NCGC National Clinical Guideline Centre

Draft for consultation

Infection: prevention and control of healthcare-associated infections in primary and community care

(partial update of NICE clinical guideline 2)

Clinical Guideline

Methods, evidence and recommendations

Draft for Consultation

Commissioned by the National Institute for Health and Clinical Excellence

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Setting higher medical standards

Royal College of Nursing

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Explaining the proposed changes in the consultation versions

This guidance is a partial update of NICE clinical guideline CG2, Infection control, prevention of healthcare-associated infection in primary and community care (published June 2003) and will replace it.

New and updated recommendations have been included on infection prevention and control in primary and community care.

Where recommendations end [2003] the evidence has not been updated since the original guideline. Yellow shading in these recommendations indicates where wording changes have been made for the purposes of clarification only. Recommendations have been labelled [2003, amended 2012] if the evidence has not been updated since the original guideline, but changes have been made that alter the meaning of the recommendation, such as incorporated guidance being updated or equality issues. Appendix D.10 contains these changes.

You are invited to comment on the new and updated evidence reviews and recommendations in this guideline only, which are shaded pink with 'Update 2012' in the right hand margin. Recommendations are marked as [2012] if the evidence has been reviewed but no change has been made to the recommendation or [new 2012] if the evidence has been reviewed and the recommendation has been added or updated.

Appendix D.10 contains recommendations from the 2003 guideline that are proposed for deletion in the 2012 update. This is because the evidence has been reviewed and the recommendation has been updated or because NICE has updated other relevant guidance and has replaced the original recommendations. Where there are replacement recommendations, details are provided. Where there is no replacement recommendation, an explanation for the proposed deletion is given. You are invited to comment on the deleted recommendations as part of the consultation on the 2012 update.

The original NICE guideline and supporting documents are available from www.nice.org.uk/guidance/CG2

Contents

Guideline development group and project team

Guideline development group members (2012)

Name	Role
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Dr Godfrey Smith	Consultant Medical Microbiologist, and Infection Prevention Doctor, Royal Liverpool and Broadgreen University Hospitals NHS Trusts (member until GDG 7).
Dr Julian Spinks	General Practitioner, Strood, Kent
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Mr Graham Tanner	Patient member, Member of National Concern for Healthcare Infections (NCHI)
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Guideline development group members (2003)

Name	Role
Dr Anne Mulhall (Chair)	Independent Consultant
Prof Robert Pratt	Project Director, Thames Valley University
Carol Pellowe	Project Manager, Thames Valley University
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Name	Role
Ian McQuarrie	District Nurse Team Leader, Langthorne Health Centre, London
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Guideline Development Group co-optees (2012)

Name	Role
Ms Kelly Alexander	Lead Antibiotic Pharmacist, Central Manchester Foundation NHS Trust
Dr Paul Averley	General Dental Practitioner
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Mr Andrew Jackson	Consultant Nurse Intravenous Therapy and Care, Rotherham General Hospital
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Proffessor Mark Wilcox	Consultant / Clinical Director of Microbiology/ Pathology, Leeds Teaching Hospitals NHS Trust. Professor of Medical Microbiology, University of Leeds. Lead on Clostridium. *difficile* infection in England, Health Protection Agency

National Clinical Guideline Centre Project team (2012)

Name	Role
Ms Joanna Ashe	Senior Information Scientist
Ms Nina Balachander	Senior Research Fellow and Project Manager (until September 2010)
Ms Sarah Bermingham	Health Economist
Dr Caroline Blaine	Research Fellow (from January 2011)
Dr Lee-Yee Chong	Senior Research Fellow
Mrs Karen Head	Senior Research Fellow and Project Manager (from September to December 2010)
Dr Jennifer Hill	Guidelines Operations Director (until March 2011)
Ms Susan Latchem	Guidelines Operations Director (from March 2011)
Dr Smita Padhi	Research Fellow (from January 2011)
Dr Sarah Riley	Senior Research Fellow and Project Manager

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Acknowledgements (2012)

The Guideline Development Group and project team would like to thank David Wonderling, Hati Zorba, Ebenezer Tetteh, Liz Avital and Cordelia Coltart (RCP clinical advisor) for all their help and support throughout the guideline. We would also like to thank Drs Kathy Zebracki, Lawrence Vogel, Caroline Anderson, and Ms. Kathleen Chlan for providing access to quality of life data collected from their research cohort of patients with spinal cord injuries.

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Guideline Review Panel (2012)

The Guideline Review Panel is an independent panel that oversees the development of the guideline and takes responsibility for monitoring concordance to NICE guideline development processes. In particular, the panel ensures that stakeholder comments have been adequately considered and responded to.

Guidelines Advisory Committee (2003)

Name	Role
Professor Martin Eccles (Chairman of the Committee)	Professor of Clinical Effectiveness, Centre for Health Services Research, University of Newcastle upon Tyne
Miss Amanda Wilde	Association of British Healthcare Industries (ABHI) representative
Mrs Joyce Cormie	Lay representative
Mrs Judy Mead	Head of Clinical Effectiveness, Chartered Society of Physiotherapy
Dr Marcia Kelson	Director, Patient Involvement Unit for NICE, College of Health, London

Stakeholder List (2012)

The full list of stakeholders is listed in Appendix C

1 Introduction

1.1 Introduction (2012)

Clinical context

A wide variety of healthcare is being delivered in primary and community care settings. Healthcare-associated infections (HCAI) arise across a wide range of clinical conditions and can affect patients of all ages. Healthcare workers, family members and carers are also at risk of acquiring an infection as a result of exposure to infections when caring for patients.

HCAI are commonly linked with invasive procedures or devices. For example: indwelling urinary catheters are the most common cause of urinary tract infections and bloodstream infections are often associated with vascular access devices.

HCAI are caused by a wide range of microorganisms. These are often carried by the patients themselves, and have taken advantage of a route into the body provided by an invasive device or procedure. Healthcare-associated infections can exacerbate existing or underlying conditions, delay recovery and adversely affect quality of life.

Patient safety has become a cornerstone of care and preventing HCAI remains a priority in the patient safety agenda. It is estimated that 300,000 patients a year in England acquire a HCAI as a result of care within the NHS[178]. In 2007, meticillin resistant *Staphylococcus aureus* (MRSA) bloodstream infections and *Clostridium difficile* infections were recorded as the underlying cause of, or a contributory factor in, approximately 9000 deaths in hospital and primary care in England.

HCAI are estimated to cost the NHS approximately £1 billion a year; £56 million of this is estimated to be incurred following discharge of patients from hospital[178]. In addition to increased costs, each one of these infections means additional use of NHS resources greater patient discomfort and a decrease in patient safety. A 'no tolerance 'attitude is now prevalent regarding avoidable HCAI.

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Rationale for the update

Since the publication of the NICE clinical guideline on the prevention of healthcare-associated infections in primary and community care in 2003, many changes have occurred within the NHS which place the patient firmly at the centre of all activities. First the NHS Constitution for England [69] defines the rights and pledges regarding the care every patient can expect. To support this the Care Quality Commission (CQC), the independent regulator of all health and adult social care in England ensures that health and social care is safe and monitors how providers comply with established standards.

New guidance is needed to reflect the fact that increasingly, as a result of the rapid turnover of patients in acute care settings, complex care is now being delivered in the community. New standards are required in relation to the care of patients and management of devices to prevent related HCAI, which will also reinforce the principles of asepsis.

This clinical guideline is a partial update of 'Infection control: prevention of healthcare-associated infection in primary and community care', NICE clinical guideline 2 (2003), and addresses areas in which clinical practice for preventing HCAI in primary and community care has changed or where the risk of HCAI is greatest or where the evidence has changed. Where high quality evidence was lacking the GDG have highlighted areas for further research.

Audience

The population covered in this guideline is all adults and children receiving healthcare where standard infection control precautions apply in primary and community care. This guideline is commissioned for the NHS, but people providing healthcare in other settings, such as private settings, may find the guidance relevant.

This guideline applies to all healthcare workers employed in primary and community care settings including ambulance services and will ensure safe practice if applied consistently. Much care is also delivered by informal carers and family members and these guidelines are equally applicable to them.

Healthcare settings covered by this guideline are:

- Primary care settings, such as general practices, dental clinics, health centres and polyclinics. This also includes care delivered by the ambulance service.
- Community care settings (such as care homes, patient's own home, schools and prisons) where NHS healthcare is provided or commissioned.

Style

The GDG recognised that there is a legal duty to implement some of the recommendations in this guideline in order to comply with legislation. The word 'must' is used in these recommendations and details of the relevant legislation are given in footnotes to the recommendations.

The GDG was also aware that the consequences of not implementing some other recommendations on patient safety would be very serious – that is, there would be a greatly increased risk of adverse events, including death. The GDG therefore concluded that that the use of the word 'must' in these recommendations is justified, in line with the guidance in chapter 9 of 'The guidelines manual (2009)'.For ease, the GDG have added details of the applicable legislation as footnotes to the relevant recommendations. All other instances of 'must' in a recommendation should be considered related to patient safety and the high risk of adverse events to patients if they are not implemented.

This update is integrated with the original recommendations and evidence from the 2003 guideline. Changes in methodology and processes since 2003 have resulted in a different presentation of the evidence that has informed the Guideline Development Group discussions in 2012. The recommendations made in this update are clearly marked as New 2012 or Amended 2012. The original recommendations for which the evidence has not been reviewed or updated are marked 2003. The 2003 recommendations that have not been deleted or replaced as part of this update remain current and applicable to the NHS and are enhanced by the revisions made in this update.

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1.2 Introduction (2003)

These guidelines were directly funded by the Department of Health (England) with additional funding from The National Institute for Clinical Excellence (NICE).

NICE commissioned the development of these guidelines from Thames Valley University under the auspices of the National Collaborating Centre for Nursing and Supportive Care. The full guidelines for preventing healthcare-associated infections in community and primary care are published by Thames Valley University and are available on its website <www.richardwellsresearch.com>, the NICE website <www.nice.org.uk> and on the website of the National Electronic Library for Health <www.nelh.nhs.uk>.

These guidelines were developed by a multidisciplinary Guideline Development Group (GDG) that represented all key stakeholders and included a patient representative.

Due to the breadth of the guideline, several members were appointed for their specialist knowledge of a particular medical device.

Conflicts of interest were formally monitored throughout the guideline development period and none was noted.

The aim of the group was to develop recommendations for practice based on the available evidence and knowledge of the practicalities of clinical practice.

The group met at approximately monthly intervals and followed the working procedures outlined by NICE.

During the scoping exercise, patient groups were contacted for their advice and visits made to specialist centres to discuss issues with patients and staff. Arrangements were made with a patients' organization to give extra support to the patient representative to be able to comment on all devices.

2 Development of the guideline

2.1 What is a NICE clinical guideline?

NICE clinical guidelines are recommendations for the care of individuals in specific clinical conditions or circumstances within the NHS – from prevention and self-care through primary and secondary care to more specialised services. We base our clinical guidelines on the best available research evidence, with the aim of improving the quality of health care. We use predetermined and systematic methods to identify and evaluate the evidence relating to specific review questions.

NICE clinical guidelines can:

- provide recommendations for the treatment and care of people by healthcare workers
- be used to develop standards to assess the clinical practice of individual healthcare workers
- be used in the education and training of healthcare workers
- help patients to make informed decisions
- improve communication between patient and healthcare worker.

While guidelines assist the practice of healthcare professionals, they do not replace their knowledge and skills.

We produce our guidelines using the following steps:

- the guideline topic is referred to NICE from the Department of Health
- stakeholders register an interest in the guideline and are consulted throughout the development process
- the scope is prepared by the National Clinical Guideline Centre (NCGC)
- the NCGC establishes a guideline development group
- a draft guideline is produced after the group assesses the available evidence and makes recommendations
- there is a consultation on the draft guideline
- the final guideline is produced.

The NCGC and NICE produce a number of versions of this guideline:

- the full guideline contains all the recommendations, plus details of the methods used and the underpinning evidence
- the NICE guideline lists the recommendations
- the NICE pathway is an online tool brings together all related NICE guidance and associated products in a set of interactive topic-based diagrams
- information for the public ('understanding NICE guidance' or UNG) is written using suitable language for people without specialist medical knowledge.

This version is the full version. The other versions can be downloaded from NICE at www.nice.org.uk

2.2 Remit

NICE received the remit for this guideline from the Department of Health. They commissioned the NCGC to produce the guideline.

The original guideline was referred from the Department of Health (DH) in July 2001 with the following remit:

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We would like NICE to produce a guideline on infection control in primary and community care. This guideline will be expected to address a standard approach to preventing and controlling healthcare-associated infections in primary and community care and additional guidance for selected healthcare interventions with a potential risk for infection.

NICE has commissioned the National Clinical Guidelines Centre for Acute and Chronic Conditions to partially update 'Infection control: prevention of healthcare-associated infection in primary and community care', NICE clinical guideline 2.

2.3 Who developed this guideline?

A multidisciplinary Guideline Development Group (GDG) comprising professional group members and consumer representatives of the main stakeholders developed this guideline (see section on Guideline Development Group Membership and acknowledgements).

The National Institute for Health and Clinical Excellence funds the National Clinical Guideline Centre (NCGC) and thus supported the development of this guideline. The GDG was convened by the NCGC and chaired by Carol Pellowe in accordance with guidance from the National Institute for Health and Clinical Excellence (NICE).

The group met every 4 to 6 weeks during the development of the guideline. At the start of the guideline development process all GDG members declared interests including consultancies, fee-paid work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG meetings, members declared arising conflicts of interest, which were also recorded. Members were either required to withdraw completely or for part of the discussion if their declared interest made it appropriate. The details of declared interests and the actions taken are shown in Appendix B.

Staff from the NCGC provided methodological support and guidance for the development process. The team working on the guideline included a project manager, systematic reviewers, health economists and information scientists. They undertook systematic searches of the literature, appraised the evidence, conducted meta analysis and cost effectiveness analysis where appropriate and drafted the guideline in collaboration with the GDG.

2.4 What this guideline update covers

This guideline covers the following populations:

All adults and children receiving healthcare where standard infection control precautions apply in primary and community care. Healthcare workers, family members and carers who provide healthcare in primary and community settings. Guideline developers will pay particular attention to the needs of different age groups, different genders, people with disabilities and minority ethnic groups.

This guideline covers the following healthcare settings:

Primary care settings, such as general practices, dental clinics, health centres and polyclinics. This also includes care delivered by the ambulance service. Community care settings (such as care homes, patient's own home, schools and prisons) where NHS healthcare is provided or commissioned. This guideline is commissioned for the NHS, but people providing healthcare in other settings, such as private settings, may find the guidance relevant.

This guideline covers the following clinical issues:

Hand hygiene including when to decontaminate hands, the choice of hand cleaning preparation and the most effective hand decontamination technique.

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Personal protective equipment (PPE) including the safe disposal of personal protective equipment in line with European Union (EU) legislation, the appropriate use of plastic aprons and fluid-repellent gowns and which gloves provide the best protection against infections.

The safe use and disposal of sharps including the choice of sharps equipment and safe disposal of sharp instruments and needles in line with current EU legislation.

Long term urinary catheters (more than 28 days) including the use of antibiotics when changing indwelling urinary catheters, the use of bladder irrigation, instillations and washouts, types of catheters to use and aseptic technique.

Percutaneous gastrostomy feeding including the use of syringes in enteral feeding systems.

Vascular access devices (VADs), including types of dressings, decontamination of ports, hubs and skin and aseptic technique.

Information and support for healthcare workers, patients and carers:

For further details please refer to the scope in Appendix A and review protocols in Appendix E.

2.5 What this guideline update does not cover

This guideline covers does not cover:

- people receiving healthcare in secondary care settings,
- advice on the diagnosis, treatment or management of specific infections,
- insertion of urinary catheters, percutaneous gastrostomies or vascular access devices,
- infection prevention measures for invasive procedures carried out by paramedic services, such as at a major trauma, other than in the clinical areas listed section 2.4,
- decontamination or cleaning of the healthcare environment and equipment, other than the clinical devices listed in 2.4.

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2.6 Structure of the updated guideline

All updated text, including evidence reviews and recommendations are marked by a shaded pink box with 'Update 2012' in the right hand margin.

2.6.1 Chapters

The structure of the updated guideline has been kept as close to the original guideline as possible:

- Standard principles general recommendations (including education of patients, carers and their healthcare workers)
- Standard principles for hand hygiene
- Standard principles for the use of personal protective equipment
- Standard principles for the safe use and disposal of sharps
- Waste disposal (including general recommendation about disposal of healthcare waste)
- Long term urinary catheterisation
- Enteral feeding
- Vascular access devices (VADs).

2.6.2 Methodology

The methodology of writing NICE guidelines has changed substantially since the previous guideline, therefore the updated sections are in a very different style and clearly present evidence tables, evidence statements and linking evidence to recommendation sections, detailed in the methodology chapter, which are not present in the sections that have not been reviewed in this update. The presentation of evidence remains the same as in the original 2003 guideline for recommendations not updated.

2.6.3 Recommendations

Recommendations made in the original 2003 guideline that were not within the scope of the partial update were reviewed to check for accuracy and consistency in light of the new recommendations made. These recommendations are marked as [2003] and yellow shading in these recommendations indicates where wording changes have been made for the purposes of clarification only.

Recommendations are marked [2003, amended 2012] if the evidence has not been updated since the original guideline, but changes have been made that change the meaning of the recommendation, such as incorporated guidance being updated or equality issues. Appendix D.10 contains these changes.

Recommendations are marked as [2012] if the evidence has been reviewed but no change has been made to the recommendation or [new 2012] if the evidence has been reviewed and the recommendation has been added or updated. All updated text and recommendations are in a shaded pink box with 'Update 2012' in the right hand margin.

Appendix D.10 contains recommendations from the 2003 guideline that have been deleted or amended in the 2012 update. This is because the evidence has been reviewed and the recommendation has been updated or because NICE has updated other relevant guidance and has replaced the original recommendations. Where there is no replacement recommendation, an explanation for the proposed deletion is given.

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2.6.4 Appendices

The appendices of the 2003 guideline have been moved to sit at the end of the guideline rather than at the end of each chapter to improve the flow of the guideline. This includes the AGREE scores, systematic review process, evidence tables and reference lists.

2.7 Relationships between the guideline and other NICE guidance

Related NICE Clinical Guidelines:

- Tuberculosis. NICE clinical guideline 117 (2011). Available from www.nice.org.uk/guidance/CG117
- Lower urinary tract symptoms. NICE clinical guideline 97 (2010). Available from www.nice.org.uk/guidance/CG97
- Needle and syringe programmes. NICE public health guidance 18 (2009). Available from www.nice.org.uk/guidance/PH18
- Surgical site infection. NICE clinical guideline 74 (2008). Available from www.nice.org.uk/guidance/CG74
- Prophylaxis against infective endocarditis. NICE clinical guideline 64 (2008). Available from http://www.nice.org.uk/guidance/CG64
- Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from www.nice.org.uk/guidance/CG54

- Urinary incontinence. NICE clinical guideline 40 (2006). Available from www.nice.org.uk/guidance/CG40
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32

NICE Related Guidance currently in development:

- Urinary incontinence in neurological disease. NICE clinical guideline. Publication expected: October 2012.
- Stroke rehabilitation. NICE clinical guideline. Publication expected: April 2012.
- Healthcare-associated infections in secondary care settings. NICE advice. Publication expected: November 2011.
- Intravenous fluid therapy in adults in hospital. NICE clinical guideline. Publication date to be confirmed.

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2.8 Background and context to the Guidelines (2003)

The prevalence of healthcare-associated infections in patients in primary and community care settings in the United Kingdom is not known. Many infections in these patients may have been acquired in hospital and only identified following early discharge into the community. The risk of infection will also be influenced by the use of various medical devices, such as urinary and central venous catheters and enteral feeding systems.

