

Health Service Circular



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sets out a specific action on the part of the recipient with a deadline where appropriate

Decontamination of medical devices

For action by: Health Authorities (England) - Chief Executive
NHS Trusts - Chief Executives
Primary Care Trusts - Chief Executives

For information to: Dental Postgraduate Deans
Directors of Education & Training
Health Authorities (England) - Directors of Nursing
Medical Schools - Deans
Post Graduate Deans
Regional Advisers in General Practice
Dental Schools - Deans
Regional Directors
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Primary Care Groups - Chief Executives
Primary Care Groups - Chairs
NHS Trusts - Medical Directors
NHS Trusts - Directors of Nursing
NHS Trusts - Chief Pharmacists
NHS Trusts - Chairs of Infection Control Committees
PHLS - Directors

Further details from: Regional decontamination leads
Contact details within this circular

Additional copies of this document can be obtained from:

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It is also available on the Department of Health web site at
<http://www.doh.gov.uk/coinh.htm>

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Decontamination of medical devices

Summary

Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to make a re-usable item safe for further use on patients and handling by staff. The effective decontamination of re-usable medical devices* is essential in reducing the risk of transmission of infectious agents.

HSC 1999/179 emphasised the importance of implementing guidance on the cleaning and sterilization of medical devices, since this is of the utmost importance in reducing the risk of transmission of infectious agents. HSC 1999/178 stated that effective cleaning of surgical instruments prior to sterilization is of the utmost importance in reducing the risk of transmission of vCJD via surgical procedures.

Following the issue of HSC 1999/179 and the reissue, on CD-ROM and *NHSnet*, of Department of Health guidance on the complete process of decontamination of medical equipment, a snapshot survey of current decontamination practices in a small number of healthcare premises in England has been carried out. A more comprehensive review of decontamination provision across the health service now needs to take place so that plans for the future can be based on national findings. There are also some immediate steps that should be taken, without waiting for the outcome of the review, to minimise any risks associated with decontamination.

This circular identifies the immediate and medium-term actions required to ensure that decontamination is carried out effectively. It also sets out the information needed to gather a robust picture of decontamination provision nationally and describes the support available to assist NHS trusts, Health Authorities and Primary Care trusts in delivering the actions required.

Action

(The website referenced in the actions below can be found at <http://www.nhsestates.gov.uk>. It contains the annexes referred to, as electronic documents for downloading and completion either electronically or in printed form.)

Chief Executives of NHS trusts should:

Immediately (By 01 November 2000):

- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Regional Office decontamination lead (listed on page 6 of this circular). Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel including, where applicable, Infection Control Teams, Sterile Service managers, Estates and Facilities managers and Theatre managers;

By 17 November 2000:

- send a report to the Regional Office decontamination lead, using the checklist (Annex A) on the website, recording the actions being taken to ensure that appropriate management arrangements are in place to oversee and improve where necessary the overall process of decontamination;
- send a report to NHS Estates (which will be forwarded on to Regional Office decontamination leads), using the audit tool (Annex B) on the website, identifying any issues of immediate potential risk to patients and staff;
- ensure that the proforma (Annex C) on the website is completed to indicate the age and condition of decontamination facilities and equipment, and is returned to NHS Estates (who will forward it to the Regional Office decontamination lead).

By 15 December 2000:

- send a report to NHS Estates (which will be forwarded on to Regional Office decontamination leads), using the action plan (Annex D) on the website, recording the actions being taken to address any issues of immediate potential risk to patients and staff;

* A medical device is any instrument, apparatus, appliance, material or other article whether used alone or in combination, intended by the manufacturer to be used for human beings for the purpose of: control of conception; diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or physiological process. Surgical instruments are medical devices.

By 31 March 2001:

- ensure that a comprehensive review is carried out of all aspects of the overall process of decontamination, and use this to complete a baseline self-assessment and develop an action plan against the controls assurance decontamination standard.

By 31 March 2002:

- have taken steps towards having systems in place to enable the tracing of surgical instrument sets to patients on whom they have been used.

