



*Action on Health Care
Associated Infections in England*

DH INFORMATION READER BOX

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Contact Details	HCAI Consultation Department of Health Room 418 Wellington House 135 – 155 Waterloo Road London SE1 8UG hcaiconsultation@dh.gsi.gov.uk
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Foreword by the Secretary of State

Our aim to reduce the levels of health and other care associated infections

Patients deserve to be treated in a safe clean environment and have the highest standards of care every time they receive treatment to minimise their risk of acquiring a health care associated infection (HCAI).

That is why we have already made tackling HCAI's a key priority in the NHS. We set a target to halve MRSA blood stream infections by 2008 last year and have a wide ranging programme of actions to achieve this.

For example we have introduced new minimum cleaning standards, the first national hand hygiene campaign, trials of a rapid screening test and directors of infection prevention and control. We have also improved our monitoring of the most significant HCAI's and recently published a guidance pack for the NHS clearly setting out a raft of clinical and performance management measures to improve hygiene.

This strategy is already having an effect and for the first time levels of MRSA in many acute hospitals are now coming down. But we now need to go a step further and ensure that action is taken across the whole of the NHS to make this best practice part of everyone's working culture.

Our plans, set out in this consultation document, are designed to give a firm statutory footing to what is accepted best practice, ensuring that health care organisations put that best practice into effect. Underpinning this will be the Healthcare Commission's new duty to assess performance, and when necessary issue improvement notices.

The independent inspection regime will therefore make a real difference and drive up standards of hygiene and infection control across the board. Ultimately, through the mechanisms set out in these proposals, where it is considered necessary, steps can and will be taken to ensure that remedial action will be put into effect.

I believe that this package of measures will build on existing progress and help us deliver the world-beating standards of hygiene in healthcare to which staff and patients aspire. I would encourage you to use the opportunity of this consultation to comment on these important proposals.

Patricia Hewitt
Secretary of State for Health

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INTRODUCTION

1. The legislative proposals set out in Part 2 of this document represent an important step in the Government's programme to tackle the problem of health care associated infection. They comprise a set of measures to apply in England which build on the duty of quality established in the Health and Social Care (Community Health and Standards) Act 2003 (H&SC Act), which places a duty on each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care they provide.
2. The H&SC Act also created two new independent inspectorates – the Healthcare Commission (HC) and the Commission for Social Care Inspection (CSCI). The HC is responsible for assessing the quality of health care and CSCI the quality of social care. The Act also set the framework for the publication of wide ranging standards – *Standards for Better Health* (July 2004) – which set out high level requirements to be taken into account in the provision of health care under the NHS. The Care Standards Act 2000 (CSA) amongst other things establishes the framework for the regulation of independent health care and care homes.
3. *Standards for Better Health* at core standard C4(a) sets health care organisations providing NHS services a specific requirement for health care acquired infections. They are required to have “systems to ensure that the risk of health care acquired infection to patients is reduced, with particular emphasis on high standards of hygiene and cleanliness, achieving year-on-year reductions in MRSA”. The NHS is currently assessed against this and all core standards by the HC.
4. These new proposals go a step further and will enable the Secretary of State to publish a specific and detailed code of practice on health care associated infection which describes a range of actions that NHS bodies should implement.
5. In addition to NHS establishments providing front-line care for patients, the policy underpinning these new proposals will also apply to independent health care organisations and care homes. It is our intention to extend the relevant principles of good practice from the new provisions to these two sectors. This will require changes to regulations issued under the CSA, and will be subject to a later and separate consultation.
6. Part 1 of this consultation document describes the nature of the problem and the action that the Government has already taken to address it, and Part 2 sets out the details of the new legislative proposals and seeks the views of key stakeholders. Part 2 also includes a small number of scenarios to illustrate how the new measures might work in practice. Finally at Part 3 we set out the draft Code of Practice.

7. We would welcome comments by Friday 23 September on all aspects of the proposals.

Part 1 - THE NATURE OF THE PROBLEM

What are health care associated infections?

8. Health care associated infections (HCAIs) are caused by a wide range of micro-organisms and, as the term suggests, are associated with medical care and treatment. The burden of HCAIs has mainly been in hospitals where more serious infections are seen. It is estimated that at any one time nine per cent of all inpatients have an infection associated with their care in hospital. However, health care, particularly invasive health care, provided in any setting can pose a risk of HCAI. That is why the proposals set out in this consultation document will be extended after a further consultation to cover registered private health care establishments and care homes.
9. Not all HCAI is preventable but up to 30 per cent may be. Hospitals are now treating patients who only a decade ago could not have been treated at all. Those patients are often very sick and vulnerable to infection. The medical procedures that they undergo may be more invasive and present a greater opportunity, than in the past, for infection to get a foothold.
10. The National Audit Office report on hospital associated infection, published in February 2000, reported that HCAI may be responsible for 5,000 deaths per year. Furthermore, the cost to the NHS associated with HCAI may be as high as £1bn a year with potential avoidable costs of around £150m annually. Though only estimates, these figures demonstrate that in addition to improving patient care and overall health outcomes for individuals, reducing these infections will also reduce costs to service providers and to tax payers.