Incorporating evidence-based infection prevention and control advice into routine clinical care activities is believed to be important in reducing the incidence of preventable healthcare-associated infections[112]. Consequently, guidelines for preventing healthcare-associated infections in caring for patients in primary and community care settings were commissioned.

2.9 Scope and Purpose of the Guidelines (2003)

The scope of these guidelines was established at the start of the guideline process, following a period of consultation, including a survey and focus group discussions with community and primary care practitioners. This consultation process has been previously described[197] and the full scoping exercise is available from the NICE website <www.nice.org.uk> (Appendix D.2).

These guidelines were developed to help prevent healthcare-associated infections (HAI) in community and primary care. They provide guidance for standard infection control precautions that may be applied by all healthcare workers to the care of all patients in community and primary care settings. They also provide guidance to non-professional carers, patients and their families.

These guidelines are intended to be broad principles of best practice which need to be incorporated into local practice guidelines. Four sets of guidelines have been developed:

- Standard Principles for preventing healthcare-associated infections in community and primary care;
- Guidelines for preventing infections associated with the use of long-term urinary catheters;
- Guidelines for preventing infections associated with the use of enteral feeding systems;
- Guidelines for preventing infections associated with the use of long-term central venous catheters.

3 Methods

3.1 Methods (2012)

This guidance was developed in accordance with the methods outlined in the NICE Guidelines Manual 2009[180].

3.1.1 Amendments to 2003 text

All text and recommendations from the previous guideline that have not been updated (therefore review questions have not been generated and evidence has not been searched for) have been left unchanged. Amendments to recommendations are detailed in Appendix D.10.

Exceptions include:

Text in previous guideline	Change made and reason for change
Must	Should or ensure. Must is only used in if there is a legal duty to apply the recommendation, or the consequences of not following a recommendation are so serious (for example, there is a high risk that the patient could die) that using 'must' (or 'must not') is justified.
Healthcare personnel	Healthcare worker. This is for consistency with other NICE guidelines and is considered a more suitable term. The GDG considered the term 'healthcare workers' to include a wider group of people than healthcare professionals, which they considered only those staff with professional qualifications.
Community and primary or community staff	Removed as all recommendations refer to primary and community settings.
Central venous catheters	Vascular access devices. The updated scope includes peripheral venous catheters and therefore some text is expanded to include all types of vascular access devices where appropriate.
Prostatomegaly	Prostatic enlargement. The GDG considered that the term prostatomegaly is an out-of-date term and that prostatic enlargement is plain language terminology.
Healthcare-associated infection (HAI)	Changed to healthcare-associated infection (HCAI). Abbreviation updated to avoid confusion as HAI may be read hospital acquired infection and not the broader healthcare-associated infection.
Methicillin resistant *Staphylococcus aureus*	Changed to Meticillin resistant *Staphylococcus aureus* to be consistent with current Department of Health terminology and the British National Formulary.

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3.1.2 Developing the review questions and outcomes

Review questions were developed in a PICO framework (patient, intervention, comparison and outcome) for intervention reviews. For qualitative reviews the SPICE framework (setting, population, intervention, comparison and evaluation methods) was used. This was to guide the literature searching process and to facilitate the development of recommendations by the guideline development group (GDG). They were drafted by the NCGC technical team and refined and validated by the GDG. The questions were based on the key clinical areas identified in the scope (Appendix A). Further information on the outcome measures is shown below and detailed in the review protocols (Appendix E).

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2

Chapter	Review questions	Outcomes
Standard principles	What information do healthcare professionals, patients and carers require to prevent healthcare-associated infections in primary and community care settings?	Information and evidence about what type of information should be provided to patients regarding hand hygiene to prevent healthcare-associated infections.
Hand hygiene	What is the clinical and cost effectiveness of when to decontaminate hands, including after the removal of gloves, on hand hygiene compliance, MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination?	Colony forming units, hand hygiene compliance, MRSA and *C. diff* reduction and cross infection and removal of physical contamination.
Hand hygiene	What is the clinical and cost effectiveness of cleaning preparations (soap and water, alcohol based rubs, non-alcohol products and wipes) for healthcare worker hand decontamination, on hand hygiene compliance, MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination?	Colony forming units, hand hygiene compliance, MRSA and *C. diff* reduction and cross infection and removal of physical contamination.
Hand hygiene	What is the clinical and cost effectiveness of healthcare workers decontaminating wrists vs. not decontaminating wrists or usual practice on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?	Colony forming units, hand hygiene compliance, MRSA and *C. diff* reduction and cross infection and removal of physical contamination and transient organisms.
Hand hygiene	What is the clinical and cost effectiveness of healthcare workers following bare below the elbow policies (short sleeves or rolled up sleeves) vs. no bare below the elbow policy (long sleeves, not rolled up or no specific restrictions) on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?	Colony forming units, hand hygiene compliance, MRSA and *C. diff* reduction and cross infection and removal of physical contamination and transient organisms.
Personal protective equipment	What is the clinical and cost effectiveness of healthcare workers wearing vinyl, latex or nitrile gloves on user preference and reduction of hypersensitivity, blood borne infections, glove porosity and tears?	Ability to perform task, blood borne infections, bodily fluid contamination, glove porosity, holes or tears, hypersensitivity and user preference.
Personal protective equipment	What is the clinical and cost effectiveness of healthcare workers wearing plastic aprons or fluid repellent gowns vs. no aprons or gowns, gloves only or standard uniform on the reduction of blood and bodily fluid and pathogenic microorganism contamination?	Blood borne viruses and bodily fluid contamination.
Sharps	What is the clinical and cost effectiveness of healthcare workers using safety needle cannulae vs. standard cannulae on compliance and user preference, infection related mortality and morbidity and sharps injuries?	Blood borne infection, compliance, infection related mortality and morbidity, sharps injuries and user preference.
Sharps	What is the clinical and cost effectiveness of healthcare workers using safety needle devices (needle free, retractable needles, safety resheathing devices) vs. standard needles on compliance and user preference, infection related mortality and morbidity and sharps injuries?	Blood borne infection, compliance, infection related mortality and morbidity, sharps injuries and user preference.

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Chapter	Review questions	Outcomes
Waste Disposal	Are there any changes in the legislations which affect the disposal of personal protective equipments in relation to patient care in the primary and community care settings?	Updated based on legislation.
Waste Disposal	Are there any changes in the legislations which affect the disposal of sharp instruments and needles in relation to patient care in the primary and community care settings?	Updated based on legislation.
Long-term urinary catheters	What is the clinical and cost effectiveness of different types of long-term indwelling urinary catheters (non-coated silicone, hydrophilic coated, or silver or antimicrobial coated/impregnated) on urinary tract infections, bacteraemia, frequency of catheter change, encrustations and blockages, mortality, and patient preference?	Symptomatic UTIs, bacteraemia, frequency of catheter change, encrustations and blockages, mortality patient preference and comfort.
Long-term urinary catheters	What is the clinical and cost effectiveness of different types of long-term intermittent urinary catheters (non-coated, hydrophilic or gel reservoir) on symptomatic urinary tract infections, bacteraemia, mortality, and patient preference?	Symptomatic UTIs, bacteraemia, mortality patient preference and comfort.
Long-term urinary catheters	In patients performing intermittent catheterisation, what is the clinical and cost effectiveness of non-coated catheters reused multiple times compared to single use on urinary tract infections, bacteraemia, mortality, and patient preference?	Symptomatic UTIs, bacteraemia, mortality patient preference and comfort.
Long-term urinary catheters	What is the clinical and cost effectiveness of bladder instillations or washouts on reduction of catheter associated symptomatic urinary tract infections and encrustations and blockages?	Symptomatic UTIs, bacteraemia, frequency of catheter change, encrustations and blockages, mortality patient preference and comfort.
Long term urinary catheters	In patients with long term urinary catheters (more than 28 days), what is the clinical and cost effectiveness of prophylactic antibiotics (single dose or short course) use during catheter change on reduction of urinary tract infections?	Antibiotic resistance, bacteraemia, mortality, patient preference, symptomatic UTIs, upper UTIs.
Enteral feeding	What is the clinical and cost effectiveness of single vs. reusable syringes used to flush percutaneous endoscopic gastrostomy (PEG) tubes on reduction of tube blockages, diarrhoea, fungal colonisation, gastrostomy site infection, peritonitis and vomiting?	Blockages or tube occlusion, diarrhoea, vomiting, fungal colonisation, gastrostomy site infection and peritonitis.
Vascular access devices	What is the most clinical and cost effective product or solution for decontamination of the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?	Catheter tip colonisation, infection related mortality, septicaemia, VAD line removal, VAD related bacteraemia, VAD related phlebitis and VAD related soft tissue infection.
Vascular access devices	What is the clinical and cost effectiveness of dressings (transparent semipermeable, impregnated or gauze and tape) covering peripherally or centrally inserted vascular access device insertion sites, including those that are bleeding or oozing, on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and	Catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, vascular access device (VAD) related bacteraemia and VAD related phlebitis.

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Chapter	Review questions	Outcomes
	phlebitis?	
Vascular access devices	What is the clinical and cost effectiveness of frequency of dressing change (from daily up to 7 days) on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and phlebitis?	Catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, VAD related bacteraemia, VAD related phlebitis.
Vascular access devices	What is the most clinical and cost effective product or solution for skin decontamination when changing VAD dressings on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?	Catheter tip colonisation, infection related mortality, septicaemia, VAD line removal, VAD related bacteraemia, VAD related phlebitis and VAD related soft tissue infection.
Vascular access devices	What is the most clinical and cost effective duration of application of decontamination product/solution to the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?	Catheter tip colonisation, infection related mortality, septicaemia, VAD line removal, VAD related bacteraemia, VAD related phlebitis and VAD related soft tissue infection.
Vascular access devices	What is the most clinical and cost effective product or solution for decontaminating VAD ports and hubs prior to access on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and frequency of line removal?	Catheter tip colonisation, infection related mortality, septicaemia, VAD line removal, VAD related bacteraemia, VAD related phlebitis and VAD related soft tissue infection.
Vascular access devices	What is the clinical and cost effectiveness of multi dose vials vs. single use vials for administrating infusions or drugs on preventing contamination of the infusate and healthcare-associated infection?	Catheter tip colonisation, infection related mortality, septicaemia, VAD line removal, VAD related bacteraemia, VAD related phlebitis and VAD related soft tissue infection.
Asepsis (Long term urinary catheters)	What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling long-term urinary catheters to reduce colony forming units, urinary tract infections, compliance, MRSA or *C. diff* reduction and mortality?	Urinary tract infections, infection related mortality, septicaemia, bacteraemia, phlebitis, compliance, MRSA or *C. diff* reduction.
Asepsis (Enteral feeding)	What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling PEGs to reduce healthcare-associated infections?	Infection related bacteraemia, infection related mortality, compliance, MRSA or *C. diff* reduction.
Asepsis (Vascular access devices)	What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling vascular access devices to reduce infection related bacteraemia, phlebitis, compliance, MRSA or *C. diff* reduction and mortality?	Catheter tip colonisation, Infection-related mortality, septicaemia, VAD related bacteraemia, VAD related phlebitis, compliance, MRSA or *C. diff* reduction.

Update 2012

3.1.3 Searching for evidence

3.1.3.1 Clinical literature search

Systematic literature searches were undertaken to identify evidence within published literature in order to answer the review questions as per The Guidelines Manual [2009][180]. Clinical databases were searched using relevant medical subject headings, free-text terms and study type filters where appropriate. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language. All searches were conducted on core databases, MEDLINE, Embase, Cinahl and The Cochrane Library. The additional subject specific database PsychInfo was used for the patient information questions. All searches were updated on 18th April 2011. No papers after this date were considered.

Search strategies were checked by looking at reference lists of relevant key papers, checking search strategies in other systematic reviews and asking the GDG for known studies. The questions, the study types applied, the databases searched and the years covered can be found in Appendix F.

During the scoping stage, a search was conducted for guidelines and reports on the websites listed below and on organisations relevant to the topic. Searching for grey literature or unpublished literature was not undertaken. All references sent by stakeholders were considered.

- Guidelines International Network database (www.g-i-n.net)
- National Guideline Clearing House (www.guideline.gov/)
- National Institute for Health and Clinical Excellence (NICE) (www.nice.org.uk)
- National Institutes of Health Consensus Development Program (consensus.nih.gov/)
- National Library for Health (www.library.nhs.uk/)

Update 2012

3.1.3.2 Health economic literature search

Systematic literature searches were also undertaken to identify health economic evidence within published literature relevant to the review questions. The evidence was identified by conducting a broad search relating to the five key areas in the guideline: long-term urinary catheters, vascular access devices, hand hygiene, sharps and personal protective equipment, in the NHS economic evaluation database (NHS EED), the Health Economic Evaluations Database (HEED) and health technology assessment (HTA) databases with no date restrictions. Additionally, the search was run on MEDLINE and Embase, with a specific economic filter, to ensure publications that had not yet been indexed by these databases were identified. This was supplemented by additional searches that looked for economic and quality of life papers specifically relating to asepsis, urinary tract infections and catheter-related bloodstream infections the same databases as it became apparent that some papers in this area were not being identified through the first search. Studies published in languages other than English were not reviewed. Where possible, searches were restricted to articles published in English language.

The search strategies for health economics are included in Appendix F. All searches were updated on 18th April 2011. No papers published after this date were considered.

3.1.3.3 Evidence synthesis

The Research Fellow:

- Identified potentially relevant studies for each review question from the relevant search results by reviewing titles and abstracts – full papers were then obtained.

- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify studies that addressed the review question in the appropriate population and reported on outcomes of interest (review protocols are included in Appendix E).
- Critically appraised relevant studies using the appropriate checklist as specified in The Guidelines Manual[180].
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix G).
- Generated summaries of the evidence by outcome (included in the relevant chapter write-ups):
  - Randomised studies: meta-analysed, where appropriate and reported in GRADE (Grading of Recommendations Assessment, Development and Evaluation) profiles (for clinical studies) – see below for details.
  - Observational studies: data presented as a range of values in GRADE profiles.
  - Qualitative studies: each study summarised in a table (available in Appendix G) where possible, and the quality of included studies assessed against the NICE quality checklists for qualitative studies [180]. Key common themes between studies which were relevant to the review question were summarised and presented with a comment of the quality of studies contributing to the themes in the main guideline document. GRADE does not have a system for rating the quality of evidence for qualitative studies or surveys, and therefore there are no GRADE quality ratings for the themes identified.

3.1.3.4 Inclusion/exclusion

The inclusion and exclusion criteria were considered according to the PICO used in the protocols, see Appendix F for full details.

A major consideration in determining the inclusion and exclusion criteria in the protocol was the applicability of the evidence to the guideline population. The GDG decided to exclude certain settings and populations that could not be extrapolated to community settings, these are detailed per review question in the protocols. See "Indirectness", section 3.1.3.10.

Laboratory studies were excluded because the populations used (volunteers, animals or *in vitro*) are artificial and not comparable to the population we are making recommendations for. These studies would undoubtedly be of very low quality as assessed by GRADE and therefore low quality RCTs, cohort studies or GDG consensus opinion was considered preferable.

Abstracts, posters, reviews, letters/editorials, foreign language publications and unpublished studies were excluded.

3.1.3.5 Methods of combining clinical studies

Data synthesis for intervention reviews

Where possible, meta-analyses were conducted to combine the results of studies for each review question using Cochrane Review Manager (RevMan5) software. Fixed-effects (Mantel-Haenszel) techniques were used to calculate risk ratios (relative risk) for the binary outcomes. The continuous outcomes were analysed using an inverse variance method for pooling weighted mean differences and where the studies had different scales, standardised mean differences were used. Statistical heterogeneity was assessed by considering the chi-squared test for significance at $p < 0.1$ or an I-squared inconsistency statistic of >50% to indicate significant heterogeneity. Where there was heterogeneity and a sufficient number of studies, sensitivity analyses were conducted based on risk of bias and pre-specified subgroup analyses were carried out as defined in the protocol.

Update 2012

Assessments of potential differences in effect between subgroups were based on the chi-squared tests for heterogeneity statistics between subgroups. If no sensitivity analysis was found to completely resolve statistical heterogeneity then a random effects (DerSimonian and Laird) model was employed to provide a more conservative estimate of the effect.

The means and standard deviations of continuous outcomes were required for meta-analysis. However, in cases where standard deviations were not reported, the standard error was calculated if the p-values or 95% confidence intervals were reported and meta-analysis was undertaken with the mean difference and standard error using the generic inverse variance method in Cochrane Review Manager (RevMan5) software. Where p values were reported as "less than", a conservative approach was undertaken. For example, if p value was reported as "p <0.001", the calculations for standard deviations were based on a p value of 0.001. If these statistical measures were not available then the methods described in section 16.1.3 of the Cochrane Handbook [121] 'Missing standard deviations' were applied as the last resort.

For binary outcomes, absolute differences in event rates were also calculated using the GRADEpro software using total event rate in the control arm of the pooled results.

3.1.3.6 Appraising the quality of evidence by outcomes

Update 2012

After appropriate pooling of the results for each outcome across all studies, the quality of the evidence for each outcome was evaluated and presented using an adaptation of the GRADE toolbox'[108]. The software (GRADEpro) developed by the international GRADE working group was used to record the assessment of the evidence quality for each outcome.

In this guideline, findings were summarised using two separate tables. The "Clinical Study Characteristics" table includes details of the quality assessment. Reporting or publication bias was only taken into consideration in the quality assessment and included in the Clinical Study Characteristics table if it is clear there was a risk of bias. Each outcome was examined separately for the quality elements listed and defined in Table 1 and each graded using the quality levels listed in Table 2. The main criteria considered in the rating of these elements are discussed below (see section 3.1.3.7 Grading of Evidence). Footnotes were used to describe reasons for grading a quality element as having serious or very serious problems. The ratings for each component were summed to obtain an overall assessment for each outcome listed in Table 3.

The "Clinical Summary of Findings" table includes pooled outcome data (where appropriate), an absolute measure of intervention effect and the summary of quality of evidence for that outcome. In the Clinical Summary of Findings table, the columns for intervention and control indicate the total of the sample size for continuous outcomes. For binary outcomes such as number of patients with an adverse event, the event rates (n/N: total number of patients with events divided by total number of patients across studies) are shown with percentages (note: this is not the results of the meta-analysis).

Table 1: Description of quality elements in GRADE for intervention studies

Quality element	Description
Limitations	Limitations in the study design and implementation may bias the estimates of the treatment effect. Major limitations in studies decrease the confidence in the estimate of the effect.
Inconsistency	Inconsistency refers to an unexplained heterogeneity of results.
Indirectness	Indirectness refers to differences in study population, intervention, comparator and outcomes between the available evidence and the review question, or recommendation made.
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the effect relative to the clinically important threshold.
Publication bias	Publication bias is a systematic underestimate or an overestimate of the underlying beneficial or harmful effect due to the selective publication of studies.

Table 2: Levels of quality elements in GRADE

Level	Description
None	There are no serious issues with the evidence.
Serious	The issues are serious enough to downgrade the outcome evidence by one level.
Very serious	The issues are serious enough to downgrade the outcome evidence by two levels.

Table 3: Overall quality of outcome evidence in GRADE

Level	Description
High	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate	We are moderately confident in the effect estimate: the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
Low	Our confidence in the effect estimate is limited: the true effect may be substantially different from the estimate of the effect.
Very low	We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

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3.1.3.7 Grading the quality of clinical evidence

After results were pooled, the overall quality of evidence for each outcome was considered. The following procedure was adopted when using GRADE:

1. A quality rating was assigned, based on the study design. RCTs start HIGH and observational studies as LOW, uncontrolled case series as LOW or VERY LOW.
2. The rating was then downgraded for the specified criteria: Study limitations, inconsistency, indirectness, imprecision and publication bias. These criteria are detailed below. Observational studies were upgraded if there was a large magnitude of effect, dose-response gradient, and if all plausible confounding would reduce a demonstrated effect or suggest a spurious effect when results showed no effect. Each quality element considered to have “serious” or “very serious” risk of bias was rated down -1 or -2 points respectively.
3. The downgraded/upgraded marks were then summed and the overall quality rating was revised. For example, all RCTs started as HIGH and the overall quality became MODERATE, LOW or VERY LOW if 1, 2 or 3 points were deducted respectively.
4. The reasons or criteria used for downgrading were specified in the footnotes.