Chief Executives of Health Authorities should:

Immediately (by 01 November 2000):

- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Regional Office decontamination lead (listed on page 6 of this circular). Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel including, where applicable, Consultants in Communicable Disease Control, Directors of Public Health, Directors of Primary Care (or equivalent), Primary Care Medical Advisors, Pharmaceutical Advisors, Directors of Nursing and Infection Control Doctors and Nurses;

By 15 December 2000:

- working with PCG Chief Executives and Clinical Governance leads where appropriate, ensure that independent contractors, including GPs (GMS & PMS), Dentists (GDS & PDS), Pharmacists and Optometrists, are aware of and understand their responsibilities for ensuring compliance with the contents of this HSC and the associated website and are encouraged to review their own practice;
- ensure that all private and voluntary healthcare providers registered under the 1984 Registered Homes Act are aware of their responsibilities for ensuring compliance with the contents of this HSC and the associated website;
- arrange for the contact details of the senior member of staff responsible for decontamination in PCTs to be recorded in a local database so that further information can be disseminated as necessary (PCTs have been instructed to send details of their relevant senior member of staff to the HA Consultant in Communicable Disease Control by 01 November 2000);

By 31 March 2001:

- ensure that inspection of registered independent healthcare providers verifies adequate compliance with Department of Health guidance on decontamination.

Chief Executives of Primary Care trusts should:

Immediately (by 01 November 2000):

- forward contact details for the senior member of staff with responsibility for managing all aspects of decontamination to the Health Authority Consultant in Communicable Disease Control. Contact details provided should include name, position, address, telephone no., fax no. and email address. A form that can be used is available on the website;
- ensure that this circular is brought to the attention of all relevant personnel, including Clinical Governance leads;

By 17 November 2000:

- where their organisation is a direct provider of community health services, send a report to the Health Authority Consultant in Communicable Disease Control, using the checklist (Annex A) on the website, recording the actions being taken to ensure that appropriate management arrangements are in place to oversee and improve where necessary the overall process of decontamination;
- where their organisation is a direct provider of community health services, send a report to NHS Estates (which will be forwarded on to the Health Authority), using the audit tool (Annex B) on the website, identifying any issues of immediate potential risk to patients and staff;
- where their organisation is a direct provider of community health services, ensure that the proforma (Annex C) on the website is completed to indicate the age and condition of decontamination facilities and equipment, and is returned to NHS Estates (who will forward it to the Health Authority).

By 15 December 2000:

- ensure through PCT Clinical Governance leads that GPs are aware of their responsibilities for ensuring compliance with the contents of this HSC and the associated website and are encouraged to review their own practice;

- where their organisation is a direct provider of community health services, send a report to NHS Estates (which will be forwarded to the Health Authority), using the action plan (Annex D) on the website, recording the actions being taken to address any issues of immediate potential risk to patients and staff;

By 31 March 2001:

- where their organisation is a direct provider of community health services, ensure that a comprehensive review is carried out of all aspects of the overall process of decontamination.

Further information and details of requirements

General

HSC 1999/179 emphasised the importance of implementing existing guidance on the cleaning and sterilization of medical devices and required Chief Executives of NHS trusts and Health Authorities to ensure that guidance was observed. A snapshot survey of current decontamination practices in a small number of NHS trusts, general medical and dental practices and private and voluntary sector hospitals has since been carried out. It is now important to ensure that any associated risks are effectively managed by all healthcare providers, at the same time as gathering a more comprehensive picture of decontamination provision across the NHS to inform medium-term action plans.

Effective management control systems

Decontamination is vital to the effective delivery of patient care. The overall decontamination process can include purchasing and acquisition of instruments and equipment, cleaning and disinfection of instruments, packaging of instruments, sterilization and transport, storage and disposal. It requires effective management systems, often spanning a range of disciplines and locations within one organisation.

The checklist (Annex A) at <http://www.nhsestates.gov.uk> identifies a number of management issues associated with decontamination. It should be used to confirm that appropriate management arrangements are in place.

Immediate risk issues

There are a number of health and safety issues associated with decontamination (including uncontrolled use of chemicals and inappropriate use of processes) that potentially put patients and staff at direct risk of injury. These apply to NHS hospitals, general medical and dental practices and private and voluntary hospitals. It is essential that all such practices should be identified and immediate checks made to ensure that they are adequately addressed. An audit tool and proforma action plan are available at <http://www.nhsestates.gov.uk> and should be used to confirm that the identified issues are being handled appropriately.

Comprehensive review of decontamination processes

Short-term actions taken to address management and immediate risk issues should be seen as the first step in a comprehensive review of decontamination practice. This review should include management arrangements, policies and procedures, facilities, purchasing (of both medical devices and decontamination equipment), washing, disinfection and sterilization practice, record-keeping, validation and maintenance. It should cover both existing practices and a strategic assessment of the way in which decontamination services are provided.

