

The Health and Social Care Act 2008

Code of Practice for the NHS on the prevention and control of healthcare associated infections and related guidance



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Action required	CEs to work with colleagues, especially Directors of Infection Prevention and Control to ensure compliance with this Code of Practice to help reduce healthcare associated infections.		
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For recipient's use			

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Part 1: Introduction

Background

The Department of Health is firmly committed to reducing healthcare associated infections (HCAI). It has produced a number of documents providing guidance on moving towards compliance with policies, best practice and evidence-based care, including: Getting ahead of the curve; Winning ways: working together to reduce healthcare associated infection in England; Towards cleaner hospitals and lower rates of infection: a summary of action; Clean, safe care – reducing infections and saving lives; Saving Lives: reducing infection, delivering clean and safe care; and Essential steps to safe, clean care: reducing healthcare-associated infections. Participation in the Saving Lives programme is one way to help demonstrate the application of this Code of Practice ('the Code').

The Health and Social Care Act 2008 establishes the Care Quality Commission (www.cqc.org. uk) in place of the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission to register, review, investigate and support improvements in the care provided to patients. This Code of Practice applies to NHS bodies carrying on a regulated activity in 2009/10. For 2010/11, a revised version of the Code covering independent healthcare and social care will be prepared.

Systems to prevent healthcare associated infections

Good management and organisation are crucial to establishing high standards of infection control. The systems for the prevention and control of infections associated with healthcare are expected to address:

- leadership;
- management arrangements;
- design and maintenance of the environment and devices;
- application of evidence-based protocols and practices for both users and staff; and
- education, training, information and communication.

Effective prevention and control of HCAI has to be embedded into everyday practice and applied consistently by everyone. It is particularly important to have a high awareness of the possibility of HCAI in both patients and healthcare workers to ensure early and rapid diagnosis. This should result in effective treatment and containment of the infection. Effective action relies on an accumulating body of evidence that takes account of current practices. This evidence base should be used to review and inform practice. All staff should demonstrate good infection control and hygiene practice. However, it is not possible to prevent all infections.

Purpose of this document

This document sets out how the Care Quality Commission will assess compliance with the requirements set out in Regulations made under section 20(5) of the Health and Social Care Act 2008, and provides guidance on how providers can meet the registration requirements relating to HCAI set out in the Regulations.

All providers must also comply with all relevant legislation, such as the Health and Safety at Work etc Act 1974 and the Control of Substances Hazardous to Health Regulations 2002 and other relevant health and safety regulations.

Failure to observe the Code may result in enforcement action by the Care Quality Commission as it may be used as evidence of a breach of the registration requirement.

In order to aid compliance with the Code of Practice, the bibliography lists supporting national guidance. It is a matter for local determination whether all of the guidance listed is appropriate to each organisation. Users may find the National Resource for Infection Control (www.nric.org.uk) a useful site to access these documents and other relevant material.

Legal framework for the prevention and control of healthcare associated infections in the NHS

From April 2009, certain NHS organisations will be legally required to register with the Care Quality Commission under the Health and Social Care Act 2008 and, as a legal requirement of their registration, must protect patients, workers and others who may be at risk of acquiring an HCAI. The relevant regulation is shown in Part 2 of this document.

This is the first requirement of registration that applies to NHS organisations. Further requirements covering other aspects of the quality and safety of care provision will apply from 2010/11 when requirements for the NHS will be aligned with those for services currently registered under the Care Standards Act 2000, for example private and voluntary healthcare and social care services. The early introduction of the requirement related to HCAI reflects the high priority of, and commitment to, reducing infections associated with NHS healthcare.

For the NHS, this new legal requirement carries forward the requirement to prevent and control HCAI under the Health Act 2006 and elements of the core standards for better health that specifically focus on dealing with infection. The action required of NHS bodies under the new requirement is essentially the same requirement as that under the 2006 Act. There is still flexibility for healthcare providers to tailor their response to HCAI according to particular local risks and circumstances. However, the response to any failure to meet the legal requirement will be different under the new system of regulation.

Until the full range of requirements under the Health and Social Care Act 2008 come into force on 1 April 2010, the standards for better health will continue to apply.

Organisations that are required to register

The NHS organisations that will be required to register are the same ones that currently have to comply with *The Health Act 2006: Code of Practice for the prevention and control of healthcare associated infections*, i.e. NHS trusts, NHS foundation trusts and primary care trusts, and NHS Blood and Transplant. This Code relates to the provision of healthcare provided directly to patients by the body in question and not those commissioned by that body from a third party. It will be an offence for these organisations not to be registered.

Other types of health and social care providers of regulated healthcare and social care activities will have to comply with an equivalent statutory requirement from 2010/11 when they also register under the Health and Social Care Act 2008. Until then, legal requirements under the Care Standards Act 2000, associated regulations and national minimum standards continue to apply, including those related to infection control.

The Care Quality Commission will monitor compliance with the statutory requirement of registration related to HCAI and will judge whether the requirement is met with reference to this Code of Practice. The Health and Social Care Act 2008 enables the Secretary of State for Health to issue this Code.