Methicillin resistant *Staphylococcus aureus* (MRSA)

11. MRSA is only one of the micro-organisms causing HCAIs. However, action to counter MRSA will have an impact on the incidence of other HCAIs. In this way it is a marker for HCAIs generally and was used for the NHS target (to reduce levels of MRSA infection year on year) because it has the best available data set.
12. Methicillin resistant *Staphylococcus aureus* (MRSA) is an antibiotic resistant form of *Staphylococcus aureus* (SA), a very common bacterium carried by around one in three healthy people. MRSA was not the first antibiotic resistant bacterium to become a problem for the health service and will not be the last. By 1960, almost all samples of SA were resistant to penicillin, and other antibiotics such as methicillin were developed to treat these infections. MRSA appeared almost immediately but there were only very low levels of infection in the UK until the appearance of two new virulent strains in the early 1990s. By 1997 MRSA was endemic in NHS hospitals and, whilst it is unlikely that it can ever be eradicated, measures can be taken to reduce rates significantly.

Whom do health care associated infections chiefly affect?

13. The organisms associated with HCAI are widespread, and a significant proportion of the population has them present on their skin. Whilst those such as patients with severe or chronic diseases or those who are immuno suppressed are more vulnerable to HCAs, they can occur in all groups and good infection control is essential to limiting their spread.
14. In most circumstances it is not harmful for healthy people to carry MRSA on the skin or in the nose but anyone identified during medical treatment as doing so will have it recorded in their notes, to inform current and any future treatment. The organism is dangerous if it enters the bloodstream, for example in a wound or through a catheter inserted into the bloodstream.

Available data and where are health care associated infections found?

15. HCAs are found in all settings and range from the minor to serious life threatening infections. Surveillance concentrates on the more serious infections and thus we only have limited data on overall infection rates.
16. Although available data indicate that the problem of HCAI is most serious in NHS hospitals they also represent a real risk in private health care settings as well as care homes caring for vulnerable people such as the elderly. Where applicable, the principles of good practice proposed in the new Code of Practice applying to the NHS will be extended to cover both independent health care establishments and care homes through the regulatory arrangements established under the CSA.

Action taken to date and current strategy

17. The Government recognises the seriousness of HCAI and has already taken significant steps to tackle the problem. The current strategy is based on a delivery plan developed with key stakeholders such as NHS trusts, Strategic Health Authorities (SHA) and the Health Protection Agency. Actions already under way include:
 - a new national target to halve MRSA bacteraemias (blood infections) in acute trusts by March 2008.
 - ensuring that infection control remains a high priority for Trust Boards, e.g., all trusts should now have a Director of Infection Prevention and Control reporting directly to the Board. These directors will publish their first annual reports on infection control in their trust in summer 2005.
 - A rapid review panel set up to assess new products with the potential to reduce HCAs has reviewed over 100 products so far.

- An improvement package of key measures, to support local delivery and reduce the risk of infection, '*Saving Lives*', was published on 16 June 2005 and is being disseminated to all NHS trusts.
- Three NHS trusts are setting up a trial of a new two hour test for MRSA screening. Early results will be available by the end of 2005 and will show if these methods can be used to improve patient care.

18. The proposals set out in Part 2 below build on that strategy.

Part 2 - PROPOSALS FOR FURTHER ACTION

19. The Government is now proposing to build on the existing strategy by introducing legislation which will ensure that best practice is adopted nationally.
20. The legislative proposals set out below impact directly on NHS organisations and have four key components:
 - A new and specific Code of Practice on the prevention and control of health care associated infection
 - A new duty on NHS bodies providing health care to follow the code with a parallel duty on the HC to assess compliance with it
 - A new discretionary power available to the HC to issue an improvement notice
 - Directions for improvement or sanctions which may be taken against those who, in the view of the Secretary Of State or Monitor, continue significantly to breach the code
21. Although comments are welcome on all four components of the proposals we are particularly keen to receive comments on the first - the Code of Practice.
22. Subject to a later and separate consultation, relevant elements of the code will be reflected in regulatory arrangements under the CSA so that independent health care establishments and care homes are also subject to enhanced standards on infection control.
23. It is also important to note that although the intention is to strengthen the regulations to reflect the code of practice in respect of care homes, the provisions themselves would only apply to health care interventions. For example, where an older person in a care home receives medical attention for a wound, then certain management practices relating to hygiene and cleanliness will apply. There are no requirements in the code that govern the provision of routine social care.

The Code of Practice

24. The new legislation will create a power for the Secretary of State to publish a code of practice concerned with tackling HCAI, setting out action which should be put in place by all NHS health care organisations providing direct care to patients. This will include all NHS trusts, NHS foundation trusts and primary care trusts
25. The code will need to be updated to reflect changes in practice and developments in knowledge. It will therefore need to exist in a form that allows such updating without undue delay.

Question -Does the Code of Practice cover sufficiently broad a scope in respect of tackling health care associated infections?

Question - Is there sufficient detail and clarity in Code of Practice in what it requires of service providers?

Duties to comply and inspect

26. It is the Government's policy that the relevant requirements of the code of practice must be put into effect by those establishments to which they apply. There will therefore be a new statutory duty on NHS health care organisations to make arrangements to put the provisions of the code into practice, backed up by action if there are significant failings in relation to the code.
27. Compliance with the code will be assessed by the HC, who will be under a parallel duty to satisfy themselves that those bodies to which the code applies conform to it in full. It will be for the Commission to consider how best it might assess compliance. The Government expects that assurance will form part of the HC's annual performance assessment against the standards and targets. By aligning the new responsibilities with current practice it will be possible to keep any additional burdens both to the Commission and to the NHS to a minimum. Furthermore, we will continue to work with the Commission to ensure that, in undertaking their statutory duties to assess performance, burdens to front line service providers are kept to a minimum. The HC's approach to assessment is set out in detail in their recent publication "Assessment for improvement".

Question - Are there any current measures that are unnecessary, or could be simplified, in the light of the introduction of these proposals?