The details of criteria used for each of the main quality element are discussed further in the following sections 3.1.3.8 to 3.1.3.11.

3.1.3.8 Study limitations

The main limitations for randomised controlled trials are listed in Table 4.

Table 4: Study limitations of randomised controlled trials

Limitation	Explanation
Allocation concealment	Those enrolling patients are aware of the group to which the next enrolled patient will be allocated (major problem in "pseudo" or "quasi" randomised trials with allocation by day of week, birth date, chart number, etc).
Lack of blinding	Patient, caregivers, those recording outcomes, those adjudicating outcomes, or data analysts are aware of the arm to which patients are allocated.
Incomplete accounting of patients and outcome events	Loss to follow-up not accounted and failure to adhere to the intention to treat principle when indicated.
Selective outcome reporting	Reporting of some outcomes and not others on the basis of the results.
Other limitations	For example: • Stopping early for benefit observed in randomised trials, in particular in the absence of adequate stopping rules • Use of unvalidated patient-reported outcomes • Carry-over effects in cross-over trials • Recruitment bias in cluster randomised trials.

Update 2012

3.1.3.9 Inconsistency

Inconsistency refers to an unexplained heterogeneity of results. When estimates of the treatment effect across studies differ widely (i.e. heterogeneity or variability in results), this suggests true differences in underlying treatment effect. When heterogeneity exists (Chi square p<0.1 or I- squared inconsistency statistic of >50%), but no plausible explanation can be found, the quality of evidence was downgraded by one or two levels, depending on the extent of uncertainty to the results contributed by the inconsistency in the results. In addition to the I- square and Chi square values, the decision for downgrading was also dependent on factors such as whether the intervention is associated with benefit in all other outcomes or whether the uncertainty about the magnitude of benefit (or harm) of the outcome showing heterogeneity would influence the overall judgment about net benefit or harm (across all outcomes).

If inconsistency could be explained based on pre-specified subgroup analysis, the GDG took this into account and considered whether to make separate recommendations based on the identified explanatory factors, i.e. population and intervention. Where subgroup analysis gives a plausible explanation of heterogeneity, the quality of evidence was not downgraded.

3.1.3.10 Indirectness

Directness refers to the extent to which the populations, intervention, comparisons and outcome measures are similar to those defined in the inclusion criteria for the reviews. Indirectness is important when these differences are expected to contribute to a difference in effect size, or may affect the balance of harms and benefits considered for an intervention.

Studies that were in settings other than primary care and community settings were downgraded using GRADE if the GDG considered that the study was indirect. For further details and any exceptions are detailed in the review protocols, see Appendix E.

3.143.11 Imprecision

Results are often imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect. This, in turn, may mean that we are uncertain if there is an important difference between interventions or not. If this is the case, the evidence may be considered to be of lower quality of the evidence lower than it otherwise would be because of resulting uncertainty in the results.

The thresholds of important benefits or harms, or the MID (minimal important difference) for an outcome are important considerations for determining whether there is a "clinically important" difference between interventions, and in assessing imprecision. For continuous outcomes, the MID is defined as "the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management" [108,129,231,232]. An effect estimate larger than the MID is considered to be "clinically important". For dichotomous outcomes, the MID is considered in terms of changes in absolute risk.

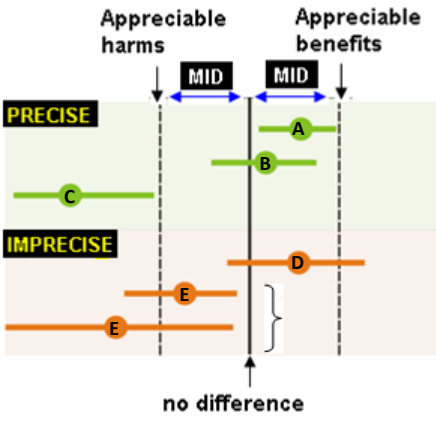
The difference between two interventions, as observed in the studies, was compared against the MID when considering whether the findings were of "clinical importance"; this is useful to guide decisions. For example, if the effect size was small (less than the MID), this finding suggests that there may not be enough difference to strongly recommend one intervention over the other based on that outcome.

The confidence interval for the pooled or best estimate of effect was considered in relation to the MID, as illustrated in Figure 1. Essentially, if the confidence interval crossed the MID threshold, there was uncertainty in the effect estimate in supporting our recommendations (because the CI was consistent with two decisions) and the effect estimate was rated as imprecise.

For the purposes of this guideline, an intervention is considered to have a clinically important effect with certainty if the whole of the 95% confidence interval describes an effect of greater magnitude than the MID. Figure 1 illustrates how the clinical importance of effect estimates were considered along with imprecision, and the usual way of documenting this is in the evidence statements throughout this guideline. Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of the effect relative to the clinically important threshold.

Update 2012

Figure 1: Imprecision and evidence statements



Position of confidence interval	Evidence statement
A	Statistically significant but not clinically important
B	It is unlikely that there is any difference
C	Statistically significant and clinically important
D	Uncertain whether there is any difference
E	Statistically significant difference of uncertain clinical importance

Source: Figure adapted from GRADEPro software and modified to reflect the application of imprecision rating in the guideline process. The effect estimates of the top three examples (A-C) were considered precise because neither the upper or lower confidence limits crossed the MID. Conversely, the bottom three examples (D and E) were considered imprecise because the CI crossed the MID in each case, and this reduced our certainty of the results.

For this guideline, there was no information in the literature on what was the most appropriate MID, and the GDG adopted the default threshold suggested by GRADE. This was a relative risk reduction of 25% (relative risk of 0.75 for negative outcomes) or a relative risk increase of 25% (risk ratio 1.25 for positive outcomes) for binary outcomes. The GDG interpreted the risk ratio and 95% confidence interval relative to the threshold, also taking into account the 95% confidence intervals of the absolute effect estimates. For continuous outcomes, a standardised mean difference (SMD) of 0.5 was considered the minimal important difference for most outcomes.

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3.1.4 Evidence of cost-effectiveness

Evidence on cost-effectiveness related to the key clinical issues being addressed in the guideline was sought. The health economist:

- Undertook a systematic review of the economic literature
- Undertook new cost-effectiveness analysis in priority areas.

3.1.4.1 Literature review

The Health Economist:

- Identified potentially relevant studies for each review question from the economic search results by reviewing titles and abstracts – full papers were then obtained.
- Reviewed full papers against pre-specified inclusion / exclusion criteria to identify relevant studies (see below for details).
- Critically appraised relevant studies using the economic evaluations checklist as specified in The Guidelines Manual[180]
- Extracted key information about the study's methods and results into evidence tables (evidence tables are included in Appendix H).
- Generated summaries of the evidence in NICE economic evidence profiles (included in the relevant chapter write-ups) – see below for details.

Inclusion/exclusion

Full economic evaluations (studies comparing costs and health consequences of alternative courses of action: cost–utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and comparative costing studies that addressed the review question in the relevant population were considered as potentially applicable economic evidence.

In the absence of any full economic evaluations, studies that reported cost per hospital, or reported average cost-effectiveness without disaggregated costs and effects, were considered for inclusion on a case-by-case basis.

Abstracts, posters, reviews, letters/editorials, foreign language publications and unpublished studies were excluded. Studies judged to be 'not applicable' were excluded (this included studies that took the perspective of a non-OECD country).

Remaining studies were prioritised for inclusion based on their relative applicability to the development of this guideline and the study limitations. For example, if a high quality, directly applicable UK analysis was available then other less relevant studies may not have been included. Where exclusions occurred on this basis, this was noted in the relevant section.

For more details about the assessment of applicability and methodological quality see the economic evaluation checklist (The Guidelines Manual)[180].

When no relevant economic analysis was identified in the economic literature review, relevant UK NHS unit costs were presented to the GDG to inform discussion of economic considerations.

NICE economic evidence profiles

The NICE economic evidence profile has been used to summarise cost and cost-effectiveness estimates. The economic evidence profile shows, for each economic study, an assessment of applicability and methodological quality, with footnotes indicating the reasons for the assessment. These assessments were made by the health economist using the economic evaluation checklist from The Guidelines Manual[180]. It also shows incremental costs, incremental outcomes (for example, QALYs) and the incremental cost-effectiveness ratio from the primary analysis, as well as information about the assessment of uncertainty in the analysis. See Table 5 for more details.

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If a non-UK study was included in the profile, the results were converted into pounds sterling using the appropriate purchasing power parity[190] and Hospital and Community Health Services Pay and Prices Inflation Index[54].

Table 5: Content of NICE economic profile

Item	Description
Study	First author name, reference, date of study publication and country perspective.
Limitations	An assessment of methodological quality of the study*: • Minor limitations – the study meets all quality criteria, or the study fails to meet one or more quality criteria, but this is unlikely to change the conclusions about cost effectiveness. • Potentially serious limitations – the study fails to meet one or more quality criteria, and this could change the conclusion about cost effectiveness • Very serious limitations – the study fails to meet one or more quality criteria and this is very likely to change the conclusions about cost-effectiveness. Studies with very serious limitations would usually be excluded from the economic profile table.
Applicability	An assessment of applicability of the study to the clinical guideline, the current NHS situation and NICE decision-making[(a)]:

Item	Description
	• Directly applicable – the applicability criteria are met, or one or more criteria are not met but this is not likely to change the conclusions about cost effectiveness. • Partially applicable – one or more of the applicability criteria are not met, and this might possibly change the conclusions about cost effectiveness. • Not applicable – one or more of the applicability criteria are not met, and this is likely to change the conclusions about cost effectiveness.
Other comments	Particular issues that should be considered when interpreting the study.
Incremental cost	The mean cost associated with one strategy minus the mean cost of a comparator strategy.
Incremental effects	The mean QALYs (or other selected measure of health outcome) associated with one strategy minus the mean QALYs of a comparator strategy.
ICER	Incremental cost-effectiveness ratio: the incremental cost divided by the respective QALYs gained.
Uncertainty	A summary of the extent of uncertainty about the ICER reflecting the results of deterministic or probabilistic sensitivity analyses, or stochastic analyses of trial data, as appropriate.

(a) Limitations and applicability were assessed using the economic evaluation checklist from The Guidelines Manual[180]

3.1.4.2 Undertaking new health economic analysis

As well as reviewing the published economic literature for each review question as described above, original economic analysis was undertaken by the Health Economist in priority areas. Priority areas for new health economic analysis were agreed by the GDG after formation of the review questions and consideration of the available health economic evidence.

Additional data for the analysis was identified as required through additional literature searches undertaken by the Health Economist, and discussion with the GDG. Model structure, inputs and assumptions were explained to and agreed by the GDG members during meetings, and they commented on subsequent revisions.

See Appendix J for details of the health economic analysis/analyses undertaken for the guideline.

3.1.4.3 Cost-effectiveness criteria

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money [180,181].

In general, an intervention was considered to be cost-effective if either of the following criteria applied (given that the estimate was considered plausible):

- The intervention dominated other relevant strategies (that is, it was both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or
- The intervention cost less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy.

3.1.5 Developing recommendations

Over the course of the guideline development process, the GDG was presented with:

- Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence tables are in Appendix G and H.
- Summary of clinical and economic evidence and quality (as presented in chapters 5 to 12).

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- Forest plots (Appendix I).
- A description of the methods and results of the cost-effectiveness analysis undertaken for the guideline (Appendix J).

Recommendations were drafted on the basis of the GDG interpretation of the available evidence, taking into account the balance of benefits and harms, quality of evidence, and costs. When clinical and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations based on consensus. Expert advisors were invited to provide advice on how to interpret the identified evidence. The considerations for making consensus based recommendations include the balance between potential harms and benefits, economic or implications compared to the benefits, current practices, recommendations made in other relevant guidelines, patient preferences and equality issues. The consensus recommendations were done through discussions in the GDG, or methods of formal consensus were applied. The GDG may also consider whether the uncertainty is sufficient to justify delaying making a recommendation to await further research, taking into account the potential harm of failing to make a clear recommendation (See 3.1.5.1).

The main considerations specific to each recommendation are outlined in the Evidence to Recommendation Sections preceding the recommendation section in each chapter.

3.1.5.1 Research recommendations

When areas were identified for which good evidence was lacking, the guideline development group considered making recommendations for future research. Decisions about inclusion were based on factors such as:

- the importance to patients or the population
- national priorities
- potential impact on the NHS and future NICE guidance
- ethical and technical feasibility.

3.1.5.2 Validation process

The guidance is subject to an eight week public consultation and feedback as part of the quality assurance process and peer review of the document. All comments received from registered stakeholders are responded to in turn and posted on the NICE website when the pre-publication check of the full guideline occurs.

3.1.5.3 Updating the guideline

Following publication, and in accordance with the NICE guidelines manual, NICE will ask a National Collaborating Centre or the National Clinical Guideline Centre to advise NICE's Guidance executive whether the evidence base has progressed significantly to alter the guideline recommendations and warrant an update.

3.1.5.4 Disclaimer

Health care providers need to use clinical judgement, knowledge and expertise when deciding whether it is appropriate to apply guidelines. The recommendations cited here are a guide and may not be appropriate for use in all situations. The decision to adopt any of the recommendations cited here must be made by the practitioners in light of individual patient circumstances, the wishes of the patient, clinical expertise and resources.

The National Clinical Guideline Centre disclaims any responsibility for damages arising out of the use or non-use of these guidelines and the literature used in support of these guidelines.

Update 2012

3.1.5.5 Funding

Update 2012

The National Clinical Guideline Centre was commissioned by the National Institute for Health and Clinical Excellence to undertake the work on this guideline.

3.2 Methods (2003)

The guidelines were developed using a systematic review process and associated protocols (Appendix D). In each set of guidelines a more detailed description is provided.

For each set of guidelines, an electronic search was conducted for current national and international guidelines. They were retrieved and subjected to critical appraisal using the AGREE Instrument[256], which provides "a framework for assessing the quality of clinical practice guidelines."

Where guidelines met the AGREE criteria they were included as part of the evidence base supporting each set of guidelines. They were also used to verify professional consensus. The emphasis given to each guideline depended on the rigour of its development and its comprehensiveness in relation to the review questions. In some instances they were used as the primary source of evidence.

Review questions for the systematic reviews of the literature were developed for each set of guidelines following advice from key stakeholders and expert advisors.

Searches were constructed for each set of guidelines using relevant MeSH (medical subject headings) and free-text terms. On completion of the main search, an economic filter was applied. The following databases were searched:

- Medline
- Cumulated Index of Nursing and Allied Health Literature (CINAHL)
- Embase
- The Cochrane Library:
- The National Electronic Library for Health
- The NHS Centre for Reviews and Dissemination (CRD)
- CRD includes 3 databases: Database of Abstracts of Reviews of Effectiveness (DARE), NHS Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA)Database
- Health CD Database
- Health Management Information Consortium Database
- The National Research Register
- The Web of Science
- The Institute of Health Technology
- Health CD Database
- Health Management Information Consortium Database
- HMIC includes 3 databases: The Department of Health Library and Information Service (DHData), Health Management Information Service (HELMIS) from the Nuffield Institute and the Kings Fund Database.

The results of each search including abstracts were printed. The first sift of citations involved a review of the abstracts. Studies were retrieved if they were:

- relevant to a review question;
- primary research/systematic review/meta-analysis;
- written in English.

Where there was no abstract, the full article was retrieved.

No research designs were specifically excluded but wherever possible, in use rather than in vitro studies were retrieved.

The second sift involved a critical review of the full text, and articles relevant to a review question were critically appraised. The SIGN data extraction form[235] was used to document the results of critical appraisal (Available from the SIGN website http://www.sign.ac.uk). A form for descriptive studies was designed by us based on the SIGN methodology.

The evidence tables and reports were presented to the GDG for discussion. At this stage, expert advice derived from seminal works and appraised national and international guidelines were considered. Following extensive discussion the guidelines were drafted.

Although economic opinion was considered for each review question, the economic scope described above did not identify any high quality cost-effectiveness evidence, e.g., economic evaluations alongside randomised controlled trials. As a result, simple decision analytic modelling was employed using estimates from published literature and expert opinion from the GDG. Results were estimated initially for a "base case," i.e., the most likely scenario. These results were then subjected to sensitivity analysis where key parameter values were varied. Areas were targeted where the impact on resource use was likely to be substantial. In addition, where there was no evidence of difference in clinical outcomes between interventions, simple cost analyses were performed to identify the potential resource consequences.

Factors influencing the guideline recommendations included:

- the nature of the evidence;
- the applicability of the evidence;
- costs and knowledge of healthcare systems.

Consensus within the GDG was mainly achieved though discussion facilitated by the group chair. Where necessary, agreement was arrived at by open voting.

4 Guideline summary

4.1 Key priorities for implementation

From the full set of recommendations, the GDG selected 10 key priorities for implementation. The criteria used for selecting these recommendations are listed in detail in The Guidelines Manual[180]. For each key recommendation listed, the selection criteria and implementation support points are indicated by the use of the letters shown in brackets below.

The GDG selected recommendations that would:

- Have a high impact on outcomes that are important to patients (A)
- Have a high impact on reducing variation in care and outcomes (B)
- Lead to a more efficient use of NHS resources (C)
- Promote patient choice (D)
- Promote equalities (E)
- Mean patients reach critical points in the care pathway more quickly (F).

In doing this the GDG also considered which recommendations were particularly likely to benefit from implementation support. They considered whether a recommendation:

- Requires changes in service delivery (W)
- Requires retraining of professionals or the development of new skills and competencies (X)
- Affects and needs to be implemented across various agencies or settings (complex interactions) (Y)
- May be viewed as potentially contentious, or difficult to implement for other reasons (Z)

Update 2012

4.1.1 Standard principles – general recommendations

1. Everyone involved in providing care should be:

- **educated about the standard principles of infection prevention and control and**
- **trained in hand decontamination, the use of personal protective equipment and the safe use and disposal of sharps. [A,B,C,D,F,X,Y] [2012]**

2. Wherever care is delivered, healthcare workers must[a] have available appropriate supplies of:

- **materials for hand decontamination**
- **sharps containers**
- **personal protective equipment. [A, B, E, W, Y] [new 2012]**

3. Educate patients and carers about:

- **the benefits of effective hand hygiene**
- **the correct techniques and timing of hand decontamination**
- **when it is appropriate to use liquid soap and water or handrub**

[a] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]):Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

- **the availability of hand decontamination facilities**
- **their role in maintaining standards of healthcare workers' hand hygiene. [A, B, C, E, X, W, Y] [new 2012]**

4.1.2 Standard principles for hand hygiene

4. Hands must be decontaminated in all of the following circumstances:

- **immediately before every episode of direct patient contact or care**
- **immediately after every episode of direct patient contact or care**
- **immediately after any exposure to body fluids**
- **immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated**
- **immediately after removal of gloves. [A, W, X] [new 2012]**

4.1.3 Long-term urinary catheters

Update 2012

5. Select the type and gauge of an indwelling urinary catheter based on an assessment of the patient's individual characteristics, including:

- **age**
- **any allergy or sensitivity to catheter materials**
- **gender**
- **history of symptomatic urinary tract infection**
- **patient preference and comfort**
- **previous catheter history**
- **reason for catheterisation. [A, B, C, D, F, W, Y, Z] [new 2012]**

6. Offer non-coated intermittent catheters for multiple use[b] to patients[c] except in the following circumstances, when a choice of single-use hydrophilic or gel reservoir catheters should be offered:

- **if the patients is unable to wash and dry catheters**
- **if no suitable facilities to wash, dry and store catheters are readily available**
- **if catheterisation is performed by a healthcare worker or anyone else other than the patient or a close family member. [A, B, C, D, F, W, Y, Z] [new 2012]**

7. All catheterisations carried out by healthcare workers should be aseptic procedures. After training, healthcare workers should be assessed for their competence to carry out these types of procedures. [A, B, C, X, Y] [2003]

[b] Refer to the manufacturer's instructions for advice on the use, cleaning and storage of catheters. See also recommendation 59 about the cleaning of reusable intermittent catheters.