Actions following breach of legal requirements

In judging whether a breach of legal requirements has occurred, the Care Quality Commission will consider whether there is evidence that action is being taken as detailed in the Code of Practice. If a registered care provider is taking an alternative approach, the provider will need to justify how its approach is better or equally effective in meeting the legal requirement. The Care Quality Commission will also be able to take into account breaches of other relevant legal requirements, for example the Health and Safety at Work etc Act 1974 and the Control of Substances Hazardous to Health Regulations 2002.

Failure to comply with the new statutory requirement is a breach of the requirements of registration under the Health and Social Care Act 2008, and the Care Quality Commission will have a wider range of enforcement powers than were available under the 2006 Act which it can use to respond to such breaches. In these circumstances, it will work closely with partners such as Monitor and strategic health authorities to encourage improvement and protect patients, staff and visitors from harm.

In cases of failure to comply with the registration requirements, the Care Quality Commission may:

- draw the breach to the registered provider's attention and give the provider an
 opportunity to put it right within a reasonable period of time;
- place a registered provider under closer scrutiny for a time;
- issue a warning notice. The notice will provide details of the breach, set out a timescale within which the provider must rectify it and make clear that further action will be taken if the breach is not rectified in time;

- impose conditions on registration. The Care Quality Commission may, at any time, impose conditions that, for example, prevent the provider using a particular ward until it complies with the Regulations;
- issue a monetary penalty notice. The Care Quality Commission has the power to offer a provider a monetary penalty notice in lieu of prosecution;
- suspend registration. The Care Quality Commission can suspend the registration of a provider, stopping it providing a service for a specified period of time. This will give the provider an opportunity to rectify any breach, and then resume service provision. However, no one would be able to access the service during that period;
- prosecute for specified offences. On successful prosecution, the courts will decide on the amount of the fine, up to a maximum of £50,000; and
- cancel registration. In extreme cases, the Care Quality Commission has the power to cancel registration.

The Care Quality Commission also has a duty to notify and publish information about certain enforcement actions so that information about failures will be available to commissioners of healthcare and to the public.

Part 2: The draft Regulations (extract)

The text below is an extract from the draft Regulations (the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009) and covers only the registration requirement of the Regulations. Please consult the Regulations themselves for details of their scope, etc. The relevant sections on the 2008 Act are included in Part 6.

Regulation of regulated activities

- 5. (1) A person registered as a service provider in respect of the carrying on of a regulated activity must, so far as reasonably practicable, ensure that the-
- (a) patients;
- (b) persons (whether employed or not) working for the purpose of the carrying on of the regulated activity; and
- (c) others who may be at risk of exposure to a healthcare associated infection arising from the carrying on of the regulated activity,

are protected against identifiable risks of acquiring such an infection by the means specified in paragraph (2).

- (2) The means referred to in paragraph (1) are-
- (a) the effective operation of systems designed to assess the risk of and to prevent, detect, treat and control the spread of, a healthcare associated infection; and
- (b) the maintenance of appropriate standards of design, cleanliness and hygiene in relation to-
 - (i) premises occupied for the purpose of the carrying on of the regulated activity; and
 - (ii) equipment used in those premises.
- (3) For the purpose of this regulation, "premises" includes a vehicle owned or used by the person registered as a service provider for transporting—
- (a) patients for the purposes of treatment; and
- (b) materials to be used in the treatment of patients in circumstances where such materials are at risk of being infected with a healthcare associated infection.

Part 3: Code of Practice for the prevention and control of healthcare associated infections

Compliance by a provider with the statutory requirement set out in Part 2 will be judged against the following criteria and the Annex.

Compliance criteria	What a service provider will need to demonstrate			
1	Have in place and operate effective management systems for the prevention and control of HCAI which are informed by risk assessments and analysis of infection incidents.			
2	Provide and maintain a clean and appropriate environment which facilitates the prevention and control of HCAI.			
3	Provide suitable and sufficient information on HCAI to the patient, the public and other service providers when patients move to the care of another healthcare or social care provider.			
4	Ensure that patients presenting with an infection or who acquire an infection during their care are identified promptly and receive appropriate management and treatment to reduce the risk of transmission.			
5	Gain the co-operation of staff, contractors and others involved in the provision of healthcare in preventing and controlling infection.			
6	Provide or secure adequate isolation facilities.			
7	Secure adequate access to laboratory support.			
8	Have and adhere to appropriate policies and protocols for the prevention and control of HCAI.			
9	Ensure, so far as is reasonably practicable, that healthcare workers are free of and are protected from exposure to communicable infections during the course of their work, and that all staff are suitably educated in the prevention and control of HCAI.			

Part 4: Supporting guidance for implementation

In order to achieve compliance with the registration requirements relating to HCAI, service providers would normally be expected to demonstrate that they have in place the policies and procedures given under each criterion listed in Part 3 and have taken account of the following guidance. This guidance is not mandatory but is considered to represent the basic steps to ensure that the criteria can be met.

There may be additional or alternative strategies that a service provider is able to justify as equivalent or more effective in achieving compliance in their circumstances. Providers are free to decide to use alternative approaches but should be prepared to justify to the Care Quality Commission how the chosen approach is equally effective or better in ensuring that the criteria are met.