28. As part of the duty to assess, the HC will be expected to include a specific report on compliance with the code as part of the report setting out its findings following its annual assessment for each NHS body. The national picture will be included in the Commission's annual State of Healthcare report which will aggregate the findings reported trust by trust.

Improvement notices

29. There will be a statutory power to enable the HC to issue improvement notices specifically in relation to compliance with the code. It will be at the discretion of the Commission whether to issue such a notice where it is of the opinion that there has been a significant breach of the code. The decision to issue an improvement notice will usually follow discussion between the NHS body in question and the Commission and is only likely to be taken when the Commission is concerned at the adequacy of the response of the organisation.
30. The improvement notice will set out clearly those elements of the code in which the establishment is in breach and will also define the period of time that the HC considers reasonable to effect compliance. In

addition, the HC may recommend steps to be taken in order to ensure compliance. However, where it makes such a recommendation it will be advisory only. It will be for local management to determine the measures it needs to put in place to comply with the code.

31. The Government proposes that there should only be one improvement notice issued before any further enforcement action. When it expires the HC must:
- either satisfy itself that nothing more need be done; or
 - where a trust is considered to remain in significant breach of the code, issue a report to the Secretary of State, or to Monitor, recommending measures to remedy the situation.

Directions for improvement and sanctions

32. Where the HC writes to the Secretary of State, or to Monitor, drawing attention to concerns over failure to follow the code of practice, and makes recommendations for action, it is the Government's aim that such steps to remedy the situation as are necessary should be taken quickly. The Secretary of State, and Monitor as the regulator for NHS foundation trusts, already have a range of powers to require an NHS organisation to take specific actions.

Use of existing powers to direct and powers of intervention

33. As currently happens when a trust is failing significantly to deliver services that take account of *Standards for Better Health* the Commission would report failings against the code to Secretary of State or Monitor, making such recommendations as it saw fit. Their response might range from requiring action such that the trust would quickly comply with the requirements of the Code of Practice through to dismissal of the Board, or of individual members, where such action was appropriate.
34. The Government has also considered whether to introduce a new power for the HC to take criminal proceedings against those trusts which fail to give effect to the Code of Practice following an improvement notice. There are two apparent attractions to doing this. Firstly, it would introduce a similar approach to that currently applying to the independent health care and care home sectors. Secondly, the threat of criminal sanctions might help to encourage compliance.
35. But introducing new criminal sanctions to apply to the NHS poses significant difficulties.
36. First is the problem of false expectations of how and when criminal sanctions might be used. There is a real danger that they would be seen as representing a means to bring to book those whose actions or inactions could be responsible for fatalities and outbreaks. The existence of criminal penalties is bound to be associated with individual

often tragic, and often well-publicised cases. In such circumstances there may well be an expectation that criminal sanctions must apply. However, any new offence would relate to the provisions of the Code and whether they were being implemented. There may therefore be no clear link between individual cases of infection and the scope for applying criminal sanctions. Not only would determining whether an organisation was in breach of the Code's provisions necessarily involve a long process, at the end of it there could be no certainty that criminal sanctions could be applied because either there was no initial breach or because, following the improvement order, matters had been put right.

37. Secondly, while at face value it is attractive to introduce similar penalty structures for both the NHS and the independent sectors, this would require the establishment of a new offence, or range of offences, and the setting of a penalty or range of penalties for breaching the new requirements. If these were to be set at a level to act as a real disincentive for health care organisations, then the resulting large fines would have the affect of removing substantial resources from patient care.
38. Thirdly, to give new prosecution powers to the HC would change the relationship between them and the NHS, which is in large part based on one where the Commission's role is to encourage improvement rather than to prosecute failure. Although the HC already has powers to recommend special measures where it sees fit, it does so sparingly. The Commission also relies heavily on self-assessment. There is a real risk that the possible use of criminal prosecutions would encourage failure to disclose and would result in a perverse incentive to drive safety underground. This would also run counter to the Government's patient safety policy, which encourages open reporting of errors and incidents so that lessons can be learned without fear of unjust persecution of individuals.
39. We therefore believe that, while criminal sanctions are a means of ensuring compliance where no other means of directing action are available, the powers of intervention that currently exist for the NHS are a more powerful and more effective tool to ensure improvement in the quality of care for, and the safety of, individual patients. We have therefore decided to reject the option of introducing new criminal sanctions in the case of breaches of the Code.

Question - Do the proposals apply sufficient pressure on health care organisations to bring about changes in approaches to tackling HCAI where these are needed?

Approach in respect of Private Health Care and Care Homes

40. As has been stated in the introduction, it is the Government's intention to ensure that enhanced standards of infection control should apply in all settings where health care is provided. It is therefore the intention

to apply measures similar to those outlined above to the independent and voluntary sectors providing health care and in care home settings.

41. Just as the proposals for the NHS build on existing legislative provision, so we propose that the current regulatory framework established by the CSA should provide the basis for stronger regulation of the independent sector. This establishes a set of regulations in respect of independent health care providers which are regulated by the HC, and a parallel set of provisions governing care homes regulated by the CSCI.
42. Where appropriate it is proposed that the principles and procedures established in the Code should be introduced into regulations issued under the CSA. It is not possible to establish the full scope of the new regulations at present since the Code itself is subject to this consultation. However, there will be a full formal consultation on any changes to CSA Regulations introduced to effect the provisions of the Code of Practice.
43. Below are two scenarios to set the context for these new proposals.

