,
NHS National Services Scotland,
Scottish Ambulance Service and
State Hospitals Board for Scotland

For information

NHS Board Directors of Finance

Chief Executive, NHS Quality
Improvement Scotland

Chief Executive, NHS Education for
Scotland

Medical and Nursing Directors, NHS
Boards

Chief Administrative Dental Officer,
Dental Hospitals

Medical Director, HPS

General Managers, Independent
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of the report was to take forward local decontamination practices within Primary Care, concentrating on General Medical and Dental Practitioners. While the risk of vCJD transmission in these local settings may be lower, there remain significant hazards from bloodborne viruses and bacterial infections.

5. The deadlines for achieving Glennie compliance have, in the main, been met by the acute sector. Some sites are still working towards full compliance and are working closely with the Department to agreed deadlines. The work on the acute sector continues and the Glennie Group is now focusing on decontamination in Primary Care.

Primary Care Strategy Group

6. The Health Department, advised by the Glennie Group, has reviewed the preliminary action plans on primary care decontamination requested from NHS Boards in early 2004. This information, the dental survey results and reviews of a number of local decontamination failure incidents over the past year have been used to inform the development of a revised strategy on local decontamination (principally in primary care) by a Glennie working group. This multidisciplinary working group, which includes a number of front line professionals, is currently developing a new, pragmatic, phased approach to improving standards in local decontamination. Education and training are key to this, as is the provision of appropriate and consistent advice and support. The initial priority is to focus on getting the working processes right, through advice, education and training. Preliminary details of the revised strategy are given in Annex A.

7. A joint CMO/CDO letter was issued on 25th November 2004 (CMO(2004)21) (a copy is available at [http://www.show.scot.nhs.uk/sehd/cmo/CMO\(2004\)21.pdf](http://www.show.scot.nhs.uk/sehd/cmo/CMO(2004)21.pdf)) and provided important information for all General Medical and Dental Practitioners and others who undertake local decontamination of surgical instruments. The letter gave details of 10 priorities for immediate action which were to be addressed at all sites as an interim measure by the end of December 2004. Details of these priority areas for action can be found in Annex B.

Revised Compliance Dates

8. NHS HDL(2003)42 set deadlines for achieving compliance in Primary Care. In reviewing the overall position the Primary Care Strategy Group has re-considered the deadlines set and developed a framework for action with target dates which include:

8.1 By 31st December 2004:

8.1.1 Action to have been taken at all local decontamination sites to address the 10 priority areas for action detailed in SEHD/CMO(2004)21 and attached at Annex B;

8.1.2 Health Protection Scotland (HPS) (formerly the Scottish Centre for Infection and Environmental Health (SCIEH)) to have developed and issued guidance on best practice for local decontamination. This guidance is available at <http://decontamination.hps.scot.nhs.uk>; and

8.1.3 The Glennie Decontamination Education Group (with representation from NHS Education Scotland (NES), HPS, NHSScotland, independent dental and medical

practice and SEHD) to have developed an outline educational framework for training in primary care.

8.2 By 31st March 2005:

8.2.1 HPS to issue and test in pilot sites an updated version of the electronic Primary Care Audit Tool (P-CATv2);

8.2.2 NHS Boards to ensure an interim assessment of compliance by all primary care sites against the priority areas for action detailed in the CDO/CMO letter is undertaken: this could if necessary be carried out on a random sampling basis;

8.2.3 For Independent Contractors, NHS Boards should offer all GPs and GDPs practising outwith NHS facilities a copy of P-CATv2 and ensure that they are aware of the issues and deadlines and the need for action plans; and

8.2.4 The Glennie Decontamination Education Group to develop an initial educational programme.

8.3 By 30th September 2005:

8.3.1 Following satisfactory testing of the P-CATv2 functionality, for Managed Services, NHS Boards should ensure that each primary care area (NHS Board health centres, directly managed dental units, such as community dental services, treatment rooms and podiatry clinics) tests the self-assessment of decontamination procedures using P-CATv2; and

8.3.2 Again, following satisfactory testing of the P-CATv2 functionality, NHS Boards should initiate the phased use of the P-CATv2 audit tool in all primary care Independent Contractor premises.

