SCOTTISH EXECUTIVE

Health Department
Directorate of Finance

20 August 2001

Dear Colleague

HEALTHCARE ASSOCIATED INFECTION: REVIEW OF DECONTAMINATION SERVICES AND PROVISION ACROSS NHSSCOTLAND

Purpose

1. This letter

- advises NHS trusts and health boards in Scotland that a report (the 'Glennie Framework') on an initial review of decontamination services and provision across NHSScotland (NHSS) is now available on the Scottish Executive Health Department's web site http://www.show.scot.nhs.uk/;
- provides a summary of key points in the report;
- details the action to be taken by NHS Trusts and the Island Health Boards.

Background

2. The 'Glennie Framework' is the first of a series of reports by a joint NHSS/SEHD Group led by John Glennie, Chief Executive Borders General Hospital NHS Trust that is undertaking a review of decontamination/sterile service provision across NHSScotland. Further details on events that led to the establishment of this Group are in NHS HDL(2001)10 - see http://show.scot.nhs.uk/publications/pubindex.htm.

3. The work on decontamination services also links to work being undertaken jointly by SEHD and NHSS on infection control, monitoring Healthcare Associated Infection, and on hospital cleaning standards. More details on these related initiatives are provided in (HDL(2001)57, and in HDL(2001)53, also at http://show.scot.nhs.uk/publications/pubindex.htm.

Addresses

For action
Chief Executives, NHS Trusts and Island Health Boards
Chief Executive, Clinical Standards Board for Scotland

For information
Chief Executives, Health Boards
Common Services Agency
Scottish Ambulance Service
State Hospitals Board for Scotland
Directors of Finance,
Health Boards and NHS Trusts

The Director, Mental Welfare Commission for Scotland.
Executive Director, SCPMDE.
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4. On decontamination services, the Department's programme has three elements:

- reducing the potential risk of person to person transmission of vCJD via surgical instruments in those clinical services that present the highest theoretical risk;
- introducing standards for monitoring NHS Trusts' decontamination processes;
- developing cost effective decontamination services in all NHS Trusts.

5. A copy of the Executive Summary of the Glennie Framework is attached at Appendix 1. In brief the Framework:

- reports on a self assessment survey (March 2001) of NHSS Trusts' decontamination services;

- reports on an independent survey of the 10 units in Scotland that provide decontamination services for devices used in neurosurgical and 'back of the eye' ophthalmological procedures, procedures assessed as having the highest theoretical risk of person to person transmission of vCJD;

- sets Technical Requirements that NHSS Trusts and Island Health Boards must meet to ensure the theoretical risks of vCJD transmission are minimalised;

- provides a framework of service reconfiguration options for trusts on upgrading decontamination provision.

6. The Technical Requirements have been set relative to the assessed level of potential risk for person to person transmission of CJD in a range of clinical procedures. Appendix 2 to this HDL summarises the clinical procedures and the risk categories (high, medium and low) into which they fall. Full details of the Technical Requirements within each risk category are provided at Appendix D.1A of the Glennie Framework. Supporting advice and guidance on the requirements are at Appendices D.1B, D.2 and D.3 of the Framework.

7. The Framework Report makes no firm recommendation on the reconfiguration options. However, to focus discussion and thinking, the Group's stated preference is for the current number of NHS central sterile service departments (CSSDs) to be reduced to 12 sites. However, the Report recommends that all local decontamination processes in the acute sector (except for flexible endoscopes for which further guidance will be forthcoming), and for minor surgical procedures undertaken by general medical practitioners, should in future be processed through the reconfigured/upgraded CSSDs. Discussions on the future configuration and provision of decontamination facilities in the wider primary care sector will be reported at a later stage.

8. Ministers have accepted the Framework Report and its recommendations and NHSS trusts and the Island Health Boards are, therefore, required to implement its recommendations and the action points detailed below.