Scenario 1

- I. Trust A – a large training hospital in a major town with known incidence of HCAI
- II. As part of their annual assessment process to determine compliance with the Secretary of State's standards (Standards for Better Health) the HC require an assurance from the Board that they comply with the hygiene standard which specifies the achievement of a year on year reduction in MRSA rates.
- III. Separately, but related, the HC will also require a statement that there is full compliance with the Code on hospital hygiene published under powers set out in the new Health Improvement and Protection Act.
- IV. In providing its annual assessment to the HC the trust states that its MRSA figures are lower than the previous years' and that there is full compliance with the Code.
- V. Evidence from elsewhere (e.g. the SHA) suggests that MRSA figures have in fact risen and patient representative bodies have commented in patient surveys that levels of cleanliness are disappointing.
- VI. The HC decide that taking all the evidence together there are grounds for an inspection of the trust and give notice that a team of inspectors will visit the trust and will want to interview key personnel.
- VII. When they arrive they establish that MRSA rates have in fact fallen, but the inspectors are not satisfied that the trust has adopted the code of practice. In particular, there is no clear clinical leadership for

infection prevention and control. Following the exchanges between the HC and the trust, it is evident that arrangements will take some time to put into place.

- VIII. The HC then issues an improvement notice recommending that specific actions be taken within 3 calendar months. Inspectors would then contact the trust to verify that the code was at that stage complied with.
- IX. At the end of 3 months while the trust has made a number of improvements in respect of compliance with the code, they have failed in significant areas and the HC is concerned that the remaining breaches are sufficiently serious to warrant writing to the Secretary of State making recommendations about how the trust should establish clear clinical leadership. The HC is particularly concerned at the lack of progress made by the trust because there are now indications that levels of MRSA are again increasing.
- X. On receipt of the report from the HC, the Secretary of State is concerned that steps be taken urgently to remedy the shortcoming identified by the Commission. The Department confirms that the SHA, as performance manager is clear about the shortcoming and that they are working, in close collaboration with the Regional Support Unit of the Department of Health to ensure that matters are rectified speedily.

Scenario 2

- I. A NHS mental health service trust provides day services on 21 different sites and inpatient care in 23 different settings including a 50 bed continuing care nursing home for 50 elderly people with severe and enduring mental health needs, a residential centre with two houses with 15 two bedded, self-contained flats for 30 residents and four group homes for a maximum of 25 residents.
- II. The trust buys in the services of the infection control team from a local acute trust.
- III. Whilst the levels of most bacteraemias have been low, there has recently been a rise in *Clostridium difficile* isolates in two of the residential centres.
- IV. The HC have undertaken the annual assessment and are concerned that whilst the trust overall meets core standard 4 there have been specific breaches of the Code of Practice. In part the Commission concludes that in the two centres particularly affected failed to reduce the reservoirs of infection and maintain high levels of hygiene because of high staff turnover levels and failures to ensure that induction and training of new staff included sufficient infection control content.
- V. An improvement notice is served on the mental health trust with a recommendation that they liaise with the acute trust providing the

infection control team. The improvement notice requires revision of training and induction procedures for new staff and provision of additional suitable information for all residents and patients within one month.

- VI. At the end of the period, the trust has worked with its infection control team to provide the revised training, worked with the team to produce suitable information for residents and also although not specifically required by the improvement notices updated toilet and kitchen facilities at the two affected residences.
- VII. The Commission takes no further action on the notice, but requests information two months later to confirm implementation of the revised training programme and makes regular checks of HPA data to check on reported levels of infection from the trust.

Part 3 – THE DRAFT CODE OF PRACTICE

1.Introduction

The prevention and control of healthcare associated infection (HCAI) is a high priority for all parts of the NHS and is equally important for healthcare services in the private, independent and voluntary sectors. This code of practice applies to NHS bodies and the services they provided directly. When commissioning services NHS bodies should satisfy themselves that contractors have appropriate systems in place to keep, so far as reasonably practicable, patients, staff and visitors safe from healthcare associated infection (HCAI) with a view to ensuring that the risk of HCAI is minimised.

For prevention and control of infection to be effective, infection prevention and control activities have to be embedded into everyday practice and applied consistently by everyone. All staff should demonstrate good infection control and hygiene practice.

The purpose of this Code of Practice is to set out criteria by which all levels of management in NHS Bodies should ensure that patients are cared for in a clean, environment, where the risk of HCAI is kept as low as possible.

The effective prevention and control of healthcare associated infections relies on an accumulating body of evidence that takes account of changes in epidemiology and advances in medical practice. This evidence base should be used to review and inform practice.

All NHS organisations must comply with all relevant legislation such as The Personal Protective Equipment Regulations and Control of Substances Hazardous to Health Regulations.

The following NHS Bodies are covered by this Code

**Primary Care Trusts,
NHS Trusts (Including Mental Health Trusts and
Ambulance Trusts) established in relation to England
Foundation Trusts**

2.Requirements for Healthcare Organisations

2.1 General considerations

NHS Bodies should have appropriate systems in place to keep, so far as reasonably practicable, patients, staff and visitors safe from healthcare associated infection (HCAI) with a view to ensuring that the risk of HCAI is minimised by application of effective evidence based protocols.

2.1.1 These systems should address:

- management arrangements for infection prevention and control
- clinical leadership for infection prevention and control in all directorates, units, or other parts of the Body

- the application of evidence based clinical protocols to minimise infection risks (see below)
- the maintenance of high standards of hygiene and cleanliness.

2.1.2 Healthcare services should be provided in environments that are:

- well designed to support the prevention of infection
- well maintained to ensure continued effectiveness

2.1.3 There should be effective communication in place between NHS healthcare Bodies to inform recipient Bodies when known or potentially infected or colonised patients are being transferred or discharged.