Management, organisation and the environment

Guidance for implementation of compliance criterion 1

Have in place and operate effective management systems for the prevention and control of HCAI which are informed by risk assessments and analysis of infection incidents.

Appropriate management systems should normally include:

- a. a board-level agreement outlining the board's collective responsibility for minimising the risks of infection and the general means by which it prevents and controls such risks;
- b. the designation of an individual as Director of Infection Prevention and Control (DIPC), to be accountable directly to the chief executive and the board (but not necessarily a member of the board);
- c. the mechanisms by which the board intends to ensure that sufficient resources are available to secure the effective prevention and control of HCAI. These should include implementing an appropriate assurance framework, infection control programme and infection control infrastructure and information systems;
- d. ensuring that relevant staff, contractors and other persons whose normal duties are directly or indirectly concerned with patient care receive suitable and sufficient information on, and training and supervision in, the measures required to prevent and control risks of infection;
- e. a programme of audit to ensure that key policies and practices are being implemented appropriately;

- f. a policy addressing, where relevant, the admission, transfer, discharge and movement of patients between departments, and within and between healthcare facilities; and
- g. designation of a decontamination lead.

Risk assessment

A provider should ensure that it has:

- made a suitable and sufficient assessment of the risks to patients receiving healthcare with respect to HCAI;
- identified the steps that need to be taken to reduce or control those risks;
- recorded its findings in relation to the first two points;
- implemented the steps identified; and
- put appropriate methods in place to monitor the risks of infection such that it is able to determine whether further steps need to be taken to reduce or control HCAI.

Directors of Infection Prevention and Control

The role of the DIPC is to:

- be responsible for the organisation's Infection Control Team (ICT) (sometimes referred to as the Infection Prevention and Control Team (IP&CT));
- oversee local control of infection policies and their implementation;
- be a full member of the ICT and to attend regularly its infection control meetings;
- report directly to the chief executive or equivalent (not through any other officer) and the board or other senior management committee;
- have the authority to challenge inappropriate clinical hygiene practice and inappropriate antibiotic prescribing decisions;
- assess the impact of all existing and new policies on HCAI and make recommendations for change;
- be an integral member of the organisation's clinical governance and patient safety teams and structures; and
- produce an annual report on the state of HCAI in the organisation for which he or she
 is responsible and release it publicly.

Assurance framework

Activities to demonstrate that infection control is an integral part of clinical and corporate governance should include:

• regular presentations from the DIPC and/or the ICT to the board. These will include trend analysis for infections and compliance with audit programmes;

- quarterly reporting to the board by clinical directors and matrons (including nurses who do not hold the specific title of 'matron' but who operate at a similar level of seniority and who have control over similar aspects of the patient or the patient's environment);
- review of statistics on incidence of alert organisms (for example, meticillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*) and conditions, outbreaks and serious untoward incidents;
- evidence of appropriate action taken to deal with occurrences of infection, including where applicable, root cause analysis; and
- an audit programme to ensure that policies have been implemented.

In accordance with health and safety requirements, where suitable and sufficient assessment of risks requires appropriate action to be taken, evidence must be available on compliance with the Code or, where appropriate, justification of a suitable better alternative.

Infection control programme

The infection control programme should:

- set objectives that meet the needs of the organisation and ensure patient safety;
- identify priorities for action;
- provide evidence that relevant policies have been implemented to reduce HCAI; and
- report progress against the objectives of the programme in the DIPC's annual report.

Infection control infrastructure

An infection control infrastructure should encompass:

- in acute hospitals, an ICT consisting of an appropriate mix of both nursing and consultant medical expertise (with specialist training in infection control) and appropriate administrative and analytical support, including adequate information technology. The DIPC is a key member of the ICT;
- in other healthcare bodies, an infection control nurse or another designated person who is responsible for infection control matters and has access to specialist expertise as necessary; and
- 24-hour access to a nominated qualified infection control doctor (ICD) or consultant in health protection/communicable disease control (CCDC).

Movement of patients

There should be evidence of joint working between the ICT, bed managers and domestic services in planning patient admissions, transfers, discharges and movements between departments and other healthcare facilities. Where necessary, ambulance trusts may need to be involved in such planning.

A provider should ensure that it provides suitable and sufficient information on a patient's infection status whenever it arranges for that patient to be moved from the care of one organisation to another, to minimise any risks to the patient and others from infection.

Guidance for implementation of compliance criterion 2

Provide and maintain a clean and appropriate environment which facilitates the prevention and control of HCAI.

A provider should normally, with a view to minimising the risk of HCAI, ensure that:

- a. it has policies for the environment that make provision for liaison between the members of the ICT and the persons with overall responsibility for facilities management;
- b. it designates lead managers for cleaning and decontamination of equipment used in treatment (a single individual may be designated for both areas);
- c. lead managers involve directors of nursing, matrons and the ICT in all aspects of cleaning services from contract negotiation and service planning to delivery at ward level;
- d. matrons have personal responsibility and accountability for delivering a safe and clean care environment and that the nurse in charge of any patient area has direct responsibility for ensuring that cleanliness standards are maintained throughout that shift;
- e. all parts of the premises in which it provides healthcare are suitable for the purpose, kept clean and maintained in good physical repair and condition;
- f. the cleaning arrangements detail the standards of cleanliness required in each part of its premises and that a schedule of cleaning frequencies is publicly available;
- g. there is adequate provision of suitable hand-washing facilities and antibacterial handrubs:
- h. there are effective arrangements for the appropriate decontamination of instruments and other equipment these should be incorporated within appropriate disinfection and decontamination policies;
- i. the supply and provision of linen and laundry supplies reflect Health Service Guidance (HSG) (95)18, *Hospital laundry arrangements for used and infected linen*, as revised from time to time; and
- j. uniform and workwear policies ensure that clothing worn by staff when carrying out their duties is clean and fit for purpose.