Implementation of Technical Requirements

9. The Framework Report recommends that:

- by December 2001, instruments used in high risk procedures must be decontaminated in processes that meet the Interim Technical Requirements

- by March 2002, instruments used in medium and low risk procedures in the **acute sector** must be decontaminated in processes that meet Interim Technical Requirements

- by March 2004, instruments, in both acute and primary care settings, should be decontaminated in processes that meet the Full Technical Requirements.

Note: further guidance on the timescale for the **primary care sector** to meet Technical Requirements for medium and low risk procedures will be provided by March 2002.

10. The initial requirement for meeting the recommendations above is for NHSS Trusts and Island Health Boards to produce an action plan that details how they propose to achieve the required compliance. The Action Plans should:

- Summarise the current level of performance in relation to the Interim and Full Technical Requirements.

- Outline planned or proposed service configuration changes.

- Detail the steps and timeframe to be taken for reaching (a) the Interim and (b) the Full requirements in terms of equipment, processes, facilities, staff and management.

- Confirm the amounts for decontamination services within current capital plans.

- Provide, in the form of an Initial Agreement (per normal Capital Procedures), an estimate of the capital and non-recurring revenue costs for making the transition from Interim to Full Technical Requirement.

12. The Action Plans for all acute trusts and Island Health Boards should be submitted to SEHD (Colette Templeton, Finance Directorate, Room 401, 16 Waterloo Place, Edinburgh, EH1 3DN) by no later than 9th November 2001.

Interface with CSBS Standard/Technical Support and Assistance

13. It is important to note that the Clinical Standards Board for Scotland (CSBS) Standards (as reported in HDL(2000)53) and the Technical Requirements described in the Glennie Framework are related but are not the same. The CSBS Standard relates to the quality of Trusts' systems to control decontamination processes, the Technical Requirements to the performance levels that Trust systems should achieve.

14. Further details on the interface are at Appendix 3, which also details the technical support and assistance being given to service providers for meeting both the CSBS and Glennie requirements. However, it should be noted that completion of the SCOTPAT documentation, coupled to the support from the SCIEH decontamination team, will provide most of the data and information required to enable Trusts to draft the Action Plan commissioned above.

Next Steps

15. The Action Plans and Interim Agreements will be assessed by the Glennie Group prior to submitting a final to SEHD with recommendations for the future reconfiguration of sterile service provision in the acute sector.

16. The Department will decide what resources may be made available in light of the Action Plan submissions and Glennie Group recommendations.

17. As indicated above, the assessment programme for the primary care sector will follow a later timetable. However, in preparation for that action, Primary Care Trusts should identify and detail those Trust managed services and sites where medium risk procedures are carried out and report these to SCIEH by end-October 2001. A template for supplying this information to SCIEH will be sent to each PC Trust in due course.

Action Summary

18. NHSS Trust and Island Health Board Chief Executives should:

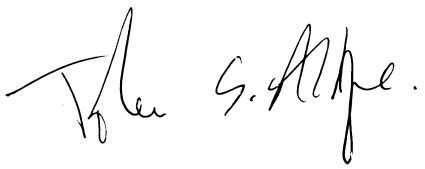
- Draw the content of this HDL to the attention of the Trust/Board's senior manager with overall responsibility for decontamination, Trust Infection Control Committees, sterile service managers, estates and facilities managers, theatre managers and all other relevant personnel.

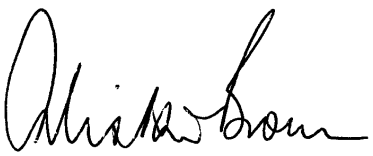
  Note: Attention should be drawn specifically to the Technical Requirements sections at Appendix D of the Glennie Framework.

- (Acute Trusts and Island Health Boards) Ensure that the required baseline assessment return is submitted to SCIEH no later than 2 weeks after the end of their Decontamination Review Team visit. Appendix 3 refers.

- (Primary Care Trusts) Ensure that the required details outlined at paragraph 17 (template to follow) are submitted to SCIEH (Mary Henry) no later than end October 2001.