2.2 Management and organisation

All NHS Bodies should have suitable management systems in place that define responsibility and accountability for infection prevention and control

2.2.1 The Board should ensure that there are effective arrangements for infection control, including relevant surveillance, within their Body and that there are clear lines of accountability between risk management, clinical governance, infection control and the senior management/chief executive.

2.2.2 A Director of Infection Prevention and Control (DIPC) should be designated within each organisation providing NHS services and will:

- oversee local control of infection policies and their implementation;
- be responsible for the Infection Control Team within the healthcare organisation;
- report directly to the Chief Executive (and not through any other officer); and the Board;
- have the authority to challenge inappropriate clinical hygiene practice as well as antibiotic prescribing decisions;
- assess the impact of all existing and new policies and plans on infection and make recommendations for change;
- be an integral member of the organisation's clinical governance and patient safety teams and structures;
- produce an annual report on the state of healthcare associated infection in the organisation(s) for which he/she is responsible and release it publicly.

2.2.3 A lead manager for cleaning services should be appointed with responsibility for ensuring their Body has a strategic cleaning plan, reviewed and approved by the board annually, through which sufficient and appropriate resources are deployed to maintain cleanliness and hygiene

The plan should include the following commitments:

- Specific roles and responsibilities for cleaning will be clear.
- Cleaning routines will be clear, agreed and well-publicised.

- Infection control teams will be consulted on the cleaning protocols when internal or external contracts are being prepared.
- Sufficient resources will be dedicated to keeping the environment clean and fit for purpose.

2.2.4 There should be an assurance framework to demonstrate that infection control is an integral part of clinical and corporate governance, reviewed at board level through activities that include:

- regular presentations from the Director of Infection Prevention and Control and/or the Control of Infection Team
- review of statistics on prevalence of alert organisms (e.g. MRSA, *Clostridium difficile*, etc) and conditions, outbreaks, and serious untoward incidents
- documentation of appropriate actions to deal with infection occurrences
- reports of an audit programme to ensure that policies have been implemented

2.2.5 An infection control programme should be prepared in advance for each year by the Infection Control Team or a person with designated responsibility for infection control, agreed and approved by senior management, and signed off at board level. This should

- set objectives
- provide evidence that relevant policies have been implemented to reduce levels of HCAI
- identify priorities for action plus
- progress against the programme objectives should be included in the DIPC's annual report

2.2.6 An Infection Control infrastructure appropriate to the NHS Body should be in place encompassing the following elements and reporting through the Director of Infection Prevention and Control to the Trust Board:

- for Acute Trusts this should be an Infection Control Team consisting of an appropriate mix of both nursing and consultant medical expertise (both with commensurate specialist training in infection control) and appropriate administrative and analytical support.
- for other NHS Bodies this role may be fulfilled by an Infection Control Nurse or designated person responsible for infection control matters. In this case there should be 24 hour access to a qualified Infection Control doctor or Consultant in Communicable Disease Control

2.2.7 There should be evidence of effective liaison between the Infection Control Team and the Bed Managers for planning patient admissions, transfers, discharges, and movements between departments. This should include written protocols for

- the admission or transfer of potential or known infectious patients
- the screening and isolation of potentially colonised or infected patients in specified risk categories
- the movement of patients between wards and diagnostic or treatment units
- 24 hour availability of infection control advice to Bed Managers

- 2.2.8** There should be documented evidence that responsibility for infection prevention and control is effectively devolved to
- all professional groups in the NHS Body
 - clinical specialties and directorates and, where appropriate, support directorates or other units
 - and that there is audited evidence of the Body's review of infection prevention and control activities and implementation of action plans to minimise the incidence of HCAI

2.2.9 NHS bodies should ensure adequate provision of isolation facilities. Their risk assessment should include considering the need for special ventilated isolation facilities.

2.2.10 A Decontamination Lead should be appointed with responsibility for ensuring that a decontamination programme is implemented throughout the NHS Body consistent with National Guidelines.

2.3 Patient care

Clinical care protocols

2.3.1 Appropriate written policies should be in place where relevant for infection prevention and control in clinical settings. These should reflect national guidelines (where applicable) and evidence based practice and be monitored via the clinical governance system. There should be documented evidence of a rolling programme of audit, revision, and update. These policies should encompass:

- Standard (universal) infection control precautions
 - Policy to be based on evidence based guidelines, which include hand hygiene and the use of personal protective equipment
 - Policy to be easily accessible to all groups of staff, patients and the public
 - Compliance to policy to be audited
 - Information on policy to be included in induction programmes for all staff groups.
- Aseptic technique
 - Clinical procedures are carried out in a manner that maintains and promotes the principles of asepsis
 - Education, training and assessment in the aseptic technique is provided to all persons undertaking such procedures
 - The technique is standardised across the organisation
 - Audit is undertaken to monitor compliance with aseptic technique
- Major outbreaks of communicable infection
 - Policies for major outbreaks of communicable infection should include, initial assessment, communication, management and organisation, investigation and control.