[c] Do not offer multiple-use catheters for use in children or young people of 16 years or under (see recommendation 40).

Update 2012

8. **When changing catheters in patients with a long-term indwelling urinary catheter:**
   - **do not offer antibiotic prophylaxis routinely**
   - **consider antibiotic prophylaxis[d] for patients who:**
   - **have a history of symptomatic urinary tract infection after catheter change or**
   - **experience trauma[e] during catheterisation. [A, B, C, W, X, Y, Z] [new 2012]**

4.1.4 Vascular access devices

9. **Healthcare workers caring for a patient with a vascular access device[f] should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline. [A, B, C, F, X, Y, Z] [2003, amended 2012]**

10. **Decontaminate the skin at the insertion site with chlorhexidine gluconate in 70% alcohol before inserting a peripheral vascular access device or a peripherally inserted central catheter. [A, B, F, W, X] [new 2012]**

4.2 Full list of recommendations

4.2.1 Standard Principles

4.2.1.1 General Recommendations

1. **Everyone involved in providing care should be:**
   - **educated about the standard principles of infection prevention and control and**
   - **trained in hand decontamination, the use of personal protective equipment and the safe use and disposal of sharps. [2012]**

Update 2012

2. **Wherever care is delivered, healthcare workers must[g] have available appropriate supplies of:**
   - **materials for hand decontamination**
   - **sharps containers**
   - **personal protective equipment. [new 2012]**

3. **Educate patients and carers about:**
   - **the benefits of effective hand hygiene**
   - **the correct techniques and timing of hand decontamination**
   - **when it is appropriate to use liquid soap and water or handrub**

[d] At the time of consultation on the guideline (July 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented

[e] The GDG defined trauma as frank haematuria after catheterisation or two or more attempts of catheterisation.

[f] The updated recommendation contains 'vascular access device' rather than 'central venous catheter'. This change has been made because peripherally inserted catheters were included in the scope of the guideline update.

[g] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

- **the availability of hand decontamination facilities**
- **their role in maintaining standards of healthcare workers' hand hygiene.[new 2012]**

4.2.1.2 Hand Hygiene

4. Hands must be decontaminated in all of the following circumstances:

- **immediately before every episode of direct patient contact or care**
- **immediately after every episode of direct patient contact or care,**
- **immediately after any exposure to body fluids**
- **immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated**
- **immediately after removal of gloves.[new 2012]**

5. Decontaminate hands preferably with a handrub (conforming to current British standards[h]), except in the following circumstances, when liquid soap and water must be used:

- **when hands are visibly soiled or potentially contaminated with body fluids or**
- **in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as norovirus, *Clostridium difficile*, or organisms that cause diarrhoeal illness). [new 2012]**

6. Healthcare workers should ensure that their hands can be decontaminated throughout the duration of clinical work by:

- **being bare below the elbow[i]**
- **removing wrist and hand jewellery**
- **making sure that fingernails are short, clean and free of nail polish**
- **covering cuts and abrasions with waterproof dressings.[new 2012]**

7. An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water before applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with all of the surfaces of the hand. The hands must be rubbed together vigorously for a minimum of 10–15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels. [2003]

8. When decontaminating hands using an alcohol handrub, hands should be free from dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry. [2003]

9. An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted. [2003]

Update 2012

[h] At the time of consultation on the guideline (July 2011): BS EN 1500: 1997

[i] For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand hygiene.

4.2.1.3 Use of personal protective equipment

10. Selection of protective equipment must[j] be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare worker's clothing and skin by patients' blood, body fluids, secretions or excretions. [2003]

11. Gloves used for direct patient care must[j] conform to current European Community (CE) standards[h] and should be appropriate for the task. [new 2012] Update 2012

12. Gloves must[j] be worn for invasive procedures, contact with sterile sites and non-intact skin or mucous membranes, and all activities that have been assessed as carrying a risk of exposure to blood, body fluids, secretions or excretions, or to sharp or contaminated instruments. [2003]

13. Gloves must[j] be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient. [2003]

14. Gloves that have been used for direct patient care or exposed to body fluids must be disposed of as clinical waste in accordance with current national legislation[k] or local policies (see section 4.2.1.5). [new 2012]

15. Alternatives to natural rubber latex gloves must[e] be available for patients, carers and healthcare workers who have a documented sensitivity to natural rubber latex. [2012]

16. Do not use polythene gloves for clinical interventions. [new 2012]

17. When delivering direct patient care:

- **wear a disposable plastic apron if there is a risk that clothing may be exposed to blood, body fluids, excretions or secretions, or**
- **wear a full-body fluid-repellent gown if there is a risk of extensive splashing of blood, body fluids, excretions or secretions, onto skin or clothing. [2012]**

Update 2012

18. When using disposable plastic aprons or gowns:

- **use them as single-use items, for one procedure or one episode of direct patient care and**
- **ensure they are disposed of correctly (see section 4.2.1.5).[2012]**

19. Face masks and eye protection must[e] be worn where there is a risk of blood, body fluids, secretions or excretions splashing into the face and eyes. [2003]

20. Respiratory protective equipment, for example a particulate filter mask, must[e] be used when clinically indicated. [2003]

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[j] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]):Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

[k] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

4.2.1.4 Safe use and disposal of sharps

21. Sharps should[l] not be passed directly from hand to hand, and handling should be kept to a minimum [2003, amended 2012]

22. Used needles should not be recapped, bent or broken before disposal. If recapping or disassembly is unavoidable:

- **a risk assessment should be undertaken and**
- **appropriate safety devices should be used. [new 2012]**

23. Used sharps must be discarded immediately by the person generating the sharps waste into a sharps container conforming to current standards.[m] [new 2012]

24. Sharps containers:

- **must[n] be located in a safe position that avoids spillage, is at a height that allows the safe disposal of sharps, is away from public access areas and is out of the reach of children**
- **must not[n] be used for any other purpose than the disposal of sharps**
- **must not[n] be filled above the fill line**
- **must[n] be disposed of when the fill line is reached**
- **should be temporarily closed when not in use**
- **should be disposed of every 3 months even if not full, by the licensed route in accordance with local policy. [new 2012]**

25. Use sharps safety devices if a risk assessment has indicated that they will provide safer systems of working for healthcare workers, carers and patients. [new 2012]

26. Train and assess all users in the correct use and disposal of sharps. [new 2012]

4.2.1.5 Waste disposal

27. Healthcare waste must be segregated immediately by the person generating the waste into colour-coded storage bags or containers, as defined by current national legislation[n] and local policies. [new 2012]

28. Healthcare waste must be labelled, stored, transported and disposed of in accordance with current national legislation[n] and local policies. [new 2012]

29. Educate patients and carers about the correct handling, storage and disposal of healthcare waste. [new 2012]

Update 2012

[l] The updated recommendation contains 'should' rather than 'must' (which is in the 2003 guideline) because the GDG considered that this is not covered by legislation (in accordance with the NICE guidelines manual, 2009).
[m] At the time of consultation on the guideline (July 2011): UN3291 and BS 7320
[n] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (available from www.dh.gov.uk/en/Publicationsandstatistics/ Publications/PublicationsPolicyAndGuidance/DH_126345)

4.2.2 Care of patients with long-term urinary catheters

4.2.2.1 Education of patients, their carers and healthcare workers

30. Patients and carers should be educated about and trained in techniques of hand decontamination, insertion of intermittent catheters where applicable, and catheter management before discharge from hospital. [2003]

31. Community and primary healthcare workers must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance. [2003]

32. Follow-up training and ongoing support of patients and carers should be available for the duration of long-term catheterisation. [2003]

4.2.2.2 Assessing the need for catheterisation

33. Indwelling urinary catheters should be used only after alternative methods of management have been considered. [2003]

34. The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible. [2003]

35. Catheter insertion, changes and care should be documented. [2003]

4.2.2.3 Catheter drainage options

36. Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected. [2003]

37. Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient. [2003]

38. Select the type and gauge of an indwelling urinary catheter based on an assessment of the patient's individual characteristics, including:

- **age**
- **any allergy or sensitivity to catheter materials**
- **gender**
- **history of symptomatic urinary tract infection**
- **patient preference and comfort**
- **previous catheter history**
- **reason for catheterisation [new 2012]**

Update 2012

39. Offer non-coated intermittent catheters for multiple use[o] to patients[p] except in the following circumstances, when a choice of single-use hydrophilic or gel reservoir catheters should be offered:

- **if the patient is unable to wash and dry catheters**
- **if no suitable facilities to wash, dry and store catheters are readily available**
- **if catheterisation is performed by a healthcare worker or anyone else other than the patient or a close family member [new 2012]**

Update 2012

40. Do not offer multiple use catheters for use in children or young people of 16 years or under. [new 2012]

41. In general, the catheter balloon should be inflated with 10 ml of sterile water in adults and 3–5 ml in children. [2003]

42. In patients for whom it is appropriate, a catheter valve may be used as an alternative to a drainage bag. [2003]

~~4.2~~2.4 Catheter insertion

43. All catheterisations carried out by healthcare workers should be aseptic procedures. After training, healthcare workers should be assessed for their competence to carry out these types of procedures. [2003]

44. Intermittent self-catheterisation is a clean procedure. A lubricant for single-patient use is required for non-lubricated catheters. [2003]

45. For urethral catheterisation, the meatus should be cleaned before insertion of the catheter, in accordance with local guidelines/policy. [2003]

46. An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection. [2003]

~~4.2~~2.5 Catheter maintenance

47. Indwelling catheters should be connected to a sterile closed urinary drainage system or catheter valve. [2003]

48. Healthcare workers should ensure that the connection between the catheter and the urinary drainage system is not broken except for good clinical reasons, (for example changing the bag in line with the manufacturer's recommendations). [2003]

49. Healthcare workers must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves. [2003]

[o] Refer to the manufacturer's instructions for advice on the use, cleaning and storage of catheters. See also recommendation 59 about the cleaning of reusable intermittent catheters.

[p] Do not offer multiple-use catheters for use in children or young people of 16 years or under (see recommendation 40)

50. Patients managing their own catheters, and their carers, must be educated about the need for hand decontamination[q] before and after manipulation of the catheter, in accordance with the recommendations in the standard principles section (section 4.2.1.). [2003, amended 2012]

51. Urine samples must be obtained from a sampling port using an aseptic technique. [2003]

52. Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor. [2003]

53. A link system should be used to facilitate overnight drainage, to keep the original system intact. [2003]

54. The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated. [2003]

55. The meatus should be washed daily with soap and water. [2003]

56. To minimise the risk of blockages, encrustations and catheter-associated infections for patients with a long-term indwelling urinary catheter:

- **develop a patient-specific care regimen**
- **do not use bladder instillations or washouts**
- **consider approaches such as reviewing the frequency of planned catheter changes and increasing fluid intake**
- **document catheter blockages. [new 2012]**

Update 2012

57. Catheters should be changed only when clinically necessary or according to the manufacturer's current recommendations. [2003]

58. When changing catheters in patients with a long-term indwelling urinary catheter:

- **do not offer antibiotic prophylaxis routinely**
- **consider antibiotic prophylaxis[r] for patients who:**
  - **have a history of symptomatic urinary tract infection after catheter change or**
  - **experience trauma[s] during catheterisation. [new 2012]**

Update 2012

59. Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. [2003]

[q] The highlighted text replaces 'Carers and patients managing their own catheters must wash their hands…' in the 2003 guideline This has been amended to reflect input from the NICE Patient and Public Involvement Programme: recommendations cannot be made directly about what patients and carers must do.

[r] At the time of consultation on the guideline (July 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented.

[s] The GDG defined trauma as frank haematuria after catheterisation or two or more attempts of catheterisation.

4.2.3 Care during enteral feeding

4.2.3.1 Education of patients, their carers and healthcare workers

60. Patients and carers should be educated about and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital. [2003]

61. Healthcare workers should be trained in enteral feeding and management of the administration system. [2003]

62. Follow-up training and ongoing support of patients and carers should be available for the duration of home enteral tube feeding. [2003]

4.2.3.2 Preparation and storage of feeds

63. Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution. [2003]

64. The system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube. [2003]

65. Effective hand decontamination must be carried out before starting feed preparation. [2003]

66. When decanting, reconstituting or diluting feeds, a clean working area should be prepared and equipment dedicated for enteral feed use only should be used. [2003]

67. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-touch technique. [2003]

68. Feeds should be stored according to the manufacturer's instructions and, where applicable, food hygiene legislation. [2003]

69. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a refrigerator, and used within 24 hours. [2003]

4.2.3.3 Administration of feeds

70. Use minimal handling and a no-touch technique to connect the administration system to the enteral feeding tube. [new 2012] Update 2012

71. Ready-to-use feeds may be given for a whole administration session, up to a maximum of 24 hours. Reconstituted feeds should be administered over a maximum 4-hour period. [2003]

72. Administration sets and feed containers are for single use and must be discarded after each feeding session. [2003]

4.2.3.4 Care of insertion site and enteral feeding tube

73. The stoma should be washed daily with water and dried thoroughly. [2003]

74. To prevent blockages, flush the enteral feeding tube before and after feeding or administering medications using single-use syringes or single-patient-use (reusable) syringes according to the manufacturer's instructions. Use:

- **fresh tap water for patients who are not immunosuppressed**
- **either cooled freshly boiled water or sterile water from a freshly opened container for patients who are immunosuppressed.[new 2012]**

Update 2012

4.2.4 Care of patients with vascular access devices

4.2.4.1 Education of patients, their carers and healthcare workers

75. Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a vascular access device[t] [2003, amended 2012]

76. Healthcare workers caring for a patient with a vascular access device[t] should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline [2003, amended 2012]

77. Follow-up training and support should be available to patients with vascular access device[t] and their carers [2003, amended 2012]

4.2.4.2 General asepsis

78. Hands must be decontaminated (see section 1.1.2) before accessing or dressing a vascular access device. [new 2012]

79. An aseptic technique, such as Aseptic Non Touch Technique (ANTT), must be used for vascular access device catheter site care and when accessing the system. [new 2012]

4.2.4.3 Vascular access device site care

80. Decontaminate the skin at the insertion site with chlorhexidine gluconate in 70% alcohol before inserting a peripheral vascular access device or a peripherally inserted central catheter. [new 2012]

81. Use a sterile, transparent semipermeable membrane dressing to cover the vascular access device insertion site. [new 2012]

82. Only consider a sterile gauze dressing covered with a sterile, transparent semipermeable membrane dressing if the patient has profuse perspiration, or if the vascular access device insertion site is bleeding or oozing. If a gauze dressing is used:

- **change it every 24 hours, or sooner if it is soiled and**

Update 2012

[t] The updated recommendation contains 'vascular access device' rather than 'central venous catheter'. This change has been made because peripherally inserted catheters were included in the scope of the guideline update.

- **replace it with a sterile transparent semipermeable membrane dressing as soon as possible. [new 2012]**

83. Change the transparent semipermeable membrane dressing covering a central venous access device insertion site every 7 days, or sooner if the dressing is no longer intact or moisture collects under it. [2012]

Update 2012

84. Leave the transparent semipermeable membrane dressing applied to a peripheral cannula insertion site in situ for the life of the cannula, provided that the integrity of the dressing is retained. [new 2012]

85. Dressings used on tunnelled or implanted central venous catheter sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner [2003]

86. Healthcare workers should ensure that catheter-site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations. [2003]

87. Decontaminate the central venous catheter insertion site and surrounding skin during dressing changes using chlorhexidine gluconate in 70% alcohol, and allow to air dry. Consider using an aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations prohibit the use of alcohol with their catheter. [2012]

Update 2012

88. Individual sachets of antiseptic solution or individual packages of antiseptic-impregnated swabs or wipes should be used to disinfect the dressing site. [2003]

4.2.4.4 General principles for catheter management

89. Decontaminate the injection port or vascular access device catheter hub before and after accessing the system using chlorhexidine gluconate in 70% alcohol. Consider using an aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations prohibit the use of alcohol with their catheter. [new 2012]

Update 2012

90. In-line filters should not be used routinely for infection prevention. [2003]

91. Antibiotic lock solutions should not be used routinely to prevent catheter-related bloodstream infections (CRBSI). [2003]

92. Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter. [2003]

93. Preferably, a single lumen catheter should be used to administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for total parenteral nutrition, and all lumens must be handled with the same meticulous attention to aseptic technique. [2003]

94. Preferably, a sterile 0.9 percent sodium chloride injection should be used to flush and lock catheter lumens. [2003]

95. When recommended by the manufacturer, implanted ports or opened-ended catheter lumens should be flushed and locked with heparin sodium flush solutions. [2003]

96. Systemic anticoagulants should not be used routinely to prevent CRBSI. [2003]

97. If needleless devices are used, the manufacturer's recommendations for changing the needleless components should be followed. [2003]

98. When needleless devices are used, healthcare workers should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system. [2003]

99. When needleless devices are used, the risk of contamination should be minimised by decontaminating the access port with either alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system. [2003]

100. In general, administration sets in continuous use need not be replaced more frequently than at 72-hour intervals unless they become disconnected or a catheter-related infection is suspected or documented. [2003]

101. Administration sets for blood and blood components should be changed every 12 hours, or according to the manufacturer's recommendations. [2003]

102. Administration sets used for total parenteral nutrition infusions should generally be changed every 24 hours. If the solution contains only glucose and amino acids, administration sets in continuous use do not need to be replaced more frequently than every 72 hours. [2003]

103. Avoid the use of multidose vials, in order to prevent the contamination of infusates. [new 2012]

Update 2012

4.3 Key research recommendations

4.3.1 Standard principles of infection prevention and control

1. What are the barriers to compliance with standard principles of infection prevention and control that patients and carers experience in their own homes?

4.3.2 Hand hygiene

2. When clean running water is not available, what is the clinical and cost effectiveness of using wipes, gels, handrubs or other products to remove visible contamination?

4.3.3 Indwelling urinary catheters: catheter selection

3. For patients using long-term indwelling urinary catheters, what is the clinical and cost effectiveness of impregnated versus hydrophilic versus silicone catheters in reducing symptomatic urinary tract infections, encrustations and/or blockages?

Update 2012

4.3.4 Indwelling urinary catheters: antibiotic prophylaxis

4. When recatheterising patients who have long-term indwelling urinary catheters, what is the clinical and cost effectiveness of single-dose antibiotic prophylaxis in reducing symptomatic urinary tract infections in patients with a history of urinary tract infections associated with catheter change?

4.3.5 Vascular access devices: skin decontamination

5. What is the clinical and cost effectiveness of chlorhexidine 2% in alcohol versus chlorhexidine 0.5% in alcohol versus chlorhexidine 2% aqueous solution versus chlorhexidine 0.5% aqueous solution for cleansing skin (before insertion of peripheral vascular access devices [VADs] and during dressing changes of all VADs) in reducing VAD-related bacteraemia and VAD site infections?

5 Standard Principles

5.1 Introduction

Update 2012

The updated review question in this chapter is:

- Education of patients, carers and healthcare workers.

The new review question in this chapter is:

- Patient information about hand hygiene.

This chapter introduces hand hygiene, personal protective equipment (PPE) and sharps. Several new questions and updates are included in the hand hygiene, PPE and sharps chapters. Key health and safety legislation[1,3,4,68,116] has also been considered when drafting these recommendations.