- (Acute Trusts and Island Health Boards) Ensure that the Action Plans, in line with paragraph 10 are submitted to SEHD for no later than 9th November 2001.





JOHN ALDRIDGE
Director of Finance

ALISTAIR BROWN
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APPENDIX 1

EXECUTIVE SUMMARY

Introduction

This is the first of a series of reports by a Group led by John Glennie, Chief Executive Borders General Hospital NHS Trust (the 'Glennie Group') that is undertaking a review of sterile service provision across NHSScotland.

The Group was established in response to recommendations in a report by a Group chaired by Dr David Old (then Reader in Medical Microbiology at the University of Dundee) that reviewed NHSScotland's compliance with published guidance on the decontamination of medical devices.

The driver behind both reviews is a public health priority to reduce the potential risk of person to person transmission of vCJD via re-usable surgical instruments.

The conclusion of the 'Old Report' was that whilst there were examples of good practice, many decontamination processes fell below current standards. In some cases, practice was unacceptably poor. As a result there is a continuing risk of adverse health occurrences to both patients and staff.

The 'Glennie Group' was established in December 2000. Membership details are at Appendix A.1 and the Group's initial remit was as follows:

- To identify the nature and scope of current sterile service provision in NHSScotland.
- To develop a framework for change with specific regard to achieving the required technical and operational standards in the most cost effective way possible .
- To identify the means of achieving change.

Review Coverage

The review included a self assessment survey by Scottish NHS Trusts and Island Health Boards of their decontamination practices and procedures. The following report refers to this survey as the Main Review. The data gathered from the review, covering management and operational aspects of service provision, underpins the Group's analyses and initial conclusions.

Additionally, an independent assessment was made of the decontamination processes in the 10 units in Scotland that carry out neurosurgical or ophthalmological procedures involving the back of the eye. This followed concerns expressed by the UK Government's Spongiform Encephalopathy Advisory Committee (SEAC) about the higher risk (theoretical) of person to person transmission of vCJD through surgical instruments used in such procedures. This is referred to as the 'Fast Track' Review.

Key Findings

The main headlines to come from both the main and fast track reviews were:

- There are 28 central sterile services departments(CSSDs) operating in Scotland. The total includes one private provider, Trust Sterile Supplies Ltd. (TSSL), based at Bellshill, Lanarkshire. A map of the 28 locations is at Appendix B.1.
- Only 4 of the 28 CSSDs (3 NHS and TSSL) are currently accredited to the required EN46002 quality standard in accordance with medical devices directive 93/42/EEC. Accreditation is awarded by a notified body appointed for this purpose by the Medical Devices Agency (MDA). Appendix D.2 refers.
- A further 3 NHS trusts have committed investment to achieve EN46002 accreditation.

- Only 1 of the 10 neurosurgery and ophthalmic surgery sites met set technical requirements (Appendix E).

- Excluding TSSL and Island Health Boards, revenue costs are approximately £15 million.

- Overall some 37 million instruments are estimated to be processed annually in CSSDs by approximately 450 NHS employed whole time equivalents (WTEs).

- Local decontamination units (LDUs)[1] process a further (estimated) 32.3 million instruments annually.

- An additional (estimated) 164 million instruments are processed locally by independent general dental practitioners annually.

- The majority of CSSDs currently operate significantly below optimum capacity levels.

- Facilities are generally operated on a single day shift system 5 to 5.5 days per week with partially manned back and night shifts systems.

- Staffing/productivity ratios differ between CSSDs with consequent variations in processing costs. The cost per item ranges between £1.11 and £0.16 against an average of £0.46.

This Report

This Report, the Glennie Framework, addresses the first two remit objectives listed above. It focuses mainly on the acute sector, the area with the highest level of risk relative to vCJD, covering activity for all centralised sterile service departments (CSSDs), all locally processed acute sector activity, dental hospital activity, and minor procedures by general medical practitioners. It does not cover, in any great detail, locally processed primary care trust (PCT) activity nor dental activity in community healthcare facilities and by private or independent dental practitioners. Further data is being collected for these areas of activity and will be reported upon at a later stage.