- The list of contacts details of those likely to be involved in outbreak management should be reviewed at least annually.
- Major outbreaks should be reported as Serious Untoward Incidents.
- Formal arrangements are in place to fund the cost of outbreaks.
- Isolation of patients
 - Isolation policy to be evidence based
 - Indications for isolation to be included in policy
 - Isolation requirements
 - Infection control of patients in isolation
 - Information on isolation to be easily accessible to all groups of staff, patients and the public
- Safe handling and disposal of sharps should include where indicated,
 - Risk assessment, risk management and training in management of needlestick injuries
 - Provision of medical devices incorporating sharps protection mechanisms
 - Policy to be based on relevant legislation and evidence based guidelines
 - Policy to be easily accessible to all groups of staff.
 - Compliance to policy to be audited
 - Information on policy to be included in induction programmes for all staff groups.
- Prevention of occupational exposure to blood-borne viruses (BBVs), including prevention of sharps injuries
 - immunisation against hepatitis B
 - measures to avoid exposure to blood-borne viruses such the wearing of gloves and other protective clothing, the safe handling and disposal of sharps and measures to reduce risks during surgical procedures.
- Management of occupational exposure to BBVs and post exposure prophylaxis:
 - designation of one or more doctors to whom health care staff and others may be referred immediately for advice following occupational blood exposure
 - provision of clear information to health care staff about reporting potential occupational exposure and arrangements for post-exposure prophylaxis for hepatitis B and Human Immunodeficiency Virus (HIV), and follow-up, in particular the need for prompt action following a known or potential exposure to HIV.
 - Follow-up of hepatitis C exposures.
- antimicrobial prescribing

- Local prescribing should wherever possible be harmonised with that in the British national Formulary (BNF) and other formularies.
- All local guidelines should include as a minimum, certain standard items of information on drug, regimen and duration
- control of infections with specific alert organisms taking account of local epidemiology and risk assessment. These should include, but are not necessarily restricted to
 - MRSA,
 - preadmission screening
 - decontamination procedures for colonised patients
 - isolation of infected or colonised patients
 - transfer of infected or colonised patients within the NHS Bodies or to other healthcare facilities
 - antibiotic prophylaxis for surgery
 - Glycopeptide resistant enterococci
 - screening of high risk groups
 - isolation and prevention of cross infection
 - decolonisation of colonised patients
 - prophylaxis for surgical procedures
 - *Clostridium difficile* infection
 - surveillance of *C. difficile* association diarrhoea
 - diagnostic criteria
 - isolation of infected patients and cohort nursing
 - environmental decontamination
 - antibiotic prescribing policies
 - Acinetobacter and other antibiotic resistant bacteria
 - surveillance of identified patients at risk and high risk environments
 - procedures for managing infected patients to prevent spread of infection
- Control of tuberculosis, including multi-drug resistant tuberculosis:
 - isolation of infected patients
 - transfer of infected or colonised patients within the NHS Bodies or to other healthcare facilities
 - treatment compliance
- Respiratory viruses
 - alert system for suspect cases
 - isolation criteria
 - infection control measures
 - terminal disinfection and discharge
- Diarrhoeal infections

- isolation criteria
 - infection control measures
 - cleaning and disinfection policy
- Viral haemorrhagic fevers (VHF)
 - Patient risk assessment and categorisation
 - All staff to be aware of the special measures to be taken for nursing VHF patients and 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 (HSIDU) or equivalent
 - Handling of patient specimens at Laboratory Containment level 4
 - Follow up of all staff in contact with the patient at every stage of care
 - Special measures for the handling of all clinical waste
- Legionella
 - All existing premises should be regularly reviewed and a realistic programme should be prepared to eradicate any shortfall. Priority should be given to patient areas, although the exact priority will depend on local circumstances.
- Handling of medical devices in procedures carried out on known/suspect CJD patients and on patients in risk categories for CJD (including disposal/quarantining procedures).
 - To assess the risks in all cases where there may be exposure to biological agents
 - when appropriate introduce measures to either prevent or adequately control exposure.
- Safe handling and disposal of clinical waste
- Ensure that the risks from healthcare waste are properly controlled. In practice this involves:
 - Assessing risk
 - Developing policies
 - Putting arrangements into place to manage risks and
 - Monitoring the way arrangements work.
 - Awareness of legislative change.
- Precautions required when handling healthcare waste should include:
 - Training and information
 - Personal hygiene
 - Segregation of wastes
 - Personal protective equipment
 - Immunisation

- Handling
 - Packaging and labelling
 - transport on and of-site
 - accidents, incidents and spillages; and
 - treatment and disposal.
- Ensure that risks from healthcare waste to the environment are managed and duties under environmental law discharged. The most important of these are:
 - The duty of care in waste management of waste
 - The duty to control polluting emissions to air
 - The duty to control discharges to sewer and
 - The obligations of waste managers
- Closure of wards departments and premises to new admissions
 - system in place for ICT advice to Chief Executive and Medical Director
 - criteria for activating system
 - management arrangements for redirecting admissions with ICT input
 - criteria for advising closure
 - cleaning and disinfection policy before re opening
- 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 therefore will not trigger safety/security alerts
- Disinfection Policy
 - The use of disinfectants is a local decision and trusts should have local policies on disinfectant use focused on specific infection risks
 - Consider the role for high level disinfectants to kill bacteria, viruses and spores
- Care of the cadaver
 - Risk assessment of potential hazards
 - Appropriate facilities and accommodation should be provided
 - Safe working practices should be followed
 - Arrangements for visitors should be in place
 - Information instruction, training and supervision should be provided
 - Health surveillance and immunisation
- Best practice guidance for the care of patients with invasive devices should be followed.

- Trust policy to be based on evidence based guidelines
- policy to be easily accessible to all relevant healthcare workers
- Compliance to policy to be audited
- Information on policy to be included in infection control training programmes for all relevant staff groups .

All policies should be clearly marked with a review date.

2.3.2 Reusable surgical instruments and other devices should be decontaminated in accordance with manufacturer's instructions and current guidelines.