The GDG considered the addition of the patient information hand hygiene review question in this update as a key area paramount to patient safety. This is also an area where there is variation in practice and important equality issues were identified.

The GDG has prioritised three recommendations in this chapter as a key priority for implementation, see sections 5.3.1.1 and 5.3.2.4.

Standard Principles provide guidance on infection control precautions that should be applied by all healthcare workers to the care of patients in community and primary care settings. These recommendations are broad principles of best practice and are not detailed procedural protocols. They need to be adapted and incorporated into local practice guidelines.

5.3 Education of patients, carers and their healthcare workers

To improve patient outcomes and reduce healthcare costs, it is essential that everyone providing care in the community is educated about hand decontamination, the appropriate use of gloves and protective clothing, and the safe disposal of sharps. Adequate supplies of soap, alcohol rub, towels and sharps bins must be made available wherever care is delivered and this may include providing healthcare workers undertaking home visits, with their personal supply. Patients and carers should request that healthcare workers follow these principles[24].

5.3.1.1 Recommendations

Recommendations	1. Everyone involved in providing care should be: • educated about the standard principles of infection prevention and control and • trained in hand decontamination, the use of personal protective equipment and the safe use and disposal of sharps. [2012]
Relative values of different outcomes	The GDG have added "and the safe use …" of sharps to this recommendation. The safe use of sharps is very important as identified from the evidence of the sharps review question (see section 8.4.1.4). Although no specific review question was asked for this recommendation, the review questions for sharps safety devices feed into this recommendation. The GDG wish to emphasise the safe use of sharps, and want to increase the awareness of safe sharps use and reduce injuries.
Trade off between clinical benefits and harms	The clinical benefit from education about standard principles (hand hygiene, personal protective equipment and sharps) would lead to decreased healthcare-associated infections, sharps injuries and a better understanding of why standard principles are important. Potential harms could be from poor or inaccurate education and therefore it is important to consider how this education should be delivered, see also 8.4.1.4 The use of sharps safety devices in section 8.4.1.4 concludes that sharps injuries were still occurring despite safety devices being introduced and thus linked these to a lack or ineffective training. GDG consensus was that without adequate education sharps injuries will continue to be a problem.
Economic considerations	Hand decontamination products, PPE and sharps disposal equipment are designed to reduce the transmission of microorganisms between healthcare workers, patients, and the environment. Healthcare workers should be educated about the proper use of such materials in order to properly perform their job. Any small increase in time or resource use is likely to be outweighed by a reduced rate of infection and injury.
Quality of evidence	See also the review questions in chapter 8 regarding safe use of sharps. No RCTs were identified for safety needle devices, but several observational studies were identified. These studies had several limitations and were all very low quality.
Other considerations	Minor changes made from the original recommendation. 'in the community' has been removed from the recommendation as the GDG considered that this may be confusing and may be interpreted as not including GP surgeries and care home. The safe use of sharps has been reviewed in the sharps chapter 8. The GDG have prioritised this recommendation as a key priority for implementation as they considered that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes, leads to a more efficient use of NHS resources, promotes patient

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	choice and means that patients reach critical points in the care pathway more quickly. See section 4.1 for further details.
Recommendations	**2. Wherever care is delivered, healthcare workers must[u] have available appropriate supplies of:** • **materials for hand decontamination** • **sharps containers** • **personal protective equipment. [new 2012]**
Relative values of different outcomes	The GDG have added "personal protective equipment" to the list of supplies that must be provided. The most important outcome is to protect healthcare workers from health care associated infections and prevent cross contamination of infections from patient to patient.
Trade off between clinical benefits and harms	Healthcare workers are required by law to be provided with appropriate supplies of hand decontamination products, PPE and sharps disposal equipment (Health and Safety at Work Act 1974[1], Health and Safety Regulations 2002[4], Control of Substances Harmful to Health Regulations 2002[116], Management of Health and Safety at Work Regulations 1999[3], Health and Social Care Act 2008[68]). This recommendation complies to current legislation and safeguards individuals from the risk, or any increased risk, of being exposed to health care associated infections or of being made susceptible, or more susceptible, to them[68].
Economic considerations	Hand decontamination products, PPE and sharps disposal equipment are designed to reduce the transmission of microorganisms between healthcare workers, patients, and the environment. Healthcare workers must be provided with the materials necessary to properly perform their job. Where healthcare workers are not currently provided with appropriate supplies, this recommendation may be associated with an implementation cost. Noncompliance with this recommendation may be associated with costs in the form of fines or litigation.
Quality of evidence	See sharps waste disposal chapter, which refers to Safe Management of Healthcare Waste[72]. No specific clinical evidence review was applicable for this recommendation. However, evidence was reviewed for effectiveness of different types of gloves and gowns versus aprons in the personal protective equipment chapter.
Other considerations	The updated recommendation includes supplies of gloves and PPE. The term 'must' is used as it is covered by legislation (Health and Safety at Work Act 1974[1], Health and Safety Regulations 2002[4], Control of Substances Harmful to Health Regulations 2002[116], Management of Health and Safety at Work Regulations 1999[3], Health and Social Care Act 2008[68]) in line with the guidance from the NICE Guidelines Manual (2009)[180].' The GDG have prioritised this recommendation as a key priority for implementation as they considered that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes and promote equalities. See section 4.1 for further details.

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[u] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

5.3.2 Review question

What information do healthcare professionals, patients and carers require to prevent healthcare-associated infections in primary and community care settings?

5.3.2.1 Focus of the review:

The review aimed to inform the GDG about what information should routinely be provided to patients and carers to prevent healthcare-associated infections. Hand hygiene was acknowledged to be simple, yet extremely effective and necessary for the prevention of healthcare-associated infections. Hence, the GDG decided to prioritise the information needs of patients and carers regarding their own hand hygiene and healthcare worker hand hygiene for the purposes of this review.

See Evidence table G.1.1, Appendix G.

5.3.2.2 Evidence reviewed

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Qualitative studies (focus group discussions, interviews), surveys and observational studies evaluating patients' perceptions regarding their own hand hygiene and participation in health care worker hand hygiene were included in the review. The findings were analysed and themes which emerged consistently were noted and are presented.

The review included studies looking at different populations and settings, including developing countries. This contributes to the strength as well as the limitations of the quality of evidence. Including information from indirect settings and populations may limit the applicability of the findings to patients cared for in the community in the UK. However, many themes were consistent irrespective of these differences and therefore will also most likely be applicable to the UK. Some of the included qualitative studies are of good quality and report in detail the sampling strategies, methods used and the analysis. Some studies have poor sampling strategies and did not report verification of results or triangulation of findings with participants. Details of methods and analysis were also not provided. The qualitative studies using interviews and focus group discussions may be in general, at risk of responder bias as people may give responses depending on the interviewer's status, style of questioning and the associated circumstances. Also, studies which used structured observations may be at risk of observer bias as people may behave differently when they are aware of being observed.

Among the surveys included, some do not report validation and piloting of questionnaires.

Details about the quality and applicability that are specific to the themes found are documented alongside the themes in Table 6.

Table 6: Summary of findings and study quality

No. of studies and study design	Themes and supporting evidence	Comments on limitations , indirectness, consistency, and other considerations
	1. General perceptions about hand washing	
4 x Survey [80,163,193,202] 1 x Cohort study [159] 1 x [Survey +Interviews] [33] 1 x [FGD +Interviews][173] 1 x Telephone survey [224]	**1.1 Hand washing is widely believed to be effective in preventing infection (including MRSA, healthcare-associated infections, flu outbreaks and wound care):** • **MRSA:** More than 80% inpatients [UK] [80], members of the public and people who had MRSA in [Ireland] [163] understood hand washing is effective in reducing transmission [80,163]. • **Inpatients:** 95% realised that hand washing was important to prevent HCAI [UK & USA] [33,159], and 98.7% of patients with wounds realised that that hands should be washed before the dressing is changed [USA][202] • **Flu prevention:** More than 80% members of the public thought hand washing was an effective prevention measure for flu [UK][173], and swine flu [224], although only 28.1% reported washing their hands more than usual because of swine flu. [UK][224] • More than 90% of participants perceived hand-washing as an effective measure to prevent H1N1 (avian flu) infection. [Korea][193]	Limitations: Two studies had poor sampling strategies (non-random sampling or convenience based sampling was used) [33,80]. Validation of questionnaires and verification of analysis was not reported in any of the surveys [80,163,193,202] Indirectness: All studies were not conducted in the target population or settings, and not conducted with the objectives of finding out what information is required by patients. 3 studies were conducted during flu outbreaks [173,193,224] and 3 among inpatients [33,80,202] Consistent themes emerged across different settings and populations
1x survey[193] 1 x Telephone survey [224]	**1.2 Perceived efficacy of washing hands is associated with hand washing:** • Perceived effectiveness of hand-washing was positively correlated (p=0.002) with hand-washing frequency [Korea][193], and actually washing hands more regularly (odds ratio 1.8. 95% CI 1.5 to 2.2) [UK] [224]	Indirectness: Both surveys were conducted to investigate perceptions during flu outbreaks[193,224] Consistency: Both UK and Korean studies showed the correlation.
3 x [Survey +Interviews][33,205,253] 1 x Survey [249] 1 x [Structured observations +Interview + FGD] [229]	**1.3 Variation in preference for alcohol gels and hand rubs :** • Hand wipes (82% of inpatients,[UK) [33], soap and water (54.3% of parents in A& E, US) [249] were the preferred options . • Rinse free alcohol gel was well received (children and teachers, UK) [229], 85% of inpatients would use it for themselves. [UK] [205] • After testing alcohol foam, wet cloth with antiseptic, alcohol wipes, bowl of soapy water and followed by a mobile sink, the mean satisfaction score for alcohol foam was slightly higher than others (unclear whether this difference is significant, statistically or clinically). Alcohol foam and the bowl of soapy water was equally preferred as the first option by ethnic minority groups (Hindus and Muslims)[UK][253]	Limitations: Small sample size and poor sampling strategy in one study (non random sampling[33]) One study was at high risk of bias as patients were asked their preference after using all the products once at the bedside. This may not be indicative of actual preference over time. Also, two of the products compared could not be used by some patients[253] Indirectness: Studies were indirect in terms of

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		population and setting (conducted among inpatients in hospitals)
1 x [Survey +Interviews] [33]	**1.4 Lack of accessibility of hand washing facilities, alcohol gels and hand rubs** • 55% reported not having been offered facilities to wash/clean hands during current hospital stay [UK][33]	Limitations: Small sample size, Non random methods of sampling used; Responder bias may have occurred as interviews were conducted by HCW. Indirect population (inpatients)[33]
	2. Factors motivating people to wash their hands:	
	2.1 Feeling of "disgust", usually related to contamination, dirt or activities prompts hand washing	
4 x [Structured observations +Interview + FGD][55,57,130,229]	Among studies done mostly in mothers, disgust was associated with: • bodily fluids or excrement: such as "after you've been to the loo" (UK)[55], "women have-periods" (mothers, India) [57] • visible dirt on hands: "bits on our hands" (children, UK)[229], dirt [Botswana][130] • unpleasant smell: "I don't want the scent of that thing [faeces] to remain on my hands."[Ghana] [57], "whenever I've had a cigarette .. I wash my hands" [UK] [55] • unpleasant feeling on hands: "... I don't particularly like the feel on my hands ...sticky"[UK 2003][55]. "stickiness",[Botswana][130]	Limitations: Poor sampling strategies (convenience based sampling/ non-random sampling) [55,57]; No details of verification of results or triangulation reported in any of the studies. Indirectness: Two studies were conducted in developing countries [57,130]. 2 studies were conducted in the UK and were also indirect in terms of population (school children[229], mothers [55]) Consistency: Disgust as a motivator of hand washing was consistent across different settings (countries), and populations (children, adults)
2 x [Structured observations +Interview + FGD][55,57] 1 x [FGD +Interviews][173] 1 x Survey[163]	**2.2 Responsibility: not wanting to pass on to others, and a responsibility of protecting others.** • **Worried about passing it to others:** > 90% of members of public, patients who had MRSA and were worried about passing it to their families [163]. • **Looking after (protecting) others:** This includes mothers who want to protect their babies and children against infection [55,57], and also the wider, members of the general public expressed a wider sense of responsibility to protect the health of 'others' in society [UK][173]	Limitations: Poor sampling strategies (convenience based sampling/non random sampling) [55,57]. No details of verification of results or triangulation reported in any of the studies. Indirectness: 1 review included studies from developing countries [57] Consistency: Consistent themes emerged across different settings and populations
1 x Survey[193], 1 x [Structured observations +Interview +	**2.3 Perceived themselves (or others) to be susceptible to infections** • Hand-washing was associated with perceived susceptibility of flu infection(p=0.001).[university students, Korea] [193], (Adjusted OR 1.5, 95% CI 1.3 to 1.8)[general public, UK 2009][224] • frightened of more germs going about … they have got no immune system really "[mothers, UK	Limitations: The frequency of hand washing was self reported, which may be different from actual practice.[193,224] Indirectness: Studies in conducted among

FGD [55] 1 x Telephone survey[224]	2003][55]	mothers and child carers[55] ; in flu outbreak situations[224,193], and in Korea[193] Consistency: Consistent themes emerge in spite of differences
3 x [Structured observations +Interview + FGD][55,57,229] 2 x Survey[202,234]	**2.4 Believed or understood that it is important in prevention of Infection** ▪ Associated with infection getting worse with hand washing not practiced before certain activities, e.g. washing hands after going to the toilet while having diarrhoea and before eating. [mothers, UK 2003][55] ▪ ' So I don't get ill' (Year 2 child);[229] ▪ Not washing hands was associated with spreading diseases (e.g. cholera and diarrhoea) to children [mothers, Uganda, Ghana 2009] " [57] ▪ Hands should be washed before dressing is changed (98.7% of public) [USA 2007][202] ▪ hand washing was considered very important after touching infected skin (87%), after coughing/sneezing (79% [234]	Limitations: Poor sampling strategies(use of convenience based sampling or non-random sampling strategies)[55,57]; Small sample size[202] Indirectness: Studies were conducted among mothers and child carers[55]; and in developing countries [57] Consistency: Consistent themes emerge in spite of differences in population and settings.
	3. Patient perceptions and experience of participation in healthcare worker hand hygiene:	
	3.1 Perceptions and experience of patients regarding their own participation in improving HCW compliance with hand hygiene:	
4 x Survey [81,151,153,270] 1 x Cohort study[159] 1 x [Survey +Interviews][205]	There were variations in studies about whether patients were comfortable or likely to ask doctors or nurses to clean their hands: ▪ 79% of inpatients reported being likely to ask, with younger patients (mean age 42) more so than older patients (mean age 60) [UK][81] ▪ About 60% of patients, with or without MRSA, did not try to ask a medical personnel to wash their hands even once since their last stay in hospital [UK][153] ▪ less than half of members in the public felt comfortable in asking [Switzerland][151] ▪ less than half of patients reported feeling comfortable in asking in one study [USA][270], but 68% of patients were comfortable in another [UK][159]. The % of actually asking when hospitalised are much lower (5%), and patients who are more comfortable are more likely to ask [USA][270] ▪ 94% of inpatient had not asked their nurse or doctor; 53% trusted that the HCWs would have already cleaned their hands [UK][205]	Limitations: Validation of questionnaire and verification of findings not reported in any of the surveys[81,151,153,270] Indirectness: All studies were conducted in acute care settings among inpatients[81,153,205,270]
	3.3 Factors affecting patient participation in implementation of hand hygiene among healthcare workers:	
4 x Survey[59,81,151,153] 1 x [Survey	Believing that it is alright to ask based on encouragement from HCW, presence of reminders, or observing similar behaviour in other patients encourages participants, for example: ▪ An explicit invitation from a HCW increased the intention to ask a physician from 29.9% to 77.8%	Limitations: Validation of questionnaire and verification of findings not reported in any of the surveys[59,81,151,153]; One study at risk of

+Interviews][205]	of respondents; (p<.001) and the intention to ask a nurse from 34.0% to 82.5%; (p<.001) [inpatients, Switzerland][151] ▪ instructed by a doctor to do so [UK][59] ▪ staff wearing badges saying it was OK, letters from their surgeon or ward manager to be encouraging to be able to ask staff to wash their hands, posters on a wall – more than 50% inpatients [UK][81] ▪ Observed other patients doing the same (about 65% of inpatients, UK)[81] ▪ Respondents reported that they were more likely to ask a nurse or doctor to clean their hands if they were given a bottle of hand rub by the hospital.[UK][205] ▪ Intention is an important factor in actually asking hand washing (covariance 0.36, p<0.001);[153]	responder bias as interviews were conducted by HCW[151] Indirectness: Indirect in terms of population and settings (conducted in acute care settings among inpatients)[59,81,151,153,205]
3 x Survey [59,81,151] 1 x Cohort study [159] 1 x [Survey +Interviews][205]	***Profession or seniority of healthcare workers*** *(HCW)* There are variations whether one group of HCW are more likely to be asked than others: ▪ The number of participants who reported themselves comfortable or willing to ask about hand washing were similar or slightly more (a few percentage points) for nurses compared to doctors [UK[59,205], even after explicit encouragement to do so [Switzerland][151] ▪ Most patients (about 76%) were not comfortable in asking nurse or doctors to wash their hands[Switzerland][151] ▪ Student nurses, trained nurses, venepuncturists and healthcare assistants were more likely to be asked to wash their hands; Surgeons, junior doctors, physiotherapists and porters were most likely never to be asked to wash their hands[UK][81] ▪ Of the patients who did ask, 141 (90%) asked nurses and 50 (32%) asked physicians whether they had washed their hands [USA][159]	Validation of questionnaire and verification of findings not reported in the surveys[59,81,151] Indirectness : All studies were indirect to the target population and settings (conducted in acute care settings among inpatients)
2 x Survey[80,153] 1 x Cohort study[159]	***Knowledge about infections, previous hospital admissions, history of infections*** Patients would be more willing to ask healthcare workers whether they have washed their hands : ▪ Patients were more anxious about asking hospital staff and therefore, less likely to ask staff to wash their hands if they had fewer admissions [UK][80] ▪ they had a history of MRSA infection [UK][80] ▪ There is a possible relationship between knowledge and asking about hand washing (covariance 0.06) [UK][153] ▪ 57% asked after reading a patient education brochure on hand washing [USA][159]	Validation of questionnaire and verification of findings not reported in the surveys[80,153] Indirectness: All studies were indirect to target population and settings (conducted in acute care settings among inpatients)

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5.3.2.3 Economic evidence:

2 No economic evidence was identified.

5.3.2.4 Recommendations:

Recommendations	**3. Educate patients and carers about:** • **the benefits of effective hand hygiene** • **the correct techniques and timing of hand decontamination** • **when it is appropriate to use liquid soap and water or handrub** • **the availability of hand washing and decontamination facilities** • **their role in maintaining standards of healthcare workers' hand hygiene. [new 2012]**
Relative values of different outcomes	The reduction of healthcare-associated infections through increased awareness and practice of hand hygiene is important. The involvement of patients to increase hand hygiene in healthcare settings will be likely to contribute to better practice of hand hygiene.
Trade off between clinical benefits and harms	Patient education has the potential to improve awareness and encourage hand hygiene compliance which may result in fewer healthcare-associated infections. The potential clinical harms are minor (skin irritation, perceived inconvenience) and are outweighed by the potential benefits.
Economic considerations	The GDG discussed patient education in the context of routine healthcare practice. It was expected that any impact on time and resource use would be minimal and would likely be offset by a reduction in infections.
Quality of evidence	Evidence was obtained from a wide range of study designs, ranging from large scale surveys to qualitative studies using interviews, focus groups, and structured observations. There are limitations (such as indirectness of populations) in the evidence. Most studies were not designed to identify the strength of association between knowledge, attitude or perception about hand hygiene in affecting behaviours. However, the themes which emerged about the perception and factors which encourage or discourage hand hygiene are consistent across settings and populations, increasing the confidence that these findings are applicable to patients in the community.
Other considerations	The GDG considered equality issues, in particular, language and disability, for example, lack of mobility and cognitive impairment in the implementation of this recommendation. Language barriers should not be a reason for non-provision of information. The GDG also considered that additional support may be required for patients and carers with learning difficulties. The GDG also discussed that there might be concerns about using handrubs that contain alcohol. It is important that patients are aware of the pros and cons of using these products. If religious beliefs are a source of concern, the patients could be made aware of the official stand of religious bodies about the product. For example, the official position of Muslim Councils of Britain is that *"External application of synthetic alcohol gel, however is considered permissible within the remit of infection control because (a) it is not an intoxicant and (b) the alcohol used in the gels is synthetic, ie, not derived from fermented fruit. Alcohol gel is widely used throughout Islamic countries in health care setting"*[176]. When information is available, the GDG felt it would be useful to direct the patients to these information sources to clarify the positions. The GDG

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	prioritised this recommendation as a key priority for implementation as they considered that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes, leads to a more efficient use of NHS resources and promotes equalities. See section 4.1 for further details.