The Report is not a blue print for future service provision. Instead it provides a Framework within which NHS trusts and the Island Health Boards can plan to upgrade and/or reconfigure their decontamination processes to comply with the Technical Requirements (listed at Appendix D.1) that the Group considered will minimise risks for the potential transmission of vCJD. It provides trusts and health boards with data and a range of options on which to develop and cost local solutions to suit local circumstances. In so doing it seeks to encourage collaboration and joint working between trusts.

Framework Criteria

The Group considered the two key issues relative to the future provision of decontamination activity were:

- Compliance with the set Technical Requirements for managing the risk of vCJD transfer.

- Identification of nature and scope of future CSSD provision with specific regard to:

    - Location
    - Activity
    - Value for Money (VFM)
    - Technical Requirements

The Group was aware that a considerable number of legislative and best practice standards exist for decontamination of re-usable medical devices. However, the Group's primary concern was to address the potential risk of transmitting vCJD through such devices.

[1] For the purpose of the Report LDUs are taken to mean ward or operating theatre or clinic or general medical or dental practice based facilities where only instruments from within that clinical department are decontaminated before use. The items of equipment employed are usually bench top sterilisers or washer disinfectors.

Accordingly, the Group devised a Technical Requirements matrix (Appendix D.1) to categorise clinical procedures into risk ratings of High, Medium and Low, and allocates the legislative/advisory standards against them at 'Interim' and 'Full' levels and across the function headings of Equipment, Facilities, Staff and Management. The risk matrix relates specifically to CJD and does not mirror other risk classifications drawn from the Microbiological Advisory Committee Manual.

The Group considered that all CSSDs must comply with the Full Technical Requirement by no later than March 2004. But in between, CSSDs dealing with high risk instruments must reach the Interim Requirement by December 2001 and all other CSSDs, dealing with medium and low risk procedures, by end March 2002. The situation for primary care trusts and dental practitioners will be addressed and reported later.

Framework Options

Options for change in service configuration were considered on the following activity scenarios, each level being related to the previous on a sequential basis:

> Level 1: All current CSSD related activity including the three dental hospitals.
>
> Level 2: All activity associated with Level 1 above plus transferring to CSSDs all localised acute hospital related activity and activity associated with minor procedures undertaken by general medical practitioners.
>
> Level 3: All the activity associated with Levels 1 and 2 above plus transferring to CSSDs all localised primary healthcare related activity managed by Primary Care Trusts (community dentistry and chiropody predominantly) and all activity associated with independent and private dental practitioners.

The key principle for all options is to make best use of the existing infrastructure by upgrading CSSDs where this is considered feasible. Where that is not the case, the options highlight possible new-build requirements.

Based on the information provided by trusts, through the main and fast track reviews, it was established that only 10 of the 24 mainland NHS sites could feasibly be upgraded to the set Technical Requirements. Additionally, it was considered that given the current state of 6 of the CSSDs in Glasgow (i.e. excluding linen services and the dental hospital), future sterile service provision in Glasgow could only be accommodated through either a new build solution, leasing or outsourcing.

At this stage, no consideration was given to whether Public/Private Partnerships (PPP), leasing or outsourcing were the preferred routes for reconfiguration. That issue will be addressed by trusts when developing their business cases at the post-Framework stage, where major investment is required.