'The environment' means the totality of a patient's surroundings when in healthcare premises. This includes the fabric of the building and related fixtures, fittings and services such as air and water supplies.

Policies on the environment

Premises and facilities should be provided in accordance with best practice guidance. The development of local policies should take account of infection control advice given by relevant expert or advisory bodies or by the ICT, and policies should address but not be restricted to:

- cleaning services;
- building and refurbishment, including air-handling systems;
- healthcare waste management;
- planned preventative maintenance;
- pest control;
- management of potable and non-potable water supplies; and
- food services, including food hygiene and food brought into the organisation by patients, staff and visitors.

Cleaning services

The arrangements for cleaning should include:

- clear definition of specific roles and responsibilities for cleaning;
- clear, agreed and well-publicised cleaning routines;
- consultation with ICTs on cleaning protocols when internal or external contracts are being prepared;
- sufficient resources dedicated to keeping the environment clean and fit for purpose; and
- details of how nurses can request additional cleaning, both urgently and routinely.

Decontamination

The decontamination lead should have responsibility for ensuring that a decontamination programme is implemented in relation to the organisation and that it takes proper account of relevant national guidelines.

The decontamination programme should demonstrate that:

- decontamination of reusable medical devices takes place in appropriate dedicated facilities;
- appropriate procedures are followed for the acquisition and maintenance of decontamination equipment;

- staff are trained in decontamination processes and hold appropriate competences for their role; and
- a monitoring system is in place to ensure that decontamination processes are fit for purpose and meet the required standards.

'Medical devices' refers to all products, except medicines, used in healthcare for diagnosis, prevention, monitoring or treatment. The range of products is very wide and includes, for example, contact lenses, condoms, heart valves, hospital beds, radiotherapy machines, resuscitators, surgical instruments and syringes, wheelchairs and walking frames.

Linen, laundry and dress

Particular consideration should be given to items of attire that may inadvertently come into clinical contact with a patient. Uniform and dress code policies should specifically support good hand hygiene.

Guidance for implementation of compliance criterion 3

Provide suitable and sufficient information on HCAI to the patient, the public and other service providers when patients move to the care of another healthcare or social care provider.

Areas relevant to the provision of such information include:

- a. general principles pertaining to the prevention and control of HCAI and key aspects of the provider's policy on infection prevention and control;
- b. the role and responsibilities of individuals in the prevention and control of HCAI, to support them when visiting patients;
- c. supporting vigilance in patients;
- d. the importance of compliance by visitors with hand hygiene and visiting restrictions;
- e. reporting breaches of hygiene and cleanliness;
- f. explanation of incident/outbreak management;
- g. feedback that is focused on the patient pathway; and
- h. provision across organisational boundaries, such as pre-admission screening and post-operative care.

Information should be developed with local patient representative organisations, including Local Involvement Networks (LINks) and Patient Advice and Liaison Services (PALS).

Guidance for implementation of compliance criterion 4

Ensure that patients presenting with an infection or who acquire an infection during care are identified promptly and receive appropriate management and treatment to reduce the risk of transmission.

Arrangements to prevent and control HCAI should be such as to demonstrate that responsibility for infection prevention and control is effectively devolved to:

- all professional groups in a provider; and
- clinical specialties and directorates and, where appropriate, support directorates or other similar units.

Guidance for implementation of compliance criterion 5

Gain the co-operation of staff, contractors and others involved in the provision of healthcare in preventing and controlling infection.

A provider should, so far as is reasonably practicable, ensure that its staff, contractors and others involved in the provision of healthcare co-operate with it, and with each other, so far as is necessary to enable the body to meet its obligations under this Code.

Guidance for implementation of compliance criterion 6

Provide or secure adequate isolation facilities.

A provider delivering in-patient care should ensure that it is able to make available, or secure the provision of, adequate isolation precautions and facilities, as appropriate for patients, sufficient to prevent or minimise the spread of HCAI. This may include facilities for day care.

Policies should be in place concerning the allocation of patients to isolation facilities, based on local risk assessment. The risk assessment should include consideration of the need for special ventilated isolation facilities. Sufficient staff should be available to care for patients safely.

Guidance for implementation of compliance criterion 7

Secure adequate access to laboratory support.

A provider should ensure that laboratories used to provide a microbiology service in connection with arrangements for infection prevention and control have in place appropriate protocols and that they operate according to the standards required for accreditation by Clinical Pathology Accreditation (UK) Ltd.

Protocols should include:

- a microbiology laboratory policy for investigation and surveillance of HCAI; and
- standard operating procedures for the examination of specimens.