A technical manual of guidance will be published later this year. This will provide detailed support to assist individual organisations in carrying out a comprehensive review of decontamination practice. Details will be notified when available, via the website at <http://www.nhsestates.gov.uk>

An HSC to be issued shortly (Controls Assurance statements 2000/2001 and establishment of the Controls Assurance Support Unit) will require NHS trusts to complete a baseline self-assessment against a new controls assurance standard on the decontamination of re-usable medical devices. The technical manual may be used by organisations to assist in completing this assessment and in developing an action plan that clearly sets out how the required standards will be achieved and maintained.

Traceability

It is important that systems are in place to allow sets of surgical instruments to be tracked through decontamination processes in order to ensure that the processes have been carried out effectively. Systems should also be implemented to enable the identification of patients on whom instrument sets have been used. This is important so that relevant patients can be identified in the event of exposure to a potential risk, and is relevant to both the primary and secondary care sectors. This requirement for traceability of instrument sets is in addition to the measures for identification and tracing of flexible endoscopes set out in HSC 1999/178.

Implementing Changes

Short-term: The review of vulnerability to immediate risk issues may require provider organisations to make some immediate investment to replace individual pieces of equipment in order to avoid disruption to the delivery of patient care. It is expected that such investment will normally be managed within existing resources.

Medium and long-term: Further information will be required in order to establish service-wide requirements, consider the relative merits of central and local provision of decontamination services and to develop detailed feasibility plans and costs. Collection of this information will be co-ordinated by Regional Offices. Long-term investment, where necessary, will be based on a strategic review of the optimum method of providing decontamination services across an extended geographical area. Implementation arrangements will be decided in the light of the review's findings.

Support

Each Regional Office has identified a lead member of staff to co-ordinate the support available to organisations to ensure that the actions required can be met. The contact details for Regional Office leads are set out below.

A Support Taskforce is being set up to work with NHS trusts, HAs, PCTs and Regional Offices to assist in meeting the recommendations of the decontamination review. This taskforce will include technical advisors with a broad range of experience of practical decontamination issues. Access to the Support Taskforce will be co-ordinated via RO leads, and further details will be notified when available.

Further advice is also available from various parts of the Department of Health and there are various professional organisations that may be able to provide assistance. Information about the advice available can be obtained via Regional Office leads.

The technical manual is a tool to guide organisations, step by step, through the issues they need to address to ensure that decontamination practices meet acceptable standards. It will be able to be used as the basis for the comprehensive review of decontamination practices and assessment against the Controls Assurance decontamination standard.

A series of briefing sessions will be held for the nominated senior managers with overall responsibility for decontamination within their organisation. These sessions will be open to every NHS trust, Health Authority and Primary Care Trust. Dates and venues will be notified via Regional Offices.

Following publication of the technical manual, additional workshops will be held targeted at specialists within organisations (for example infection control doctors and nurses, sterile service managers, estates and facilities professionals, health and safety advisors, risk managers).

Regional Office decontamination leads

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Associated Documentation

"Decontamination Guidance" CD-ROM issued with HSC 1999/179, and available on *NHSnet* at <http://nww.doh.nhsweb.nhs.uk/health/decontamination-guidance.htm>

HSC 1999/123: Governance in the new NHS: Controls assurance statements 1999/2000 risk management and organisational control.
HSC 1999/178: Variant Creutzfeldt Jakob Disease: minimising the risk of transmission.
HSC 1999/179: Controls assurance in infection control: decontamination of medical devices.
HSC 2000/002: The management and control of hospital infection.
Forthcoming HSC: Controls assurance statements 2000/2001 and establishment of the controls assurance support unit.

MDA DB 2000(04): Single-use medical devices: Implications and consequences of reuse.

MDA SN 2000(18): Handling of surgical instruments on loan from another organisation

Guidelines for Implementing Controls Assurance in the NHS. Guidance for Directors. (Nov. 1999)

Controls Assurance Standards 1999/2000: Risk Management and Organisational Controls: Infection Control Standard.

Useful websites

NHS Estates: <http://www.nhsestates.gov.uk>

Medical Devices Agency: <http://www.medical-devices.gov.uk>

NHS Purchasing and Supply Agency: <http://www.pasa.doh.gov.uk>

Controls Assurance:

Internet: <http://www.doh.gov.uk/riskman.htm>

NHSnet: <http://nww.doh.nhsweb.nhs.uk/nhs/riskman.htm>

This Circular has been issued by:

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