- Systems to protect both patients and staff from the transmission of infection from medical devices and other equipment which come into contact with patients or their body fluids by minimising the risk of transmission of infectious agents are required
- Decontamination is the combination of processes (including cleaning, disinfection and sterilization) used to render a reusable item safe for further use on patients and handling by staff. The effective decontamination of reusable surgical instruments is essential.
- systems should 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 the instrument sets have been used.

2.3.3 Policies should be in place for handling instruments designed for single use only or limited re-use.

2.3.4 Policies for the purchase and maintenance of all clinical equipment should take into account infection control advice.

2.3.5 For all appropriate clinical settings there should be written evidence should be available of local surveillance and use of comparative data where available. There should be ongoing local collection of data on alert organisms, alert conditions, and wound infection (a recognised scoring system should be in use for this) by clinical unit or specialty. There should be timely feedback to clinical groups with a written record of actions taken and achievements over time.

2.3.6 Organisations should take part in reporting schemes to the Health Protection Agency (HPA) as directed by the Department of Health.

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

2.3.8 There should be a policy on and appropriate provision of isolation facilities (source, protective and management of outbreaks).

2.4 The environment

2.4.1 All NHS Bodies should have written local policies, including a strategic estates plan, which reflect statutory requirements and national guidelines on the provision of a good environment. The development of these policies should take account of infection control advice and will include but not be restricted to:

- Cleaning services
- Building and refurbishment (including air handling systems)
- Clinical waste management
- Planned preventive maintenance
- Pest control
- Management of potable and non-potable water supplies
- Food services including food hygiene and food brought in to the organisation by patients, staff and visitors.

2.4.2 These policies will be subject to a rolling programme of review and update and should be clearly marked with a review date.

2.4.3 The strategic cleaning plan should detail:

- Cleaning frequencies
- Cleaning procedures
- Cleaning equipment and materials (of proven efficacy)
- Responsibilities and accountabilities of staff responsible for planning, managing and delivering cleaning services
- Training arrangements which ensure that cleaning staff do not work unsupervised until competent to do so.

2.4.4 Policies on provision of laundry services should be in line with national guidelines

2.4.5 Policies on provision of linen should be in line with national guidelines. These policies should include staff uniforms which should be clean, fit for purpose and project a professional image.

2.5 Healthcare Workers

2.5.1 NHS Bodies should ensure that all staff have access to Occupational Health Services.
Services should include:

- health screening for communicable diseases
- management of exposure to healthcare associated infections
- relevant immunisations.

2.5.2 Occupational health policies for prevention and management of communicable infections in health care workers, including those infected with blood borne viruses, management of occupational exposure to

BBVs and post exposure prophylaxis infected with blood borne viruses.
These will include:

- Arrangements for identifying and managing hepatitis B, HIV and hepatitis C infected health care workers and restricting their practice as necessary in line with DH guidance.
- Liaising with the UK Advisory Panel for Healthcare Workers Infected with Blood-borne Viruses when advice is needed on procedures which may be carried out by blood-borne virus infected health care workers and when patient notification may be needed.

2.5.3 NHS Bodies should include prevention and control of infection in induction programmes for new staff, including:

- regular staff
- support staff,
- agency/locum staff
- staff employed by contractors.

2.5.4 NHS Bodies should include prevention and control of infection in training programmes for all staff or be satisfied that adequate training is given, including:

- regular staff
- support staff,
- agency/locum staff
- staff employed by contractors.

2.5.5 There should be a documented programme on ongoing education for existing staff (including support staff, agency/locum staff and staff employed by contractors), which will include:

- update of policies,
- feedback of audit results
- examples of good practice,
- action needed to correct deficiencies.

2.5.6 There should be a record of training and updates for all staff.

2.5.7 Prevention and control of infection should be included in job descriptions, personal development plans and appraisal for all staff groups.

2.6 Other

2.6.1 Support for infection prevention and control should be provided by a Microbiology Laboratory accredited by Clinical Pathology Accreditation (UK) Ltd.

- There should be a written microbiology laboratory policy for investigation of HCAI and surveillance
- Standard Operating Procedures should be in place for the examination of specimens.

2.6.2 NHS Bodies should provide written information for service users and the public. Areas covered should include:

- general principles pertaining to the prevention and control of healthcare associated infection.
- the individual's role and responsibilities in the prevention and control of healthcare associated infection when visiting patients..

2.6.3 NHS Bodies should produce a written rolling programme ensures that all policies and procedures are continually reviewed and updated.

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THE CONSULTATION PROCESS

1. The proposals that are set out in this document have been developed with the involvement of a number of key stakeholders. We have sought the views of professional experts, particularly with reference to the development of the Code of Practice through meetings and other discussions and the proposals have been developed taking their views into account.
2. This process of involvement is continuing throughout the consultation process. During the formal consultation, the Department will be working closely with stakeholders to ensure that the issues are tested and whether the proposals are practicable and achievable throughout the NHS.
3. Finally, we look to patients, the public, clinicians and managers to give us their comments on the approach we are taking and especially to address the specific questions posed in the document. In particular:
 - Does the Code cover sufficiently broad a scope in respect of tackling health care associated infections and is there sufficient detail and clarity in what it requires of service providers?
 - Are there any key areas of health provision not covered by these proposals?
 - Do the proposals apply sufficient pressure on health care organisations to bring about changes in approaches to tackling HCAI where these are needed?
 - Are there any current measures that are unnecessary, or could be simplified, in the light of the introduction of these proposals?

RESPONDING TO THE CONSULTATION

When you should submit your contributions by?