Clinical care protocols

Guidance for implementation of compliance criterion 8

Have and adhere to appropriate policies and protocols for the prevention and control of HCAI.

The appropriate core policies are:

- in the case of services provided in an acute trust, all of them; and
- in the case of any other healthcare body to which the Annex applies, the policies specified in the Annex.

A provider should, in relation to preventing, reducing and controlling the risks of HCAI, have in place the appropriate core policies concerning the matters mentioned in (a) to (m) below.

- a. Standard (universal) infection control precautions
- b. Aseptic technique
- c. Outbreaks of communicable infection
- d. Isolation of patients
- e. Safe handling and disposal of sharps
- f. Prevention of occupational exposure to blood-borne viruses, including prevention of sharps injuries
- g. Management of occupational exposure to blood-borne viruses and post-exposure prophylaxis
- h. Closure of wards, departments and premises to new admissions
- i. Environmental disinfection policy
- j. Decontamination of reusable medical devices
- k. Antimicrobial prescribing
- l. Reporting HCAI to the Health Protection Agency (HPA) as directed by the Department of Health
- m. Control of outbreaks and infections associated with specific alert organisms.

Providers should also consider the need for policies specified in Part 5 of this Code.

a. Standard (universal) infection control precautions

- The policy should be based on evidence-based guidelines, including those on hand hygiene and the use of personal protective equipment.
- The policy should be easily accessible to all groups of staff, patients and the public.
- Compliance with the policy should be audited.
- Information on the policy should be included in induction programmes for all staff groups.

b. Aseptic technique

- Clinical procedures should be carried out in a manner that maintains and promotes the principles of asepsis.
- Education, training and assessment in the aseptic technique should be provided to all persons undertaking such procedures.
- The technique should be standardised across the organisation.
- Audit should be undertaken to monitor compliance with the technique.

c. Outbreaks of communicable infection

- The degree of detail in the policy should reflect local circumstances to take into account at-risk patients and clinical specialties.
- Policies for major outbreaks of communicable infection should include initial assessment, communication, management and organisation, and investigation and control.
- The contact details of those likely to be involved in outbreak management should be reviewed at least annually.
- Significant outbreaks should be reported as serious untoward incidents.
- Formal arrangements should be in place to fund the cost of dealing with outbreaks.

d. Isolation of patients

- The isolation policy should be evidence-based and reflect local risk assessment of in-patients.
- Indications for isolation should be included in the policy, as should procedures for the infection control management of patients in isolation.
- Information on isolation should be easily accessible to all groups of staff, patients and the public.

e. Safe handling and disposal of sharps

Relevant considerations include:

- risk management and training in prevention and management of needlestick injuries;
- provision of medical devices that incorporate sharps protection mechanisms where there are clear indications that they will provide safe systems of working for healthcare workers;
- policy that is easily accessible to all groups of staff;
- auditing of policy compliance; and
- inclusion of information on the policy in induction programmes for all staff groups.

f. Prevention of occupational exposure to blood-borne viruses, including prevention of sharps injuries

Measures to avoid exposure to blood-borne viruses should include:

- immunisation against hepatitis B;
- the wearing of gloves and other protective clothing;
- the safe handling and disposal of sharps, including the provision of medical devices that
 incorporate sharps protection where there are clear indications that they will provide
 safe systems of working for healthcare workers; and
- measures to reduce risks during surgical procedures.

g. Management of occupational exposure to blood-borne viruses and post-exposure prophylaxis

Management should include:

- designation of one or more doctors to whom healthcare staff and others may be referred immediately for advice following occupational blood exposure;
- provision of clear information to healthcare staff about reporting potential occupational exposure – in particular the need for prompt action following a known or potential exposure to human immunodeficiency virus (HIV) or hepatitis B; and
- arrangements for post-exposure prophylaxis for blood-borne viruses.

h. Closure of wards, departments and premises to new admissions

- A system should be in place for the provision of advice by the DIPC/ICT to the chief executive and medical director.
- There should be clear criteria in relation to closures.
- Management arrangements for redirecting admissions should be drawn up with ICT input.
- The policy should address the need for environmental decontamination prior to reopening.

i. Environmental disinfection policy

- The use of disinfectants is a local decision, and there should be local policies on disinfectant use which focus on specific infection risks.
- If appropriate, the role of high-level disinfectants to kill bacteria, viruses and spores should be considered.

j. Decontamination of reusable medical devices

- Effective decontamination of reusable medical devices is essential. There should be a system to protect patients and staff that minimises the risk of transmission of infection from medical devices and other equipment that comes into contact with patients or their body fluids.
- Decontamination is the combination of processes, including cleaning, disinfection and sterilisation, used to render a reusable item safe for further use on patients and handling by staff.
- Reusable medical devices and other devices should be decontaminated in accordance with manufacturers' instructions and current guidelines.
- Systems should ensure adequate supplies of reusable medical devices and should allow reusable medical devices 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 the medical devices have been used.

k. Antimicrobial prescribing

- Local prescribing should, where appropriate, be harmonised with that in the *British National Formulary* (BNF).
- All local guidelines should include information on the regimen and duration of particular drugs.
- Procedures should be in place to ensure prudent prescribing and antimicrobial stewardship.