Therefore, for the purposes of developing options, the Group considered that the future maximum number of NHS mainland CSSD sites should be 12, i.e. 10 upgrades and 2 new builds. On this basis the estimated cost for reconfiguration to 12 sites, including investment for Fast Track upgrading, was calculated as:

Net capital costs	£17,031,000
Non recurring Revenue Costs	£8,235,100
Recurring Revenue Costs	£2,152,500

Costings were also made for a service configuration based on 11, 10 and 9 sites. The variations to the above estimates were not significant and fell in the following ranges for 11 sites down to 9 sites:

Net capital costs	£16,831,000 - £16,381,000
Non recurring Revenue Costs	£6,443,900 - £6,737,300
Recurring Revenue Costs	£2,162,500 - £2,217,500

Irrespective of the number of CSSDs maintained, to allow the local acute activity to be processed centrally (per Level 2 options) the following costs will be incurred. These are additional to the costs detailed above and relate specifically to upgrading the facilities at Ninewells Hospital (Tayside).

Capital costs	£3,000,000
Non recurring Revenue Costs	£337,847
Recurring Revenue Costs	£2,028,110

Options: Key Points Summary

Level 1 Options

- A maximum of 10 CSSDs are capable of being upgraded to meet the set technical requirements.
- Glasgow requires a maximum of two facilities (new build/ leased/ contract out).
- To ensure acceptable operational capacity is achieved there should be a maximum of 12 CSSDs and a minimum of 9.
- Capital requirements range from £17.031 million for 12 sites to £16.381million for 9 sites.
- Approximately £8.5 million is required for additional instrumentation and non-capital equipment.
- Recurring revenue costs of approximately £2 million per annum will be incurred.

Level 2 Options

- All locally processed acute sector activity can be accommodated within the Level 1 options.
- Inclusion would incur additional capital costs of £3 million, non-recurring revenue of £0.338 million, and recurring revenue of £2.028 million.

Level 3 Options

- Only 3.5 percent of locally processed primary health care sector activity and activity associated with independent and private dental practitioners can be accommodated within Level 1 and 2 options.

Preferred Option

The Group decided not to make a firm recommendation on any option. This reflects the complexity and incompleteness of the data and the extent to which reliance must, at this stage, be placed on assumptions and estimates. It also reflects the strong view of the Group that for the required reconfiguration to be implemented effectively and timeously, it must have NHS trust ownership and support.

However, the Group considered it should identify a preferred option on which discussions for local solutions could be based. The Group's considerations are at section 4.4 of the Report and the conclusion, particularly in light of capacity and contingency considerations, the 12 site option is the preferred model.

Recommendations

- With immediate effect, all posterior ophthalmic and neurosurgical re-usable instrumentation must be processed locally in line with the 'Protocol for Local Decontamination of Surgical Instruments' (Appendix D.3)

- By end December 2001, all posterior ophthalmic and neurosurgical re-usable instrumentation should transfer to CSSDs that meet the Interim Technical Requirements per Appendices D.1.

- By end March 2002, all other CSSDs must comply with Interim Technical Requirements.

- By no later than March 2004, and within individually set timescales, all reconfigured CSSDs/sites must comply with the Full Technical Requirements.

- By end October 2001, all acute trusts to prepare a local action plan to detail how they will progress to both the Interim and Full Technical Requirements.

- Action plans with capital/non-recurring investment proposals for reaching the Full Technical Requirement to be supported by an Interim Agreement submission.

- Any central resources made available by SEHD should be:

    - for capital and non-recurring revenue purposes only;

    - limited to works that secure the Full Technical Requirement;

    - for schemes that align to the Framework or offer viable alternatives.

- Agreed investment proposals to be processed in accordance with SEHD's Capital Investment procedures and within stipulated timescales.

- Further work is undertaken for the remaining activity associated with primary care trusts and independent dental practitioners.

Action & Next Steps

The NHS trusts involved in the Fast Track reviews have already presented action plans for bringing their facilities up to the Interim Technical Requirement by the due date of December 2001. Given the potentially high risk nature of services in this area, the Scottish Executive Health Department has agreed to fund duly approved upgrading costs.

All NHS trusts will be advised by SEHD to prepare action plans for making their service provision compliant to the Interim and Full Technical Requirement. The submission deadline for acute NHS trusts is end October 2001. The deadline for primary care trusts will be set later, following further data collection and analysis by the Glennie Group.