5.4 Research recommendation

1. What are the barriers to compliance with standard precautions of infection prevention and control that patients and carers experience in their own homes?

Why this is important

Recent changes to the delivery of healthcare mean that care is increasingly delivered within a patient's home environment. Infection prevention in this setting is just as important as in hospital. There are currently approximately six million unpaid carers in the UK, a number that is likely to increase with an aging population. The association between carer training and infection rates is unknown. Current mandatory surveillance of healthcare-associated infections indicates that the majority are attributable to areas other than acute health provision. Currently, no evidence from the UK exists in this area.

A qualitative study is needed to investigate the themes surrounding the barriers to patient and carer compliance with the standard principles of infection prevention in their own homes. It would be important to assess whether lack of awareness or knowledge is a barrier. If patients and carers have received education this should be assessed to see if this was applicable to the patient's home setting. Areas of low compliance in the home environment need to be identified. The findings could have far-reaching implications for discharge planning and duty of care.

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6 Standard principles for hand hygiene

6.1 Introduction

The updated review questions in this chapter are:

- When to decontaminate hands?
- Which hand cleaning preparation to use?

The evidence and text from the previous guideline that has been superseded by this update is included in Appendices D.6 and D.9.

New review questions included in this chapter are:

- Should wrists be washed?
- Should sleeves be rolled up for clinical care?

These two new review questions are important and have been prioritised for inclusion in this update as they continue to be contentious and healthcare workers need to be able to identify best practice based on the evidence. Although current practice is that wrists should be washed as part of hand hygiene, there is uncertainty as to whether there is evidence to support this. In addition, there is a need to identify an end point to the areas of the hand to be included. It is recognised that workwear should not impede effective hand hygiene, as detailed and reviewed in section 4.2.1.3, and should not come into contact with patients when delivering direct patient care or environmental surfaces when cleaning.

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Sections not updated in this chapter are:

- Hand washing techniques
- Skin damage due to hand decontamination.

The GDG has prioritised one recommendation in this chapter as a key priority for implementation, see section 6.3.1.4.

The following section provides the evidence for recommendations concerning hand hygiene practice. The difficulty of designing and conducting ethical, randomised controlled trials in the field of hand hygiene, together with the lack of studies conducted in community and primary care means that recommendations in some areas of hand hygiene are predominantly based on expert opinion derived from systematically retrieved and appraised professional, national and international guidelines that focus on nosocomial infection. In reducing the length of hospital stay, care previously delivered only in hospitals has progressively shifted to outpatient and home settings. In addition, healthcare practitioners are increasingly working across the boundaries of acute and community care and invasive procedures are performed in outpatient clinics, nursing home and home settings. These factors create the potential for patients to be at greater risk of acquiring a healthcare-associated infection outside the hospital setting.

The areas discussed include:

- assessment of the need to decontaminate hands;
- the efficacy of hand decontamination agents and preparations;
- the rationale for choice of hand decontamination practice;
- technique for hand decontamination;
- care to protect hands from the adverse effects of hand decontamination practice.

6.2 Why is hand decontamination crucial to the prevention of healthcare-associated infection in the community?

Overviews of epidemiological evidence conclude that hand-mediated transmission is a major contributing factor in the current infection threats to hospital in-patients. These include both meticillin-sensitive and meticillin-resistant *Staphylococcus aureus* (MRSA), and multi-resistant Gram-negative aerobes and enterococci. The transmission of microorganisms from one patient to another via the hands, or from hands that have become contaminated from the environment, can result in adverse outcomes. Primary exogenous infection is a direct clinical threat where microorganisms are introduced into susceptible sites, such as surgical wounds, intravascular cannulation sites, enteral feeding systems or catheter drainage systems. Secondary endogenous infection creates an indirect clinical threat where potential pathogens transmitted by the hands establish themselves as temporary or permanent colonisers of the patient and subsequently causes infection at susceptible sites. Evidence from two previous reviews[208] conclude that in outbreak situations contaminated hands are responsible for transmitting infections and our previous systematic review indicates that effective hand decontamination can significantly reduce infection rates in gastro-intestinal infections and in high-risk areas, such as intensive care units[208].

Our systematic review identified two clinically-based trials[89,226] and two descriptive studies that confirmed the association between hand decontamination and reductions in infection[107,204]. In a non-randomised controlled trial (NRCT) a hand washing programme was introduced and in the post intervention period respiratory illness fell by 45%[226]. A further NRCT, introducing the use of alcohol hand gel to a long-term elderly care facility, demonstrated a reduction of 30% in HCAI over a period of 34 months when compared to the control unit[89]. One descriptive study demonstrated the risk of cross infection resulting from inadequate hand decontamination in patient's homes[107].

Expert opinion is consistent in its assertion that effective hand decontamination results in significant reductions in the carriage of potential pathogens on the hands and logically decreases the incidence of preventable HCAI leading to a reduction in patient morbidity and mortality[24,128,143].

6.3 When to decontaminate hands

6.3.1 Review question

Several hand hygiene guidelines and policies have been introduced detailing when hands should be decontaminated. This review questions aims to determine when hands should be decontaminated by looking at the implementation of published hand hygiene guidance and whether hand hygiene compliance has increased and infection has reduced.

What is the clinical and cost effectiveness of when to decontaminate hands, including after the removal of gloves, on hand hygiene compliance, MRSA and *C diff.* reduction or cross infection, colony forming units and removal of physical contamination?

The GDG considered that colony forming units (CFUs) and hand hygiene compliance were the most important outcomes for this review question.

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6.3.1.1 Clinical evidence

Four cohort studies were identified, where the intervention was the introduction of a hand hygiene guideline (before and after implementation studies). All studies aimed to increase hand hygiene compliance through a multi-modal hand hygiene intervention. Allegranzi et al., 2010[7] implemented the World Health Organisation (WHO) hand hygiene improvement strategy (including the 5 moments of hand hygiene) in a hospital in Mali, Africa. Aragon et al., 2005[15] implemented the Centres for Disease Control (CDC) 2002 guideline in one US hospital and Larson et al., 2007[145] implemented the same guideline in 40 US hospitals. Rosenthal et al., 2005[220] implemented the Association for Professionals in Infection Control (APIC) hand hygiene guideline in a hospital in Buenos Aires, Argentina.

No studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.2.1, Appendix G, Forest Plots in Figure 1-5, Appendix I.

Table 7: After vs. before implementation of a hand hygiene guideline - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Implementation of APIC guideline						
Hand hygiene compliance - overall[220]	1	Observational studies	Serious limitations[(a)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Nosocomial infections – per 1000 bed days[220]	1	Observational studies	Serious limitations[(a)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Implementation of WHO 5 moments of hand hygiene						
Hand hygiene compliance - overall[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – before patient contact[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – before aseptic task[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – After body fluid exposure risk[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – After patient contact[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – After contact with patient surrounding[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Healthcare-associated infections – Overall[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Healthcare-associated infections – Urinary tract infections[7]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Healthcare-associated infections –	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]

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Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Primary blood stream infections[7]						
Implementation of CDC 2002 guideline						
Hand hygiene compliance – Before patient care[15]	1	Observational studies	Serious limitations[(d)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance – After patient care[15]	1	Observational studies	Serious limitations[(d)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Catheter associated urinary tract infection[145]	1	Observational studies	Serious limitations[(e)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Central line associated blood stream infection[145]	1	Observational studies	Serious limitations[(e)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Colony forming units	0	RCT or observational studies				
MRSA reduction or cross infection	0	RCT or observational studies				
C. diff reduction or cross infection	0	RCT or observational studies				
Removal of physical contamination	0	RCT or observational studies				

(a) Authors note that in addition to the implementation of a hand hygiene guideline other CVC and urinary catheter specific infection control interventions were also being conducted simultaneously.
(b) Hospital intervention rather than community.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(d) Unclear as to the exact population of patients and HCW involved in the study. Limited baseline data given.
(e) Baseline hand hygiene compliance not stated.

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Table 8: After vs. before implementation of a hand hygiene guideline - Clinical summary of findings

Outcome	Before	After	Relative risk	Absolute effect	Quality
Implementation of APIC guideline					
Hand hygiene compliance - overall	358/1639 (21.8%)	155/1932 (8%)	RR 2.72 (2.28 to 3.25)	138 more per 1000 (103 more to 181 more)	VERY LOW
Nosocomial infections – per 1000 bed days	N/R	N/R	RR 0.59 (0.47 to 0.75)	N/R	VERY LOW
Implementation of WHO 5 moments of hand hygiene					
Hand hygiene compliance - overall	358/1639 (21.8%)	155/1932 (8%)	RR 2.72 (2.28 to 3.25)	138 more per 1000 (103 more to 181 more)	VERY LOW
Hand hygiene compliance – before patient contact	91/439 (20.7%)	23/503 (4.6%)	RR 4.53 (2.92 to 7.03)	161 more per 1000 (88 more to 276 more)	VERY LOW
Hand hygiene compliance – before aseptic task	34/230 (14.8%)	11/425 (2.6%)	RR 5.71 (2.95 to 11.06)	122 more per 1000 (50 more to 260 more)	VERY LOW
Hand hygiene compliance – After body fluid exposure risk	94/229 (41%)	34/215 (15.8%)	RR 2.6 (1.84 to 3.67)	253 more per 1000 (133 more to 422 more)	VERY LOW
Hand hygiene compliance – After patient contact	201/505 (39.8%)	91/559 (16.3%)	RR 2.44 (1.97 to 3.04)	234 more per 1000 (158 more to 332 more)	VERY LOW
Hand hygiene compliance – After contact with patient surroundings	15/410 (3.7%)	15/457 (3.3%)	RR 1.11 (0.55 to 2.25)	4 more per 1000 (15 fewer to 41 more)	VERY LOW
Healthcare-associated infections – Overall	22/144 (15.3%)	25/134 (18.7%)	RR 0.82 (0.49 to 1.38)	34 fewer per 1000 (95 fewer to 71 more)	VERY LOW
Healthcare-associated infections – Urinary tract infections	10/144 (6.9%)	8/134 (6%)	RR 1.16 (0.47 to 2.86)	10 more per 1000 (32 fewer to 111 more)	VERY LOW
Healthcare-associated infections – Primary blood stream infections	1/144 (0.7%)	3/134 (2.2%)	RR 0.31 (0.03 to 2.95)	15 fewer per 1000 (22 fewer to 44 more)	VERY LOW
Implementation of CDC 2002 guideline					
Hand hygiene compliance – Before patient care	696/1698 (41%)	761/2537 (30%)	RR 1.37 (1.26 to 1.48)	111 more per 1000 (78 more to 144 more)	VERY LOW
Hand hygiene compliance – After patient care	707/955 (74%)	784/1104 (71%)	RR 1.04 (0.99 to 1.1)	28 more per 1000 (7 fewer to 71 more)	VERY LOW
Catheter associated urinary tract infection	524/173154 (0.3%)	498/171625 (0.3%)	RR 1.04 (0.92 to 1.18)	0 more per 1000 (0 fewer to 1 more)	VERY LOW
Central line associated blood stream infection	771/161954 (0.5%)	848/153003 (0.6%)	RR 0.86 (0.78 to 0.95)	1 fewer per 1000 (0 fewer to 1 fewer)	VERY LOW

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6.3.1.2 Cost-effectiveness evidence

Two studies were identified which evaluated the costs and consequences associated with relevant hand hygiene guidance. Cummings et al 2010[53,53] developed a mathematical model to estimate the cost of noncompliance between patient contacts and potential contamination of surfaces after exposure; Stone et al 2007[247,248] evaluated the relationship between adherence to CDC guidelines and the cost of hand hygiene products at 40 US hospitals.

No cost-effectiveness evidence was identified in the previous 2003 guideline. The following brief analysis was in the section comparing different hand hygiene decontamination products in the 2003 guideline but seems better placed here, since it was not a comparative analysis of different hand hygiene products but an estimate of the cost-effectiveness of alcohol handrub compared to 'not washing':

> *'Economic analysis of cost effectiveness is based on the assumption that the rate of infection in primary and community care is 4%, i.e. half that in hospital, and that alcohol gel reduces infection rate in 30% or 25%, i.e. to 2.8% or 3.0% compared to not washing. For every 1000 patients, between 10 and 12 infections would be avoided. If each infection resulted in a nurse visit (estimated cost £25) then between £250 and £300 would be saved in avoided costs. This is without the possibility of Accident and Emergency Department attendances and/or inpatient stays. Therefore, if the cost of an alcoholic handrub is within 25 pence of the cost of conventional handwashing, it will be cost saving. If one were to include patient outcomes (i.e. avoiding infection with the associated morbidity and mortality) and hospital attendance, the cost effectiveness of hand hygiene with alcohol rubs would increase.'*

The true baseline rate of infection in the community is far more complex than this estimate suggests[118] and the assumed reduction in the rate of infections is slightly greater than that observed for overall infections in the clinical studies included in our review[6,7]. For other, more severe infections such as vascular and urinary catheter-associated infections, baseline rates are much greater and the relative risk reduction associated with hand washing is variable[7,15]. It is important to take into account different patterns of resistance, cost, morbidity, and mortality associated with different infections to gain an accurate estimate of cost-effectiveness for different infection control interventions. Given that these assumptions are overly simplistic, plus the fact that this analysis did not take into account any measure of compliance to hand hygiene guidance or downstream cost and quality of life consequences resulting from infection, this analysis has serious limitations and is only partially applicable.

Table 9: Hand hygiene guidance – Economic summary of findings

Study	Limitations	Applicability	Other comments
Cummings 2010[53]	Minor limitations[(a)]	Partially applicable [(c)]	Outcomes: MRSA colonisation and MRSA infection after noncompliant patient contact episodes; cost per noncompliant episode.
Stone 2007[248]	Potentially serious limitations [(d)]	Partially applicable [(d)]	Outcomes: Difference in hand hygiene product costs between hospitals with high and low rates of compliance to CDC guidelines

(a) Cost of hand decontamination product not accounted for.
(b) US Hospital perspective - rate of patient contact, exposure, and transmission may be different in a UK community setting; health effects not expressed as QALYs.
(c) Not a comparative analysis; no measure of patient outcome (i.e. infection rates) and no account of the cost of infection.
(d) USA Hospital perspective, no measure of patient outcome.

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Table 10: Hand hygiene guidance – Economic summary of findings

Study	Incremental cost	Incremental effects	ICER	Uncertainty
Cummings 2010[53]	Each time healthcare workers do not wash their hands between patients was associated with a cost of £1.29, £34.14 depending on whether the MRSA status of the first patient is known or unknown. Not washing hands before direct contact with one patient after coming in contact with another patient's environment was associated with a cost of £1.01.	N/A	N/A	A 1% and 5% increase in compliance to guideline recommendations resulted in hospital-wide savings of £25, 772 and £128, 863, respectively.
Stone 2007[248]	Hospitals with high compliance had an annual hand hygiene product cost that was £2, 995 greater than hospitals with low compliance.	N/A	N/A	N/A

6.3.1.3 Evidence statements

Clinical

There is a statistically significant and clinically important increase in hand hygiene compliance (before patient contact, before aseptic task, after body fluid exposure and after patient contact) with the implementation of the WHO 5 moments. (VERY LOW QUALITY)

It is uncertain whether there is any difference in hand hygiene compliance after contact with patient surroundings, or healthcare-associated infections with the implementation of the WHO 5 moments. (VERY LOW QUALITY)

There is a statistically significant and clinically important increase in hand hygiene compliance before patient care with the implementation of the CDC 2002 hand hygiene guideline. (VERY LOW QUALITY)

It is unlikely that there is any difference in hand hygiene compliance after patient care, or in catheter associated UTIs with the implementation of the CDC 2002 hand hygiene guideline. (VERY LOW QUALITY)

There is a statistically significant decrease of uncertain clinical importance in central line associated blood stream infections with the implementation of the CDC 2002 hand hygiene guideline. (VERY LOW QUALITY)

There is a statistically significant and clinically important increase in hand hygiene compliance and a statistically significant decrease in nosocomial infections per 1000 bed days with the implementation of the APIC hand hygiene guideline. (VERY LOW QUALITY)

No studies were identified that reported colony forming units, MRSA reduction or cross infection, C. diff reduction or cross infection or removal of physical contamination.

Economic

Noncompliance with hand hygiene guidance is associated with infection-related costs (MINOR LIMITATIONS AND PARTIALLY APPLICABLE). Although compliance with hand hygiene guidelines is associated with an increase in the use of hand hygiene products (POTENTIALLY SERIOUS LIMITATIONS AND PARTIALLY APPLICABLE), it is likely that

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this cost will be offset by a reduction in infections and infection-related costs (MINOR LIMITATIONS AND PARTIALLY APPLICABLE).