8.4 By 31st December 2005:

8.4.1 On the basis of the self-assessment of decontamination procedures, (see para 8.3.1) NHS Boards to assess the cost-effectiveness of LDU/CDU/single use processes and make option appraisal decisions for each site;

8.4.2 NHS Boards to have for all for all managed units a prioritised and phased compliance action plan, based on risk assessment and submit these action plans to SEHD for onward transmission to the Decontamination Technical Advisory Panel (DTAP) for consideration;

8.4.3 NHS Boards to have in place a monitoring programme of compliance by Independent Contractors – see Annex C on the roles and responsibilities of NHS Boards; and

8.4.4 NES to implement the decontamination educational programme.

8.5 **Over the next 5 years (i.e. by 31 December 2009):**

8.5.1 NHS Boards in consultation with SEHD and others to develop and implement a strategy for the replacement of manual washing and/or ultrasonic baths with automated washer/disinfectors. In view of the limited ability of manufacturers to meet the necessary demand for replacement equipment, commissioning and servicing. The replacement cycle will need to be commenced in 2006 and phased over the remaining 4 year period; and

8.5.2 The physical environment and equipment is to be upgraded at all local decontamination sites.

9. This framework has been endorsed by the Glennie Group.

Roles and Responsibilities of NHS Boards

10. Annex C set out how the Full Technical Requirements for Decontamination, published in the Sterile Services Provision Review Group 1st Report (the Glennie Report), can be assessed and enforced within Primary Care by NHS Boards.

Practical Help and Advice

Health Protection Scotland (HPS) Website

11. The HPS website can be accessed via the following link <http://decontamination.hps.scot.nhs.uk>. The site is updated weekly to ensure it is accurate and up to date. The website gives access to the following areas:

- Decontamination Team Members and Mission Statement/Objectives
- Latest News
- Current Projects
- Forum Groups
- Courses & Conferences
- Useful Links
- FAQ's

Guidance on achieving compliance in Local Decontamination Units

12. Guidance on best practice in achieving compliance in Local Decontamination Units is now available on the Health Protection Scotland website. This document provides a summary of the options available to achieve compliance with current technical requirements (TRs) as published by the Sterile Services Provision Review Group (Glennie Group) for the decontamination of reusable medical devices in a primary care setting.

13. The LDU guidance is not intended to replace expert advice available from Authorised Persons (Sterilizers) who should be consulted for further detailed guidance and, in particular, guidance on the choice, validation, maintenance, testing and operation of decontamination equipment.

Decontamination Documentation System (DDS)

14. The Decontamination Documentation System (DDS) is a web-based application which will assist primary care practices in achieving best practice within existing facilities. The package allows a practice to produce a bespoke Decontamination Manual specific to the circumstances within their practice. The system will be available on www.nhsscotland.com/DDS from 15th January 2005.

15. To use the system the user will be asked to register to obtain secure access and will have to enter details of the facilities available for decontamination. This should take no more than twenty minutes to complete. Once the details have been entered the program will download the completed Decontamination Manual. The manual will be in RTF format that can be read by any word-processor program. As facilities and/or equipment within the practice are upgraded the registered user can re-enter the program to produce a revised version of the Decontamination Manual.

16. Training days have already taken place in NHS Boards and further training will be scheduled for early in 2005; anyone interested in attending should contact Ann Conacher, Project Manager (Decontamination) at ann.conacher@hps.scot.nhs.uk.

Guidance on Endoscope Re-processing

17. Guidance on the requirements for decontamination equipment, facilities and management in Endoscope Reprocessing Units is now available on the HPS website. This document gives a summary of the options available to achieve a compliant provision for decontamination of reusable flexible endoscopes.

18. The guidance is a working draft for consultation and comments should be submitted to Joan Sneddon at HPS (joan.sneddon@hps.scot.nhs.uk) by 31st March 2005.

19. The endoscope guidance is not intended to replace expert advice available from Authorised Persons (Sterilizers) who should be consulted for further detailed guidance and, in particular, guidance on the choice, validation, maintenance, testing and operation of decontamination equipment.

Action

20. NHS Board Chief Executives should comply with the revised compliance dates, address the Action Points at Annex C and bring the contents of this HDL to the attention of:

- All General Medical and Dental Practitioners, podiatrists, optometrists, and other healthcare professionals engaged in the local decontamination of re-useable instruments;
- Senior Infection Control Managers (per HDL(2001) 10) for onward dissemination to infection control teams and those involved in local decontamination;
- Sterile Services Managers;
- Directors of Public Health;
- Consultants in Public Health Medicine (CD&EH);
- Consultants in Dental Public Health;
- Clinical Directors of Dental Services;

- Risk Management Committees;
- Clinical Governance Committees;
- Directors, Primary Care Estates; and
- Any other relevant staff.

Yours sincerely

P. S. Collings

PETER COLLINGS
Director of Performance Management and Finance

Outline of the revised phased approach to Local Decontamination

1. The initial priority is to focus on getting the working processes right, through advice, education and training. The issues listed in Annex B should be addressed at all sites by the end of December 2004.
2. An education and training programme in local decontamination is currently being developed by the Glennie Decontamination Education Group, and this will be backed up by Glennie Group guidance on local decontamination. It is hoped that these will be in place within the next three to six months.
3. This programme should facilitate the reintroduction of the P-CAT electronic audit tool which aims to assist individual sites and NHS Boards in identifying further areas for improvement, and start to inform option appraisals for future ways of working.
4. The medium to long term (one to five year) decontamination objectives will include issues of training at a more advanced level, aiming to make physical premises fit for purpose, and improved equipment (e.g. use of automated washer/disinfectors).