I. Reporting HCAI to the HPA as directed by the Department of Health

This includes a mandatory requirement for NHS trust chief executives to report all cases of MRSA bacteraemia and all cases of *C. difficile* infection in patients aged two years or older. Reporting should include procedures for dealing with serious untoward incidents.

m. Control of outbreaks and infections associated with specific alert organisms

This should take account of local epidemiology and risk assessment. These infections must include, as a minimum, MRSA, *C. difficile* infection and transmissible spongiform encephalopathies.

MRSA

The policy should make provision for:

- screening of patients on admission, which should include screening of all elective admissions by March 2009 and provision for screening of emergency admissions at presentation as soon as is practical;
- decontamination procedures for colonised patients, as appropriate;
- isolation of infected or colonised patients;
- transfer of infected or colonised patients within NHS bodies or to other healthcare facilities; and
- antibiotic prophylaxis for surgery.

C. difficile

The policy should make provision for:

- surveillance of *C. difficile* infection;
- diagnostic criteria;
- isolation of infected patients and cohort nursing;
- environmental decontamination;
- antibiotic prescribing policies; and
- a statement concerning contraindication of antimotility agents in symptomatic antimicrobial-associated diarrhoea.

Transmissible spongiform encephalopathies

The policy should make provision for the management of known or high-risk patients.

Relevant policies for other specific alert organisms

The specific alert organisms and matters that follow are relevant to any acute trust. They may also be relevant to certain other NHS bodies to which criterion 8 applies, depending on their spectrum of activity.

Glycopeptide-resistant enterococci:

- screening of high-risk groups;
- isolation and prevention of cross-infection; and
- prophylaxis for surgical procedures.

Acinetobacter and other antibiotic-resistant bacteria:

- surveillance of identified patients at risk and of high-risk environments; and
- procedures for managing infected patients to prevent spread of infection.

Control of tuberculosis, including multi-drug-resistant tuberculosis:

- isolation of infectious patients;
- transfer of infectious patients within NHS bodies or to other healthcare facilities; and
- treatment compliance.

Respiratory viruses:

- alert system for suspect cases;
- isolation criteria;
- infection control measures; and
- terminal disinfection and discharge.

Diarrhoeal infections:

- isolation criteria;
- infection control measures; and
- cleaning and disinfection policy.

Viral haemorrhagic fevers (VHF):

- patient risk assessment and categorisation;
- appropriate staff to be aware of the special measures to be taken for nursing VHF patients, and to be properly trained in the application of full isolation procedures;
- confirmed cases to be handled under full isolation measures in a high-security infectious diseases unit or equivalent;
- handling of patient specimens at the appropriate containment level;
- follow-up of all staff in contact with the patient at every stage of care; and
- special measures for the handling of all healthcare waste.

Legionella:

• premises should be regularly reviewed for potential sources of infection, and a programme should be prepared to minimise any risks. Priority should be given to patient areas, although the exact priority will depend on local circumstances.

Any provider that should have in place any of the core policies mentioned above should, having regard in particular to the healthcare it provides, also consider whether it would be appropriate for it to have in place any of the additional policies or to take any of the measures mentioned in Part 5 of this Code with a view to minimising the risk of HCAI.

If such a provider considers that it is appropriate for it to have in place any of those policies or take any of those measures, it should take into account the content of Part 5 insofar as it is relevant to making those arrangements, including the content of guidance and other publications referred to in any relevant citation.

The sufficiency and suitability of any policy implemented in accordance with this provision of the Code should be monitored via the clinical governance system, and there should be evidence of a rolling programme of audit, revision and update.

All policies should be clearly marked with a review date.

Healthcare workers

Guidance for implementation of compliance criterion 9

Ensure, so far as is reasonably practicable, that healthcare workers are free of and are protected from exposure to communicable infections during the course of their work, and that all staff are suitably educated in the prevention and control of HCAI.

A healthcare worker is any person whose normal duties concern the provision of treatment, accommodation or related services to patients and who has access to patients in the normal course of their work. This term includes not only front-line clinical and paraclinical staff, but also some staff employed in estates and facilities management, such as cleaning staff and engineers.

Providers should ensure that policies and procedures are in place in relation to the prevention and control of HCAI such that:

- a. all staff can access relevant occupational health services;
- b. occupational health policies on the prevention and management of communicable diseases in healthcare workers, including immunisation, are in place;
- c. prevention and control of infection is included in induction programmes for new staff, and in training programmes for all staff;
- d. there is a programme of ongoing education for existing staff (including support staff, agency/locum staff and staff employed by contractors);
- e. there is a record of relevant immunisations;
- f. there is a record of training and updates for all staff; and
- g. the responsibilities of each member of staff for the prevention and control of infection is reflected in their job description and in any personal development plan or appraisal.

Occupational health services

Occupational health services should include:

- pre-employment and ongoing health screening for communicable diseases;
- management of exposure to HCAI, which should include provision for emergency treatment out of hours;
- relevant immunisations; and
- having arrangements in place for regularly reviewing the immunisation status of healthcare workers and providing vaccinations to staff as necessary in line with Immunisation Against Infectious Diseases and other Department of Health guidance.