6.3.1.4 Recommendations and link to evidence

Recommendations	**4. Hands must be decontaminated in all of the following circumstances:** • **immediately before every episode of direct patient contact or care** • **immediately after every episode of direct patient contact or care** • **immediately after any exposure to body fluids** • **immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated** • **immediately after removal of gloves. [new 2012]**
Relative values of different outcomes	The GDG felt that reducing colony forming units (CFUs), and improving hand hygiene compliance were the most important outcomes. However, CFUs were not reported in any of the included studies. Healthcare-associated infections were reported in the studies and were considered to be an important outcome by the GDG. Reduction of MRSA and *Clostridium difficile* (*C. diff*) infections, prevention of MRSA and C. diff cross infections, and the removal of physical contamination were also felt to be important outcomes. However, none of these outcomes were reported in the included studies.
Trade off between clinical benefits and harms	When considering the evidence, the GDG wrote this recommendation cognisant of the fact that the World Health Organisation (WHO) 5 moments of hand hygiene being the current international model of when to decontaminate hands which is widely implemented in the UK. The potential benefits of this recommendation are: • protection of patients • protection of healthcare workers • protection of healthcare environment • prevention cross infection of pathogenic organisms. The evidence shows that there is an increase in hand hygiene compliance before and after patient contact with the implementation of the WHO 5 moments, but no difference after contact with patient surroundings. This is the same finding as with the implementation of the CDC 2002 guideline; increased hand hygiene compliance before patient care, but no statistically significant difference in hand hygiene compliance after patient care. Hence, the recommendation does not specifically separate out hand decontamination after contact with a patient's surroundings as a separate bullet point. Catheter associated UTIs and nosocomial infections per 1000 bed days were shown to decrease with the implementation of the CDC 2002 and APIC guidelines, respectively. Potential harms include the effect of continual washing on hands and skin condition (leading to dry cracked hands being more susceptible to increased infections and thus the spread of infection), which may depend on the product used (see section 6.4 below) and impact on staff time. Additional harms could include increased numbers of skin allergies from continual handwashing/decontamination, leading to additional occupational health visits. The GDG did not consider that a separate recommendation was

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	necessary to address these potential harms.
Economic considerations	The GDG agreed that any marginal increase in costs (in terms of staff time and product cost) associated with increased compliance to hand hygiene guidance will likely be offset by a corresponding reduction in infection rates. It is possible that only a small improvement in compliance to hand hygiene guidelines is necessary in order for healthcare organisations to realise cost savings.
Quality of evidence	Four very low quality cohort studies were identified. The population is indirect (not in community settings) and one study is based in a low income country[7]. There is also a variation in the intervention used, which is the hand hygiene guideline implemented. There are different guidelines implemented (WHO, CDC and APIC) and the guideline implementation involves a multi-modal hand hygiene strategy, which is not just the implementation of a new strategy of when to decontaminate hands, but also introducing handrubs to increase compliance and education about how to decontaminate hands effectively. Therefore the effects on compliance and infection could be attributed to the increased availability of handrub and improved hand decontamination technique as well as the strategy of when to decontaminate hands. No evidence was identified looking at hand decontamination specifically after the removal of gloves, but GDG consensus was that this should be included. It was included in the previous guideline under the PPE section relating to glove disposal. The part of the original recommendation in the PPE section relating to hand decontamination after removal of gloves has now been incorporated into this recommendation.
Other considerations	The GDG considered that this recommendation relates to patient safety and that the consequence of not implementing it mean that the risk of adverse events are so severe, that the use of the word 'must' is appropriate in line with guidance from the NICE Guidelines Manual (2009)[180]. The recommendation is consistent with the WHO 5 Moments of hand hygiene. Aseptic tasks are covered within the first bullet point under direct patient contact or care. There can be problems in accessing water and clean towels in the community setting, and the GDG acknowledge that there is variation in level of resources across the country and in homes. The GDG felt that it was important that all healthcare staff have access to alcohol handrub to decontaminate hands whatever the setting and those working in the community should have access to hand washing kits where it is not available e.g. soap, paper towels and/or wipes. Please see recommendation 5.3.1.1 in the standard precautions chapter detailing the importance of access to hand decontamination supplies. The GDG have prioritised this recommendation as a key priority for implementation as they consider that it has a high impact on outcomes that are important to patients. For further details see section 4.1.

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6.4 Choice of hand cleaning preparation

6.4.1 Review question

The following question aims to determine which is the most clinical and cost effective hand cleaning preparation. This is an important question given that a wide variety of products exist, including variations in concentrations of alcohol contained in products. The GDG considered the most important outcomes to be colony forming units (CFUs), hand hygiene compliance, removal of physical contamination and general reduction of cross infection.

What is the clinical and cost effectiveness of cleaning preparations (soap and water, alcohol based rubs, non-alcohol products and wipes) for healthcare worker hand decontamination, on hand hygiene compliance, MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination?

6.4.1.1 Clinical evidence

Four trials were identified (two RCTS and two randomised crossover trials) comparing alcohol handrub with antiseptic handwash [103,144] or non-antiseptic handwash[279]. Alcohol handrub containing 45% 2-propanol and 30% 1-propanol was used in Girou et al., 2002[103], Winnefeld et al., 2000[279] and Zaragoza et al., 1999[284] and the handrub in Larson et al., 2001[144] contained 61% ethanol. All of these studies were included in the previous 2003 guideline, no additional studies were found from the update search.

See Evidence Table G.2.2, Appendix G, Forest Plots in Figure 8, Appendix I.

Table 11: Alcohol handrub vs. non-antiseptic soap - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Log 10 CFU (Finger print technique) 152,284	2	Crossover	Serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
CFU (Mean log change) 279	1	RCT	Serious limitations [(c)]	No serious inconsistency	Serious indirectness[(b)]	N/A[(d)]
Hand hygiene compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
C. diff reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

(a) Crossover study, healthcare workers used both intervention and control
(b) Hospitals setting rather than community.
(c) Unclear allocation concealment.

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(d) No standard deviation reported so confidence intervals are unknown, therefore unknown whether effect is precise or not.

Table 12: Alcohol handrub vs. non-antiseptic soap - Clinical summary of findings

Outcome	Alcohol handrub	Non-antiseptic soap	Relative risk	Absolute effect	Quality
Log 10 CFU (Finger print technique)	86	86	-	MD 0.76 lower (0.93 to 0.59 lower)	LOW
CFU (Mean log change)	26	25	-	Intervention: -0.342 Control: +0.122 P = 0.004[(a)]	LOW

(a) No standard deviation reported, p value reported as stated in the study.

Table 13: Alcohol handrub vs. antiseptic soap - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Log 10 CFU (Finger print technique)[152]	1	Crossover	Serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
CFU (Finger print technique)[103]	1	RCT	Serious limitations [(d)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
CFU - 2 weeks (Glove juice technique)[144]	1	RCT	Serious limitations [(d)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
CFU - 4 weeks (Glove juice technique)[144]	1	RCT	Serious limitations [(d)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
C. diff reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

(a) Crossover study, healthcare workers used both intervention and control.
(b) Hospitals setting rather than community.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(d) Unclear allocation concealment.

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Table 14: Alcohol handrub vs. antiseptic soap - Clinical summary of findings

Outcome	Alcohol handrub	Antiseptic soap	Relative risk	Absolute effect	Quality
Log 10 CFU (Finger print technique)	43	43	-	MD 0.2 lower (0.35 to 0.05 lower)	VERY LOW
CFU (Finger print technique)	12	11	-	MD 34 lower (104.98 lower to 36.98 higher)	VERY LOW
Log 10 CFU - 2 weeks (Glove juice technique)	26	26	-	MD 0.09 higher (0.39 lower to 0.57 higher)	LOW
Log 10 CFU - 4 weeks (Glove juice technique)	26	24	-	MD 0.08 higher (0.42 lower to 0.58 higher)	LOW

Table 15: Antiseptic soap vs. non-antiseptic soap - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Log 10 CFU (Finger print technique)[152]	1	Crossover	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision
Hand hygiene compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
C. diff reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

(a) Crossover study, healthcare workers used both intervention and control.
(b) Hospitals setting rather than community.

Table 16: Antiseptic soap vs. non-antiseptic soap - Clinical summary of findings

Outcome	Antiseptic soap[(a)]	Non-antiseptic soap[(a)]	Relative risk	Absolute effect	Quality
Log 10 CFU (Finger print technique)	43	43	-	MD 0.56 lower (0.77 to 0.35 lower)	LOW

(a) Number of healthcare workers in each study arm.
(b) Mean log change in CFUs given for intervention and control.

6.9.1.2 Cost-effectiveness evidence

Two trial-based cost-analyses[45,144] and one cost-consequence analysis[248] comparing the use of alcohol handrub to non-antiseptic soap were included. For a list of excluded studies and reasons for exclusion, please refer to Appendix L.

The GDG were also presented with the current UK prices of hand decontamination cleaning preparations to inform decision making.

No economic studies were identified in the previous 2003 guideline. In the previous guideline, the informal economic evaluation presented in section 6.3.1.2 was included under the current section.

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However, this evaluation did not consider the cost-effectiveness of alternative hand decontamination cleaning preparations and was therefore not considered appropriate for this question.

Table 17: Alcohol handrub vs. non-antiseptic soap – Economic summary of findings

Study	Limitations	Applicability	Other Comments
Cimiotti 2004 [45]	Potentially serious limitations[(a)]	Partially applicable[(b)]	Outcomes: observed hand hygiene quality; direct product cost; application time per product
Larson 2001 [144]	Potentially serious limitations[(c)]	Partially applicable[(d)]	Outcomes: mean microbial count; application time per product
Stone 2007 [248]	Potentially serious limitations[(e)]	Partially applicable[(f)]	Outcomes: Difference in hand hygiene product costs between hospitals with high and low rates of compliance to CDC guidelines

(a) Non-randomised cross-over study design; subjective outcome measure of hand hygiene quality.
(b) Neonatal ICU; US hospital perspective.
(c) No patient outcomes, no consideration of uncertainty, industry funded.
(d) Surgical ICU; US hospital perspective
(e) No comparative analysis.
(f) USA Hospital perspective, no measure of patient outcome.

Table 18: Alcohol handrub vs. non-antiseptic soap – Economic summary of findings

Study	Incremental cost	Incremental effects	ICER	Uncertainty
Cimiotti 2004[45]	Alcohol handrub is £30 less costly per 1000 hand hygiene episodes	Better quality hand hygiene, and less time required per hand regimen with alcohol-based product	Alcohol-based product dominant	N/R
Larson 2001[144]	Alcohol handrub is £0.09 less costly per shift	Greater reduction in microbial cultures, fewer deviations from protocol, and less time required per hand regimen with alcohol-based product	Alcohol-based product dominant	N/R
Stone 2007[248]	Hospitals with a high ratio of alcohol handrub use had an annual hand hygiene product expenditure that was £3, 174 greater than hospitals with a low ratio of alcohol handrub use.	N/A	N/A	N/A

Table 19: Hand hygiene product costs

	Alcohol-based handrub	Non-antiseptic liquid Soap	Antiseptic Soap	Paper towels
Mean cost per litre (£)	3.16	4.79	7.13	1.07 (250 sheets)

Source: Based on average 2010 Supply Chain[185] prices.

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6.4.1.3 Evidence statements

Clinical	There is a statistically significant reduction of uncertain clinically importance in mean log change in CFUs and it is unlikely that there is any difference in log 10 CFUs after use of alcohol handrubs compared to handwashing with non-antiseptic soap and water. (LOW QUALITY)
	There is a statistically significant, but not clinically important, reduction in log 10 CFUs after use of alcohol handrubs compared to antiseptic soap and water. (VERY LOW QUALITY)
	It is uncertain whether there is any difference in CFUs (glove juice technique) with alcohol handrubs compared to antiseptic soap and water. (LOW QUALITY)
	There is a statistically significant, but not clinically important, reduction in log 10 CFUs after use of antiseptic soap compared to non-antiseptic soap and water. (LOW QUALITY)
	No studies were identified that reported hand hygiene compliance, MRSA reduction or cross infection, C. diff reduction or cross infection or removal of physical contamination.
Economic	On a per-hand hygiene episode basis, alcohol-based handrub appears to be less costly and lead to better hand hygiene practice than non-antiseptic soap. (POTENTIALLY SERIOUS LIMITATIONS AND PARTIALLY APPLICABLE EVIDENCE)

6.4.1.4 Recommendations and link to evidence

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Recommendations	**5. Decontaminate hands preferably with a handrub (conforming to current British Standards[v]), except in the following circumstances, when liquid soap and water must be used:** • **when hands are visibly soiled or potentially contaminated with body fluids or** • **in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as norovirus, *Clostridium difficile*, or organisms that cause diarrhoeal illness). [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes to be colony forming units (CFUs), hand hygiene compliance, removal of physical contamination and general reduction of cross infection of all infections. However the only outcome reported in the included studies were colony forming units.
Trade off between clinical benefits and harms	The benefits of implementing this recommendation are the reduced spread of potential pathogens and to prevent the spread of HCAI. In addition, the GDG considered that the visibility of alcohol handrub and hand cleaning enhances the patient experience (as a form of reassurance that infection control precautions are being used). The GDG felt that it also reinforces good basic practice for self care. The evidence shows that alcohol handrubs are as effective, if not more effective, at reducing CFUs on hands compared to hand washing. Alcohol handrub has also been linked to increased hand hygiene compliance, which is also found in the multi model hand hygiene interventions included in the 'when to wash your hands' review question, see section 6.3.1.4. The exceptions in the bullet points for when to perform hand washing are based on GDG consensus as no RCT evidence was identified but are also

[v] At the time of consultation on the guideline (July 2011): BS EN 1500: 1997

	consistent with WHO guidance. Potential harms are the effect of continual washing on hands and skin condition and the danger of ineffective 'over the counter' (not conforming to current European and British Standards) compliant handrubs being used. The GDG did not feel a separate recommendation was warranted to mitigate against the potential harm of continual hand washing other than recommendation 6.7.1.1 and have specified within the new recommendation that handrub used should meet the specified European and British Standard.
Economic considerations	The GDG agreed that alcohol handrub is likely to be cost saving in terms of staff time and product costs except in outbreak situations. The GDG thought that in situations where there is potential for the spread of alcohol-resistant organisms, soap and water is the only appropriate cleaning preparation.
Quality of evidence	Three very low to low quality RCTs were identified comparing alcohol rubs to hand washing with soap and water. All of these studies were downgraded for indirectness as they are hospital based and not in community settings. These studies all had relatively small sample sizes and an imprecise estimate of effect. The studies identified only reported one outcome that was prioritised by the GDG, CFUs, which showed no statistical difference with alcohol handrubs compared to hand washing with soap and water. However, GDG consensus was used to recommend handrub based on the long established role of alcohol in hand decontamination, acknowledging that poor RCT evidence was attributed to manufacturers performing laboratory tests to meet EU standards and not necessarily requiring further RCT evidence to prove efficacy. No RCTs or cohort studies were found for visibly soiled hands. The RCTs identified stated that healthcare workers should wash hands with soap and water if hands were visibly soiled and thus the intervention group (handrub) washed their hands in this situation.
Other considerations	The GDG considered that this recommendation relates to patient safety and that the consequence of not implementing it means that the risk of adverse events are so severe, that the use of the word 'must' is appropriate and in line with guidance from the NICE Guidelines Manual (2009)[180]. The GDG noted that although there was no evidence available for non-alcohol handrubs they did not want to prevent such products being used if they meet European and British Standards. Therefore, the recommendation specifies a 'handrub conforming to current European and British Standards', rather than an 'alcohol' handrub. BS EN 1500 is the British Standard test for determining the bactericidal efficacy of hygienic hand disinfection (handrubs)[27]. The hands of 12-15 volunteers are artificially contaminated with Escherichia coli and treated in a crossover design with the test or reference product (60 second application of 60% 2-propanol. The tested handrub should not be significantly less effective than the reference alcohol). There can be problems in accessing water and clean towels in the community setting, and the GDG acknowledge that there is variation in levels of resources across the country and in homes. It is important that all healthcare staff have access to handrub to decontaminate hands whatever setting and those working in the community should have access to hand washing kits where running water and clean towels are not available e.g. soap, paper towels and/or wipes. Please see recommendation 5.3.1.1 in the standard precaution general recommendation detailing importance of access to hand decontamination supplies. Also see the recommendation on hand hygiene technique in section 6.6.1.1 as training in proper hand decontamination methods is important. The GDG discussed that it may be difficult in the community to determine which patients were infected with *C. diff* or MRSA and recommended that

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	those caring for patients with any diarrhoeal illness should wash their hands with liquid soap and water. The GDG also discussed that there might be concerns about using handrubs that contain alcohol. It is important that patients are aware of the pros and cons of using these products. If religious beliefs are a source of concern, the patients could be made aware of the official stand of religious bodies about the product. When information is available, it would be useful to direct the patients to these information sources to clarify the positions. For example, the official position of the Muslim Councils of Britain is that *"External application of synthetic alcohol gel..... is considered permissible within the remit of infection control because (a) it is not an intoxicant and (b) the alcohol used in the gels is synthetic, i.e., not derived from fermented fruit. Alcohol gel is widely used throughout Islamic countries in health care setting"*[176].

6.5 Decontaminating wrists and bare below the elbow policy

6.5.1 Review question

What is the clinical and cost effectiveness of healthcare workers decontaminating wrists vs. not decontaminating wrists or usual practice on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?

What is the clinical and cost effectiveness of healthcare workers following bare below the elbow policy (short sleeves or rolled up sleeves) vs. no bare below the elbow policy (long sleeves, not rolled up or no specific restrictions) on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?

The GDG considered cross infections as the most important outcome.

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6.5.1.1 Clinical evidence

No RCT or cohort studies examined whether wrists should be washed in regular hand decontamination. One RCT compared the effectiveness of hand washing between a group with bare below the elbow uniform policy vs. another group with usual uniform.

The GDG defined bare below the elbow (BBE) as not wearing false nails or nail polish when delivering direct patient care. Not wearing a wrist-watch or stoned rings. Healthcare workers garments should be short sleeved or be able to roll or push up sleeves when delivering direct patient care and performing hand hygiene.

It is recognised that healthcare workers delivering direct patient care in the outdoor environment (for example ambulance staff) would still be required to wear long sleeved high visibility and inclement weather clothing in accordance with health and safety legislation. Local uniform policy should reflect these requirements while also allowing the wearer to perform effective hand hygiene when delivering direct patient care.

See Evidence Table G.2.3, Appendix G, Forest Plots in Figure 13, Appendix I.

Table 20: Bare below the elbow (BBE) policy vs. control (usual uniform)- Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Compliance: Percentage of the areas of the hands (wrist & palm) missed [88]	1	RCT	Serious limitation[(a)]	No serious inconsistency	No serious indirectness[(b)]	Serious imprecision[(c)]
Compliance: Percentage of the areas of the wrists missed [88]	1	RCT	Serious limitation[(a)]	No serious inconsistency	No serious indirectness[(b)]	Serious imprecision[(c)]
Compliance: Percentage of the areas of the palms missed [88]	1	RCT	Serious limitation[(a)]	No serious inconsistency	No serious indirectness[(b)]	Serious imprecision[(c)]
Colony forming units	0	RCT				
Cross infection of MRSA	0	RCT				
Cross infection of C. diff	0	RCT				
Removal of physical contamination and transient organisms	0	RCT				

(a) Randomisation allocation and concealment method not reported. Participants were aware of the observation and evaluation of their hand washing - there is a risk of performing better (i.e. wash hand more thoroughly) than usual.
(b) Indirect population. The study only recruited medical students and doctors working in a teaching hospital. Other healthcare professionals were not recruited and there were no further information about the population. Outcomes were indirect – measured % of areas of missed by the alcohol gel. However, the GDG believe this is not serious indirectness and did not lower their confidence of the results.
(c) Actual values were not reported, and number of participants in each arm not reported. Number of participants were obtained from authors.

Table 21: Bare below elbow policy vs. control (usual uniform) group - Clinical summary of findings

Outcome	BBE policy	Control	Relative risk	Absolute effect	Quality
Compliance: Percentage of the areas of the hands (wrist & palm) missed	9.3 ± 9.2	11.1 ± 7.2	Not applicable	1.80 [-4.46, 0.86]	LOW
Compliance: Percentage of the areas of the wrists missed	38.9±38.7	52.8 ±27.9	Not applicable	-13.9%[-24 to 3.3][(a)]	LOW
Compliance: Percentage of the areas of the palms missed	7.2± 7.1	8.2±6.4	Not applicable	-1.00 [-3.17, 1,17]	LOW

(a) Calculated by NCGC based on the information from authors – BBE policy arm had 73 participants, control arm had 76 participants.

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6.5.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified in the update search and none was included in the previous 2003 guideline.

This question was not thought relevant for economic consideration.

6.5.1.3 Evidence statements

Clinical	It is unlikely there is any difference in the percentage areas missed on the palms and on the whole hand during hand washing with alcohol handrub in the bare below the elbow policy group compared to the control group. There is statistically significant decrease of uncertain clinical importance in the percentage of areas on the wrists missed during hand washing with alcohol handrub in bare below the elbow policy group compared to the control group (LOW QUALITY). No studies were identified that reported colony forming units, cross infection of MRSA, cross infection of *C. diff* or removal of physical contamination and transient organisms.
Economic	No economic studies were identified.