It is important to note that full compliance with Glennie Technical Requirements for local decontamination (see web links below) does not necessarily require use of an automated washer/disinfector. The mandatory elements however do relate to :

- having explicit policies for purchasing of instruments;
- ensuring effective segregation of clean and dirty processes;
- use of personal protective equipment for operators;
- appropriate use of the correct cleaning materials and methods;
- appropriate use and proper maintenance of automated machinery (ultrasonic baths and sterilisers, water treatment units);
- appropriate storage of instruments;
- training needs assessment and delivery;
- documentation of processes; and
- quality assured processes through appropriate documentation.

Web Links:


- The Glennie Report (2001): Appendix D3 (*Protocol for local decontamination of surgical instruments*): <http://www.show.scot.nhs.uk/sehd/publications/sspr/sspr-14.htm>
- The Glennie Report (2001): Appendix D1A (*Decontamination technical requirements: section on low risk category*): <http://www.show.scot.nhs.uk/sehd/publications/sspr/sspr-11.htm>

Local decontamination of instruments in primary care and related settings

Please share and discuss these priorities which should be addressed at all sites as an interim measure by the end of December 2004 with all members of your team, and regularly review and audit the decontamination processes within your practice.

Priorities for immediate action

1. Don't re-use 'single use' items

Single use items should be labelled as such - the symbol used on packaging is 

Specifying a medical device as single-use is the responsibility the manufacturer of the device. Once removed from the packaging there may be no labelling on the device itself – ensure that it is clearly segregated from re-usable devices of similar appearance.

2. Ensure that decontamination equipment (washer-disinfectors, ultrasonic cleaners, heat sealers, sterilizers, water treatment units) is used in accordance with the manufacturers instructions.

If you don't have the instruction manual for your ultrasonic cleaner, steriliser, or other equipment, make sure you get a copy - please read it and follow the written instructions. Your NHS Board Authorised Person (Sterilisers) or Scottish Healthcare Supplies may have a copy of the appropriate steriliser instructions if the manufacturer can't supply one – contact details are in Annex 2.

3. Ensure that decontamination equipment is properly maintained day-to-day.

Change the water in the reservoir of benchtop steam sterilizers regularly – at least daily – using purified bacteria-free water (this can be freshly distilled or reverse osmosis water, or sterile water for irrigation – there may be local bulk purchasing arrangements for the latter).

Change the solution in the ultrasonic bath regularly – at least each morning /afternoon session, or more frequently if there is a high throughput of contaminated instruments.

Remember that reverse osmosis (RO) and distillation equipment need regular maintenance too – check the manufacturer's instructions.

4. Ensure that decontamination equipment is tested regularly to ensure that it is working.

Is your steriliser working properly? If not, all your work counts for nothing. Get your steriliser tested now, and get it serviced quarterly by a qualified person.

Do you know if your ultrasonic cleaner is actually working? You can carry out a test for your ultrasonic bath now (see Annex 2), and add this to your maintenance contract.

5. Ensure that the load to be sterilized is appropriate for the type of sterilizer being used.

Don't wrap instruments or place them inside a solid bowl before sterilising in a bowl & instrument type sterilizer (also known as an unwrapped instruments and utensils steriliser) – they won't sterilise reliably. Only wrap before sterilising if you have a

vacuum type steriliser - if in doubt, consult the instructions. If you are wrapping after sterilization, remember to visually check instruments for dryness first.

6. Ensure you have pressure vessel insurance for pressure vessels in your practice.

If you have a steam sterilizer of any type, you are legally required to have specific pressure vessel insurance. NB standard generic insurance policies do not cover this. Your insurance broker or Primary Care Estates advisor can help. There may be local discounts for bulk policy purchase available.

7. Ensure the layout of your decontamination facility is fit for purpose.

Decontamination should be segregated from other activities so that cross-contamination cannot occur.

The flow of work should be a one-way trip from dirty at one end of the bench to sterile at the other. Don't splash or drip dirty water onto sterilised instruments, or onto the surfaces they will be laid out on. If space is short, clean up between parts of the process

Don't use the same sink for cleaning instruments prior to sterilisation and other activities (e.g. general cleaning, food/drink preparation, hand washing), and especially keep cups and plates well away from where they could be splashed while cleaning dirty instruments. If you have only one all-purpose sink, use dedicated bowls to clean and rinse instruments as an interim measure, and decontaminate the bowls regularly. When cleaning instruments by hand, keep brush and instruments under the water while scrubbing to prevent splashes and aerosols.