The Glennie Group's second report, due in the latter part of 2001, will summarise the acute trusts' action plans and make costed recommendations for reconfiguring decontamination services and the pace of implementation.

DECONTAMINATION PROCESSES: TECHNICAL REQUIREMENTS

Clinical procedures*

Categorisation by risk for all types of CJD

High risk procedures

- All procedures that involve piercing the dura, or contact with the trigeminal and dorsal root ganglia, or the pineal and pituitary glands.
- Procedures involving the optic nerve and retina.

Medium risk procedures

- Other procedures involving the eye, including the conjunctiva, cornea, sclera and iris.
- Procedures involving contact with lymphoreticular system (LRS).
- Anaesthetic procedures that involve contact with LRS during tonsil surgery (for example laryngeal masks).
- Procedures in which biopsy forceps come into contact with LRS tissue.

Low risk procedures

- All other invasive procedures including other anaesthetic procedures and procedures involving contact with the cerebrospinal fluid.

* Further risk assessment to be undertaken on categorisation of dental tissues that are currently considered as low risk.

APPENDIX 3

NOTE ON INTERFACE BETWEEN CAREY REPORT STANDARDS AND GLENNIE FRAMEWORK TECHNICAL REQUIREMENTS

HDL(2001)53 advised of Ministers' acceptance of recommendations made by a joint SE Health Department/NHSScotland working group chaired by Richard Carey, Chief Executive of Highland Acute Hospitals NHS Trust. The Carey Group was established to develop a comprehensive framework for use by NHSScotland in managing the risks of infection and to advise on standards and compliance thereon. Annexes to the Carey Report set out draft standards for infection control, hospital cleaning services, and the decontamination of re-usable medical devices. These standards have now been adopted by the Clinical Standards Board for Scotland (CSBS).

It is important to note that the CSBS Standards and the technical requirements set by the Glennie Framework are related but are not the same. The former relates to the quality of Trusts' systems to control decontamination processes, the latter to the performance levels which the Trust systems should achieve.

CSBS now has responsibility for consulting on and piloting the standards, and ultimately establishing an accreditation process for each. The pilot for decontamination services is taking the form of a baseline assessment of practices at organisation level. To assist the process, the Property and Environment Forum (P&EF) has produced the Scottish Process Assessment Tool (SCOTPAT), the principal objectives of which are to:

- enable NHSScotland organisations to develop a detailed picture of decontamination provision based upon an assessment of current practices against CSBS standards and best practice guidance;
- enable NHSScotland organisations to identify areas of risk;
- highlight areas for potential service centralisation or rationalisation within the organisation;
- enable a consistent approach to data collection and recording of decontamination issues.

SCOTPAT is an initial self assessment tool for decontamination processes. The forms will be available on the SHOW and P&EF web sites from mid to end-August. To assist organisations in the completion of the forms, and associated tasks, the Health Department commissioned SCIEH to establish a team of decontamination experts to visit all acute trusts and Island Health Boards by end September. The SCIEH team will provide training on the use of SCOTPAT and the techniques for completing the baseline assessment. Thereafter, acute trusts are tasked with reporting the outcome of their individual baseline assessment, against the CSBS standards, to SCIEH by 2 weeks following the visit of the Decontamination Review Team.

Additionally, acute trusts must submit, by 9th November at the latest, an Action Plan to the Department for achieving compliance with the Interim and Full Technical Requirements for medium and low risk procedures (per Appendix 2) by the due dates (at paragraph 9 at the front of this HDL).

Completion of the SCOTPAT documentation, coupled to the support from the SCIEH decontamination team, will provide most of the data and information required to draft the Action Plan.

Primary care trusts will be required to undertake the same baseline assessment and report processes outlined above at a later point in time. In the first instance they are being asked to submit, to SCIEH by end-October 2001, information on the sites where medium risk decontamination procedures are being carried out.