Comments and other responses should reach the Standards Consultation mailbox at the latest by **Friday 23 September 2005**.

Where you should submit your contribution?

By email to: hcaiconsultation@dh.gsi.gov.uk

By post to:

HCAI Consultation
Department of Health
Room 418
Wellington House
135 – 155 Waterloo Road
London, SE1 8UG

What should you submit?

Please submit your views using the questions set out on the following pages. These include details about yourself and the specific questions on the proposal and an opportunity for you to make additional comments.

The information you send to us may need to be passed to colleagues within the Department of Health and/or published in a summary of responses to this consultation. We will assume that you are content for us to do this and if you are replying by e-mail, that your consent overrides any confidentiality disclaimer that is generated by your organisation's IT system, unless you specifically include a request to the contrary in the main text of your submission to us.

PERSONAL DETAILS

Title

Mr/Mrs/Ms/Dr/Professor/other

First Names

Surname Name

Address

Post Code

Email address

IF YOU ARE REPLYING ON BEHALF OF A GROUP OR ORGANISATION:

Name of organisation

Address (if different from above)

Post Code

Email address

QUESTIONS.

1. Does the Code of Practice cover sufficiently broad a scope in respect of tackling health care associated infections?
2. Is there sufficient detail and clarity in Code of Practice in what it requires of service providers?
3. Do the proposals apply sufficient pressure on health care organisations to bring about changes in approaches to tackling HCAI where these are needed?
4. Are there any current measures that are unnecessary, or could be simplified, in the light of the introduction of these proposals?

Thank you

Please add here any other comments:

GLOSSARY

Assurance Framework:

Describes organisational objectives, identifies potential risks to their achievement and gaps in assurance.

Clinical Audit:

A quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes, and outcomes of care are selected and systematically evaluated against specific criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in health care delivery.

Care Home:

A care home provides accommodation, together with nursing or personal care, for any of the following persons:

- (a) persons who are or have been ill;
- (b) persons who have or have had a mental disorder;
- (c) persons who are disabled or infirm;
- (d) persons who are or have been dependent on alcohol or drugs.

But an establishment is not a care home if it is-

- (a) a hospital;
- (b) an independent clinic; or
- (c) a children's home.

Clinical Governance:

A framework through which NHS organisations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.

Clinical Pathology Accreditation (UK) Ltd:

CPA provides a means to accredit Clinical Pathology Services and External Quality Assessment Schemes (EQA). It involves an external audit of the ability to provide a service of high quality by declaring a defined standard of practice, which is confirmed by peer review.

Clinical Protocols:

Step-by-step instructions explaining how to perform clinical tasks.

Corporate Governance:

In the NHS the system by which an organisation is directed and controlled, at its most senior levels, in order to achieve its objectives and meet the necessary standards.

CSA:

The Care Standards Act 2000, which amongst other things provides the legislative structure for the registration and inspection of private and voluntary health care and care homes.

Duty of quality:

Section 45 of the Health and Social Care (Community Health and Standards) Act 2003 states that “It is the duty of each NHS body to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care provided by and for that body.”

Foundation Trust:

A public benefit corporation established by the Health and Social Care (Community Health and Standards) Act 2003 which is authorised to provide goods and services for the purpose of the health service.

Health Care:

Services provided for, or in connection with, the prevention, diagnosis or treatment of illness, and the promotion and protection of public health.

Health care associated infection:

All infections acquired as a direct or indirect result of health care in either a hospital or community setting.

HC:

The Healthcare Commission.

Healthcare Commission:

Established in April 2004 as the independent body encompassing the work of the Commission for Health Improvement (CHI). It will inspect health care provision in accordance with national standards and other service priorities and will report directly to Parliament on the state of health care in England and Wales.

H&SC Act:

Health and Social Care (Community Health and Standards) Act 2003.

Laboratory SOPs:

Laboratory standard operating procedures

Medical Devices:

All products, except medicines, used in health care for diagnosis, prevention, monitoring or treatment. The range of products is very wide: it includes contact lenses and condoms; heart valves and hospital beds; resuscitators and radiotherapy machines; surgical instruments and syringes; wheelchairs and walking frames.

Monitor:

The independent regulator of NHS Foundation Trusts.

MRSA:

Methicillin resistant *Staphylococcus aureus*.

NHS Body:

A Primary Care Trust, Strategic Health Authority or NHS Trust, all or most of whose hospitals, establishments and facilities are situated in England, or an NHS Foundation Trust or special health authority performing functions only or mainly in respect of England.

Health care organisation:

English NHS bodies, cross SHAs and other organisations and individuals, including the independent and voluntary sectors, which provide or commission health care for individual patients and the public.

Patient:

Those in receipt of health care provided by or for an English NHS body or cross-border SHA.

Primary Care Trust (PCT):

A local health organisation responsible for – managing local health services. PCTs work with Local Authorities and other agencies that provide health and social care locally to make sure the community's are being met.

Risk Management:

Covers all the processes involved in identifying, assessing and judging risks, assigning ownership, taking actions to mitigate or anticipate them, and monitoring and reviewing progress.

Serious Untoward Incidents:

An accident or incident when a patient, member of staff (including those working in the community), or member of the public suffers serious injury, major permanent harm or unexpected death in hospital, other health service premises or other premises where NHS care is provided and where actions of health service staff are likely to cause significant public concern.

Strategic Health Authorities (SHA):

Responsible for:

- developing plans for improving health services in its local area;
- making sure local health services are of a high quality and are performing well;
- increasing the capacity of local health services so they can provide more services; and
- making sure national priorities are integrated into local health service plans.