Occupational health services, in respect of blood-borne viruses, should include:

- arrangements for health clearance of new healthcare workers and for identifying
 and managing healthcare workers infected with hepatitis B, HIV or hepatitis C and
 restricting their practice as necessary in line with Department of Health guidance; and
- liaising with the UK Advisory Panel for Healthcare Workers Infected with Blood-borne
 Viruses when advice is needed on procedures that may be carried out by blood-borne
 virus-infected healthcare workers, and when patient tracing, notification and offer of
 blood-borne virus testing may be needed.

Induction, training programmes and ongoing education

Induction and training programmes for new staff and ongoing education for existing staff should all incorporate the principles and practice of infection prevention and control. These include:

- ensuring that policies are up to date;
- feedback of audit results;
- examples of good practice; and
- action needed to correct deficiencies.

Part 5: Additional policies for consideration

This part relates to the clinical care protocols section of Part 4. In addition to the core policies mentioned, providers should consider whether any or all of the following policies are relevant to their organisation and implement them appropriately to reduce the risk of infection.

Handling of medical devices in procedures

The risks when handling medical devices in procedures carried out on known/suspect Creutzfeldt-Jakob disease (CJD) patients and on patients in risk categories for CJD (including disposal/quarantine procedures) should be assessed. This should apply in all cases where there may be exposure to biological agents. When appropriate, measures should be introduced either to prevent or to adequately control exposure.

Safe handling and disposal of healthcare waste

The risks from healthcare waste should be properly controlled. In practice, this involves healthcare waste from healthcare premises. Control should include:

- assessing risk;
- developing appropriate policies;
- putting arrangements into place to manage risks;
- monitoring the way arrangements work; and
- being aware of legislative change.

Precautions in connection with handling healthcare waste should include:

- training and information;
- personal hygiene;
- segregation of wastes;
- the use of appropriate personal protective equipment;
- immunisation;
- appropriate procedures for handling such waste;
- appropriate packaging and labelling;
- suitable transport on-site and off-site;

- clear procedures for dealing with accidents, incidents and spillages; and
- appropriate treatment and disposal of such waste.

Systems should be in place to ensure that the risks to patients from exposure to infections caused by healthcare waste present in the environment are properly managed, and that duties under environmental law are discharged. The most important of these are:

- duty of care in the management of waste;
- duty to control polluting emissions to the air;
- duty to control discharges to sewers; and
- obligations of waste managers.

Packaging, handling and delivery of laboratory specimens

Biological samples, cultures and other materials should be transported in a manner that ensures they do not leak in transit and are compliant with current legislation.

Care of the cadaver

Appropriate procedures should include:

- risk assessment of potential hazards;
- the provision of appropriate facilities and accommodation;
- safe working practices;
- arrangements for visitors;
- information, instruction, training and supervision; and
- health surveillance and immunisation (where appropriate).

Care of patients whose treatment involves the use of invasive devices

The policy should be based on evidence-based guidelines and should be easily accessible by all relevant healthcare workers. Compliance with the policy should be audited. Information on policy should be included in infection control training programmes for all relevant staff groups.

Instruments for single use only or limited reuse

Policies should be in place for handling devices designed for single use only or limited reuse.

Purchase, cleaning and maintenance of equipment

Policies for the purchase, cleaning and maintenance of all clinical equipment should take into account infection control advice given by relevant expert or advisory bodies or by the ICT.

Surveillance and data collection

For all appropriate clinical settings, there should be evidence of local surveillance and use of comparative data where available in order to monitor infection rates and to assess the risk of infection. This evidence should include data on alert organisms, and other HCAI where appropriate, alert conditions and wound infection by clinical unit or specialty. Where appropriate, or where they exist, recognised definitions should be employed.

Providers should consider voluntary reporting to the HPA as requested by the HPA.

There should also be timely feedback to clinical units, with a record of actions taken and achievements as a result of surveillance. Post-discharge surveillance of wound infection should be considered and, where practical, should be implemented.

Dissemination of information

There should be a local protocol for the dissemination of information about HCAI between healthcare organisations. This is to facilitate surveillance and optimal management of patients with infections in the wider community.

Isolation facilities

There should be a policy concerning the appropriate provision of isolation facilities. This should address:

- potential sources of infection;
- the use of protective measures and equipment; and
- the management of outbreaks.

Part 6: Relevant sections from the Health and Social Care Act 2008

Key registration-related provisions

Section 20(5) allows regulations to be made to make provision for the prevention and control of HCAI and may include such provision as the Secretary of State considers appropriate for the purpose of safeguarding individuals (whether receiving health or social care or otherwise) from the risk, or any increased risk, of being exposed to HCAI or of being made susceptible, or more susceptible, to them.

Section 20(6) says that 'healthcare associated infection' means any infection to which an individual may be exposed or made susceptible (or more susceptible) in circumstances where:

- (a) health or social care is being, or has been, provided to that or any other individual; and
- (b) the risk of exposure to the infection, or of susceptibility (or increased susceptibility) to it, is directly or indirectly attributable to the provision of that care.

Section 20(7) says that 'healthcare associated infection' does not include an infection to which the individual is deliberately exposed as part of any healthcare.