8. Use the correct detergent solution for manual cleaning.

*Use a neutral detergent intended for use with medical devices, at the correct dose, in the right volume of water, at a hand-hot temperature. **Plain water won't do the job.***

Don't use inappropriate cleaning agents: chlorhexidine (hand) scrub makes proteins stick to metal and does not aid cleaning; abrasive cleaners can cause scratches which can trap contamination.

9. Staff involved in decontamination should wear suitable personal protective equipment - eye and mouth protection, gloves, waterproof apron.

Remember that good hand hygiene and basic infection control precautions are essential for staff and patient safety.

10. When buying new instruments, always check with the supplier that they are compatible with your own decontamination processes.

Some instruments have very specific requirements for decontamination. If you can't meet these requirements given the facilities and procedures you use locally, decontamination may be ineffective and the manufacturer's warranty may be invalid.

Decontamination in Primary Care: Responsibilities of NHS Boards

Purpose

1. This Annex sets out how the Full Technical Requirements for Decontamination, published in the Sterile Services Provision Review Group 1st Report (the Glennie Report), can be assessed and enforced within Primary Care by NHS Boards.
2. The responsibility for ensuring compliance with the General Medical Services contract rests with NHS Boards however, it is for local decision-making how that responsibility is carried out but all NHS Boards are expected to have a system in place.

General Medical Practitioners

3. The majority of GP practices are NHS based however some do undertake some private treatments and only a few practices treat only private patients. The General Medical Services contract for General Practitioners contains two references to compliance with central decontamination standards.

- a) In Contractual and Statutory Requirements there are two mandatory areas:

- (i) that the premises, equipment and arrangements for infection control and decontamination meet the minimum national standards; and

- (ii) that all practices have in place systems of clinical governance which enable quality assurance of its services and promote quality improvement and enhanced patient safety. (The underpinning structures within the practice, which will assure embedding of clinical governance through a nominated lead).

- b) Under Practice Management the requirements are optional and include:

- (i) the arrangements for instrument sterilisation to comply with national guidelines as applicable to Primary Care.

4. The Practice Accreditation Scheme has been developed by Royal College for General Practitioners (RCGP), supported by NHS Quality Improvement Scotland (NHS QIS). In light of the reporting and monitoring requirements of the new GMS Contract, NHS QIS has decided not to support the Practice Accreditation Scheme in the future, however, RCGP will continue the Quality Practice Award developed by them. In addition training practices have to be assessed for suitability for training.

5. Draft National Care Standards for independent medical and general practitioner services will shortly be issued for consultation. These draft standards include a standard for comprehensive policy and procedures for the prevention and control of infection that reflect current relevant legislation and professional guidance.

General Dental Practitioners

6. Whilst some dental services are provided wholly within either the NHS or private sectors, the majority of dental practices carry out a mixture of private and NHS work. Consultation on the draft National Standards for Dental Services, jointly developed by the National Care Standards Committee on behalf of Scottish Ministers and NHS QIS ended on 24th September 2004 and responses are currently being considered. In these draft standards, providers of dental services are expected to have comprehensive policies and procedures that reflect current best practice, guidelines and legislation with practice inspections to be undertaken every 3 years.

7. The requirement for practice inspections is set down in regulation 5A and paragraph 33 of Schedule 1 to the NHS (General Dental Services) (Scotland) Regulations 1996. The power to inspect was discretionary until 2001 but has been mandatory in certain circumstances since then. Regulation 5A gives the NHS Board the discretion to inspect the premises of any dentist applying for inclusion in Part A of its dental list but also requires NHS Boards to inspect a completely new practice i.e. a practice which is not currently or has not previously been on its list, before allowing the dentists who practise there onto the list. The responsibility of ensuring compliance with the set standards rests with the NHS Board.

Other issues

8. 1All private dental and medical services are covered by the Regulation of Care (Scotland) Act 2001 (the Act) and the regulations associated with the Act require services to have appropriate procedures for the control of infection.

9. Assessment and enforcement for GPs and GDPs working in the private sector will be the responsibility of the Scottish Commission for the Regulation of Care (the Care Commission). The Care Commission's timetable relative to independent medical practitioners and dentists is not yet certain but it is likely that the Care Commission will not take responsibility for such assessments until 2006.

10. It is the legal and professional responsibility of all independent contractors including dental and medical practitioners to ensure the adequate control of infection and decontamination of instruments in their practice regardless of whether the work is carried out for NHSScotland or wholly within the private sector.

Action

11. NHS Boards are asked to:

- implement local arrangements to ensure General Practitioners, under the General Medical Services contract comply with the Glennie national decontamination standards; and
- ensure compliance of General Dental Practitioners through the existing Practice Inspection process with the Glennie national decontamination standards.

Scottish Executive Health Department
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