Section 21(1) says that the Secretary of State may issue a Code of Practice on compliance with any requirements of regulations under section 20 which relate to the prevention or control of HCAI.

Section 35 says that regulations under this Chapter may provide that a contravention of, or failure to comply with, any specified provision of the regulations is to be an offence, but may not provide for an offence to be triable on indictment or to be punishable with imprisonment or with a fine exceeding:

- (a) in the case of regulations under section 20 (regulation of regulated activities), £50,000; or
- (b) in any other case, level 4 on the standard scale.

Key enforcement-related provisions

Section 10 provides that any person who carries on a regulated activity without being registered with the Care Quality Commission is guilty of an offence, and is liable on summary conviction to a fine of up to £50,000 or up to 12 months' imprisonment, or both, and on indictment to an unlimited fine or up to 12 months' imprisonment, or both.

Section 12(5) allows the Care Quality Commission to add, vary or remove conditions in relation to a person's registration as a service provider at any time.

Section 17 allows the Care Quality Commission to cancel a provider's registration on specific grounds.

Section 18 allows the Care Quality Commission to suspend a provider's registration for a specified period of time.

Sections 26–28 set out the procedure that the Care Quality Commission must follow for notifying the service provider of certain proposed actions, allowing the provider to make representations about those proposed actions within 28 days, then notifying the provider of its decision. The actions include a proposal to grant registration subject to conditions, to refuse registration, to cancel or suspend registration, or to add, vary or remove conditions in relation to the registration.

Section 29 allows the Care Quality Commission to issue a warning notice to a registered provider, for example when it has failed to comply with its HCAI registration requirements.

Sections 30–31 set out how the Care Quality Commission will operate its enforcement powers under the 'urgent' process. Section 30 allows the Commission to apply to a justice of the peace to cancel registration immediately; and under section 31, the Commission can suspend, or extend the period of suspension of, a provider's registration, or add, vary or remove conditions in relation to the registration immediately, where it believes that any person will or may be exposed to the risk of harm.

Section 32 provides that an appeal against any decision of the Care Quality Commission (except a decision to give a warning notice under section 29) or an order made by a justice of the peace under section 30 can be made to an independent tribunal within 28 days after service on the person of the notice of the decision or order.

Sections 33–37 set out further offences relating to registration, including the offence of a service provider failing to adhere to the conditions of its registration. If convicted of an offence under these sections, the registered provider would be liable to a fine of up to £50,000, depending on the offence.

Section 39 requires the Care Quality Commission to give a copy of a notice of proposals, a notice of decisions, a warning notice and a notice for an urgent procedure for suspension, variation, etc. under section 31 to certain bodies, including relevant primary care trusts, relevant local authorities, Monitor, etc. Regulations (which come into force on 1 April 2009) prescribe cases in which a copy of the notice does not need to be given (see Regulation 9 of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009).

Sections 62–65 set out the Care Quality Commission's powers to enter and inspect premises, and require information, documents, etc. and explanations. They provide that obstructing entry and inspection, or failing to provide documents, information, etc. or an explanation, without a reasonable excuse, is an offence.

Section 76 provides that any person who knowingly or recklessly discloses confidential personal information held by the Care Quality Commission is guilty of an offence.

Sections 86–87 allow the Care Quality Commission to issue a penalty notice in lieu of prosecution for fixed penalty offences; the provider is offered an opportunity to pay the penalty notice and thereby discharge any liability to conviction for the offence to which the notice relates. It may be used, for example, for a relatively minor offence where the provider has subsequently complied with the condition in question. Of course, the provider may face further enforcement action for any new (repeat) offences. Regulations (which come into force on 1 April 2009) have been made under these provisions in relation to penalty notices (see Regulation 7 of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009).

Section 88 requires the Care Quality Commission to issue guidance about how it will use its enforcement powers.

Section 89 provides that regulations can require or authorise the Care Quality Commission to publish certain information about the enforcement action it has taken (see Regulation 8 of the Health and Social Care Act 2008 (Registration of Regulated Activities) Regulations 2009, which come into force on 1 April 2009).

Annex: Application of compliance criteria and guidance to non-acute trusts

Compliance	NHS body				
criteria	NHS Blood and	d and			
	Ambulance	Mental health	Transplant	Primary care trust	
1	✓	✓	✓	✓	
2	*	✓	✓	✓	
3	**	✓	**	✓	
4	✓	✓	_	✓	
5	✓	✓	✓	✓	
6	-	✓	-	✓	
7	-	✓	✓	✓	
8a	✓	✓	✓	✓	
8b	✓	✓	✓	✓	
8c	-	✓	_	✓	
8d	-	✓	-	✓	
8e	✓	✓	✓	✓	
8f	✓	✓	✓	✓	
8g	✓	✓	✓	✓	
8h	-	✓	_	✓	
8i	-	✓	_	✓	
8j	✓	✓	✓	✓	
8k	_	✓	_	✓	
81	-	-	-	-	
8m	-	✓	-	✓	
9	✓	✓	✓	✓	

✓ Applicable.

- Not applicable.
- * Certain aspects of cleaning, for example healthcare waste management, planned preventative maintenance and pest control, are of relevance to ambulance trusts.
- ** While patient information may not be appropriate, information for other service providers may be necessary.

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