6.5.1.4 Recommendations and link to evidence

Recommendations	6. **Healthcare workers should ensure that their hands can be decontaminated throughout the duration of clinical work by:** • **being bare below the elbow**[w] • **removing wrist and hand jewellery** • **making sure that fingernails are short, clean and free of nail polish** • **covering cuts and abrasions with waterproof dressings. [new 2012]**
Relative values of different outcomes	The GDG considered cross infections as the most important outcome. The GDG also considered compliance to hand hygiene practices, the effectiveness of removal of physical contamination (bodily fluids and dirt) and the reduction of microbial counts as measured by colony forming units (CFUs) to be the most important considerations.
Trade off between clinical benefits and harms	This recommendation could lead to better hand hygiene and more effective hand decontamination. There is some evidence that healthcare professionals following bare below the elbow uniform policies are less likely to miss the wrist area when washing hands. The GDG are aware of obligations for staff to follow local uniform policy. There are no clinical harms from this recommendation.
Economic considerations	The additional staff time taken to adhere to this recommendation is minimal. Any potential reduction in infections associated with compliance to this recommendation would result in cost savings.
Quality of evidence	No RCT or cohort studies comparing decontaminating the wrists against not

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[w] For the purposes of this guideline, the GDG considered bare below the elbow to mean; not wearing false nails or nail polish; not wearing a wrist-watch or stoned rings; wearing short-sleeved garments or being able to roll or push up sleeves when delivering direct patient care and performing hand hygiene.

	decontaminating the wrist in hand hygiene were found. There were also no relevant laboratory studies comparing bacterial counts on the wrists. Only one RCT was found comparing the impact of bare below the elbow vs. usual practice on the thoroughness of hand and wrist decontamination. The quality of evidence was low. Without any data of infections, it is difficult to interpret the clinical importance of the areas missed during handwashing. There is no evidence that washing the wrist helps to reduce infections. Recommendations for nails and covering cuts and abrasions came from the previous edition of this guideline. Clinical questions for these factors were not included in the guideline update.
Other considerations	The GDG developed this recommendation based on consensus. The GDG developed the recommendation after considering the evidence and were aware of current policies and guidelines in this area from the Department of Health[70], WHO[282] and professional bodies such as the Royal College of Nursing[223]. The recommendation is congruent with the uniform or hand hygiene policies of these bodies. The final two bullet points of this recommendation were not reviewed for this update and therefore are taken directly from the 2003 guideline: making sure that fingernails are short, clean and free of nail polish and covering cuts and abrasions with waterproof dressings. The GDG recognise that healthcare workers are either reluctant or cannot remove wedding rings and are aware that some local dress code policies consider that one plain band is acceptable. The evidence related to what specifically constitutes bare below the elbow was not reviewed for this guideline and the GDG could not make a more detailed recommendation in this area. For the purposes of this guideline the GDG considered bare below the elbow to mean; not wearing false nails or nail polish, not wearing a wrist-watch or stoned rings, wearing short sleeved garments or be able to roll or push up sleeves when delivering direct patient care and performing hand hygiene. The second bullet point in this recommendation, 'removing wrist and hand jewellery' is taken from the 2003 guideline. The specific evidence for wrist and hand jewellery was not reviewed in this update and the GDG felt that this should be left unchanged. The GDG wanted to reinforce the message that wrist and hand jewellery should be removed, in addition to being bare below the elbow, as they thought that bare below the elbow may be interpreted only as rolling sleeves up. Other considerations when policies are developed at local level include equality and diversity issues, such as whether plain wedding bands and items of cultural significance. The GDG were aware that exposure of the forearms is not acceptable to some staff because of their faith, such as with the Islamic faith. However, they discussed the fact that the NHS has already issued guidance along with multi-faith representatives, Department of Health and NHS employers[70] to ensure that local dress code policies are sensitive to the obligations of faith groups whilst maintaining equivalent standards of hygiene. This guidance states that uniforms may include provision for sleeves that can be full length when staff are not engaged in direct patient care activity, uniforms can have three-quarter length sleeves, but that any full or three-quarter length sleeves must not be loose or dangling. Sleeves must be able to be rolled or pulled back and kept securely in place during hand washing and direct patient care activity. Also, disposable over-sleeves, elasticated at the elbow and wrist, may be used but must be put on and discarded in exactly the same way as disposable gloves. Strict procedures for washing hands and wrists must still be observed. Because the advice for different cultural groups regarding hand hygiene remains the same despite sensitivities to cultural or faith dress requirements,

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	the GDG did not feel that a separate recommendation was necessary to address the issues outlined above.

6.6 Is hand decontamination technique important?

Investigations into the technique of hand decontamination are limited. Our systematic review identified one RCT comparing different durations of handwashing and handrubbing on bacterial reduction that found no significant differences between the two study groups[152]. One laboratory study investigating methods of hand drying found no statistically significant differences between the four methods studied[111].

Recommendations are therefore based on existing expert opinion that the duration of hand decontamination, the exposure of all aspects of the hands and wrists to the preparation being used, the use of vigorous rubbing to create friction, thorough rinsing in the case of handwashing, and ensuring that hands are completely dry are key factors in effective hand hygiene and the maintenance of skin integrity[24,209].

6.6.1.1 Recommendations

7. **An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water before applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with all of the surfaces of the hand. The hands must be rubbed together vigorously for a minimum of 10-15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels. [2003]**

8. **When decontaminating hands using an alcohol handrub, hands should be free of dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry. [2003]**

6.7 Does hand decontamination damage skin?

Expert opinion concludes that skin damage is generally associated with the detergent base of the preparation and/or poor handwashing technique[24,209]. However, the frequent use of hand preparation agents may cause damage to the skin and normal hand flora is altered which may result in increase carriage of pathogens responsible for healthcare-associated infection[24,209]. In addition, the irritant and drying effects of hand preparations have been identified as one of the reasons why healthcare practitioners fail to adhere to hand hygiene guidelines[24,209]. A previous systematic review found no consistent evidence to suggest that any product currently in use caused more skin irritation and damage than another[208].

Our systematic review identified six studies of which three were RCT conducted in clinical settings[23,144,279]. They compared the use of alcohol-based preparations with soap and the self assessment of skin condition by nurse. In these studies a greater level of irritation was associated with the use of soap. Two further studies, one clinically based quasi experimental study and one descriptive clinical study concluded that alcohol-based handrubs caused less skin irritation[91,144,203]. A laboratory study demonstrated a strong relationship between the frequency of handwashing with a chlorhexidine preparation and dermatitis[203].

Expert opinion suggests that hand care is an important factor in maintaining regular hand decontamination practices and assuring the health and safety of healthcare practitioners[24,209].

6.7.1.1 Recommendation

9. **An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted. [2003]**

6.8 Research recommendations

2. **When clean running water is not available, what is the clinical and cost effectiveness of using wipes, gels, handrubs or other products to remove visible contamination?**

Why is this important?

Community healthcare workers often encounter challenges in maintaining hand hygiene when there is no access to running water. This particularly affects ambulance service staff, who often provide emergency care at locations where running water is not available. No evidence from randomised controlled trials is available on the most effective way for community-based healthcare workers to remove physical contamination, such as blood, from their hands in the absence of running water. In recent years, hand hygiene products that can be used without running water, such as gels, handrubs and wipes, have become available. However, their efficacy and suitability in actual clinical practice for use with visibly dirty hands has not been determined. A randomised controlled trial is required to compare hand wipes (detergent and disinfectant), hand gels and other hand hygiene products that can be used without running water, to determine the most effective way to remove physical dirt in the absence of running water, in order to make a recommendation for their use in real situations. The primary outcome measure should be colony-forming units on the basis of the adenosine triphosphate (ATP) surface test.

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7 Standard principles for the use of personal protective equipment

7.1 Introduction

The updated review questions in this chapter are:

- choice of gloves (latex, vinyl or nitrile)
- when to wear aprons or gowns.

The evidence and text from the previous guideline that has been superseded by this update is included in Appendices D.6 and D.9.

No new review questions are included in this chapter. The recommendation about gloves conforming to CE standards has been moved to the top of the gloves section (section 7.2.1.1), to emphasise its importance.

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Sections not updated in this chapter are:

- when to wear gloves
- gloves as single use items
- when to wear facemasks, eye protection and other facial protection.

The primary role of personal protective equipment (PPE) is to reduce the risk of transmission of microorganisms between patients, healthcare workers and the environment. The recommendations in this chapter are in line with Health and Safety requirements (Health and Safety Regulations 2002[4], Health and Safety at work Act 1974[1]).

Disposal of PPE is included in a separate general waste disposal chapter (see chapter 9).

This section discusses the evidence and associated recommendations for the use of personal protective equipment by healthcare workers in primary and community care settings and includes the use of aprons, gowns, gloves, eye protection and facemasks.

7.2 Infection Control Dress Code – protect your patients and yourself!

Expert opinion suggests that the primary uses of personal protective equipment are to protect staff and patients, and reduce opportunities for the transmission of microorganisms in hospitals[96,278]. However, as more healthcare is undertaken in the community,[156,186,242] the same principles apply. A trend to eliminate the unnecessary wearing of aprons, gowns and masks in general care settings has evolved over the past twenty years due to the absence of evidence that they are effective in preventing HCAI[96].

The decision to use or wear personal protective equipment must be based upon an assessment of the level of risk associated with a specific patient care activity or intervention and take account of current health and safety legislation[63,87,114,115].

7.2.1.1 Recommendation

10. Selection of protective equipment must[x] be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare workers' clothing and skin by patients' blood, body fluids, secretions or excretions. [2003]

7.3 Gloves: their uses and abuses

Since the mid-1980s the use of gloves as an element of personal protective equipment has become an everyday part of clinical practice for healthcare workers[37,46,87,96,105,132]. Expert opinion agrees that there are two main indications for the use of gloves in preventing HCAI[37,46,87,96]:

- to protect hands from contamination with organic matter and microorganisms;
- to reduce the risks of transmission of microorganisms to both patients and staff.

7.3.1 To glove or not to glove?

Gloves should not be worn unnecessarily as their prolonged and indiscriminate use may cause adverse reactions and skin sensitivity[46,209]. As with all items of personal protective equipment the need for gloves and the selection of appropriate materials must be subject to careful assessment of the task to be carried out and its related risks to patients and healthcare practitioners[46,209]. Risk assessment should include consideration of:

- who is at risk (whether it is the patient or the healthcare practitioner) and whether sterile or non-sterile gloves are required;
- the potential for exposure to blood, body fluids, secretions or excretions;
- contact with non-intact skin or mucous membranes during general care and invasive procedures.

Gloves must be discarded after each care activity for which they were worn in order to prevent the transmission of microorganisms to other sites in that individual or to other patients. Washing gloves rather than changing them is not safe and therefore not recommended[46,209].

7.3.2 Do gloves leak?

A previous systematic review provided evidence that gloves used for clinical practice leak when apparently undamaged[208]. In terms of leakage, gloves made from natural rubber latex (NRL) performed better than vinyl gloves in laboratory test conditions. Revised standards (2000) relating to the manufacture of medical gloves for single use have been devised and implemented[28-30]. These require gloves regardless of material to perform to the same standard.

Expert opinion supports the view that the integrity of gloves cannot be taken for granted and additionally, hands may become contaminated during the removal of gloves[37,46,87,96,209]. Our systematic review found evidence that vancomycin resistant enterococcus remained on the hands of healthcare workers after the removal of gloves[254]. Therefore, the use of gloves as a method of barrier protection reduces the risk of contamination but does not eliminate it and hands are not necessarily clean because gloves have been worn.

[x] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

7.3.2.1 Recommendations

Recommendations	11. Gloves used for direct patient care must[y] conform to current European Community (CE) standards[z] and should be appropriate for the task. [new 2012]
Relative values of different outcomes	The GDG agreed that healthcare worker preference and glove punctures were the most important outcomes for this recommendation.
Trade off between clinical benefits and harms	Although one study found that latex gloves had significantly fewer punctures compared to nitrile gloves, all single use gloves that meet BS EN 455, (1-4)[31] are required to meet the same resistance to punctures or holes, irrespective of glove material. BS EN 455-2 specifies the requirements and gives test methods for physical properties of single use medical gloves (i.e. surgical gloves and examination/procedure gloves) in order to ensure that they provide and maintain, when used, an adequate level of protection from cross contamination for both patient and user.
Economic considerations	The cost of gloves is the main economic consideration. If all gloves conform to European Community standards and there is no clinical reason to prefer one type of glove over another, the least costly option will represent the most cost-effective.
Quality of evidence	One low quality crossover trial with one outcome was identified. This study was downgraded due to study limitations including no randomisation and allocation concealment and a very low sample size of five dentists. See evidence review ion section 7.4.
Other considerations	This recommendation is a 'must' as it is covered by legislation detailed in the footnotes in line with the guidance from the NICE Guidelines Manual (2009)[180]. The GDG made changes to the original recommendation based on a consensus decision that gloves should be fit for purpose or 'appropriate for the task' (allow enough sensitivity, for example to feel a vein to take blood), be the correct size and take any allergy into consideration. It was important in light of health and safety legislation to amend the recommendation to highlight the obligation for healthcare workers to use gloves that conform to the relevant European and British standard. This recommendation has been moved to the beginning of the gloves section as the GDG considered it to be very important. The evidence behind the recommendation was searched for under the type of glove material in question (section 7.4).

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12. Gloves must[y] be worn for invasive procedures, contact with sterile sites and non-intact skin or mucous membranes, and all activities that have been assessed as carrying a risk of exposure to blood, body fluids, secretions or excretions, or to sharp or contaminated instruments. [2003]

13. Gloves must[y] be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient. [2003]

[y] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

[z] At the time of consultation on the guideline (July 2011): BS EN 455-2:2009.

Recommendations	14. Gloves that have been used for direct patient care or exposed to body fluids must be disposed of as clinical waste in accordance with current national legislation[aa] or local policies. (see chapter 9) [new 2012]
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be the safe disposal of clinical waste as addressed in chapter 9.
Trade off between clinical benefits and harms	The likelihood of cross contamination is greatly reduced by the immediate disposal of gloves as clinical waste. Failure to comply with this recommendation could result in legislative action. Further recommendations for waste disposal are in chapter 9.
Economic considerations	If healthcare organisations are currently improperly disposing of clinical waste then compliance with this recommendation may be associated with implementation costs.
Quality of evidence	New guidance based on legislation[72] informed this recommendation.
Other considerations	This recommendation is a 'must' as it is covered by legislation detailed in the footnote, in line with guidance from the NICE Guidelines Manual (2009)[180]. The GDG considered it important to update the original recommendation as a result of legislatory requirements in waste disposal and as part of the findings from the review question considered in chapter 9. The second half of the original recommendation has been removed (hands decontaminated after the gloves have been removed) as this is now included in the hand hygiene chapter, see recommendation 6.3.1.4.

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7.4 Which types of gloves provide the best protection against healthcare-associated infections?

7.4.1 Review question

The following review question was prioritised to determine which type of gloves provides the best protection against infection. A wide variety of gloves are available and it was considered that there is currently variation in types of gloves used in practice. The GDG stated that hypersensitivity and user preference were the most important outcomes for this question. Polythene gloves were included in the search, however no studies were identified.

What is the clinical and cost effectiveness of healthcare workers wearing vinyl, latex or nitrile gloves on user preference and reduction of hypersensitivity, blood borne infections, glove porosity and tears?

7.4.1.1 Clinical evidence

One crossover trial was identified, comparing non-powdered nitrile gloves with non-powdered latex gloves[175]. This study was also included in the previous 2003 guideline for this review question.

[aa] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

See Evidence Table G.3.1, Appendix G, Forest Plots in Figure 14, Appendix I.

Table 22: Non-powdered nitrile vs. non-powdered latex gloves - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Glove punctures[175]	1	Crossover	Very serious limitations [(a)]	No serious inconsistency	No serious indirectness	No serious imprecision
Blood borne infections	0	RCT or observational studies				
Glove porosity	0	RCT or observational studies				
Hypersensitivity	0	RCT or observational studies				
User preference	0	RCT or observational studies				
Ability to perform task	0	RCT or observational studies				

(a) Not randomised and no allocation concealment. Very low sample size (5 dentists), likely to be underpowered.

Table 23: Non-powdered nitrile vs. non-powdered latex gloves - Clinical summary of findings

Outcome	Non-powdered nitrile	Non-powdered latex	Relative risk	Absolute effect	Quality
Glove punctures	58/1020[(a)] (5.7%)	19/1000[(a)] (1.9%)	RR 2.99 (1.8 to 4.99)	38 more per 1000 (15 more to 76 more)	LOW

(a) Numbers given are number of punctures from the total number of gloves used.

7.4.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified in the update search.

No economic evidence was identified in the previous 2003 guideline. The previous guideline included a table outlining the costs for each type of glove and recommends that 'Healthcare personnel should be aware of the cost differential in gloves and should select the most appropriate for the activity.' In the absence of any published cost-effectiveness analyses, current UK glove costs were presented to the GDG to inform decision making.

Table 24: Glove costs

	Latex	Nitrile	Vinyl
Cost per 100 gloves (£)	3.70	5.31	2.35

Source: Based on average NHS Supply Chain Catalogue[185] prices.

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7.4.1.3 Evidence statements

3 Clinical — There is a statistically significant and clinically important decrease in glove punctures
4 with latex gloves compared to nitrile gloves (LOW QUALITY).

5 No studies were identified that reported blood borne infections, glove porosity,
6 hypersensitivity, user preference or ability to perform tasks.

7 Economic — No relevant cost-effectiveness data were identified.

7.4.1.4 Recommendations and link to evidence

Recommendations	15. Alternatives to natural rubber latex gloves must[bb] be available for patients, carers and healthcare workers who have a documented sensitivity to natural rubber latex. [2012]
Relative values of different outcomes	The GDG stated that hypersensitivity and user preference were the most important outcomes for this recommendation.
Trade off between clinical benefits and harms	The benefit of using non-latex gloves for those who have an allergy to latex (contact urticaria) is that they avoid allergic reactions and future adverse reactions by properly documenting their condition. This will require additional occupational health assessments.
Economic considerations	Because latex gloves are not a valid option for individuals with latex sensitivity, the comparatively greater cost of nitrile gloves is not a relevant consideration.
Quality of evidence	No clinical evidence found. One study compared latex to nitrile gloves, but healthcare workers with latex allergy were randomised to the nitrile group. No sensitivity to latex was reported by those healthcare workers using latex gloves.
Other considerations	This recommendation is a 'must' as it is covered by legislation detailed in the footnote in line with guidance from the NICE Guidelines Manual (2009)[180]. A minor change has been made to the order of wording of this recommendation following update to the previous guideline.

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Recommendations	16. Do not use polythene gloves for clinical interventions. [new 2012]
Relative values of different outcomes	The GDG stated that blood borne infections and bodily fluid contamination were the most important outcomes for this recommendation and that hands are protected from harmful microorganisms.
Trade off between clinical benefits and harms	Stating that 'powdered gloves should not be used' has been removed from this recommendation as an update to the previous guideline. The recommendation in the previous guideline referred to latex powdered gloves that are associated with latex allergy. Corn starch used in powdered latex gloves is thought to be a source of latex sensitisation, beacause the natural rubber latex easily binds to it, transporting it through the skin and into the circulation. However, alternative powdered gloves are now available that are non-latex and thus avoid this problem.

[bb] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

	Although no evidence for the use of polythene gloves was identified as part of the update, GDG consensus was that polythene gloves are inappropriate for clinical use as they do not provide sufficient protection against microorganisms for healthcare workers or patients, and do not meet current British standards[31] and as such should remain in the guideline as a 'do not use' recommendation.
Economic considerations	Although polythene gloves may be less expensive than other types of gloves, they are not appropriate for clinical interventions and do not represent a valid alternative to latex, nitrile, or vinyl gloves. If healthcare workers are currently using polythene gloves for clinical interventions, compliance with this recommendation will be associated with an implementation cost.
Quality of evidence	No clinical evidence was identified for polythene gloves.
Other considerations	Polythene gloves may be appropriate for other tasks (such as food preparation), but they are not suitable for clinical interventions.

17.5 When should plastic aprons or fluid repellent gowns be worn?

17.5.1 Review question

The following review question was prioritised to determine when a disposable apron should be worn or when a fluid repellent gown was more appropriate. This question was highlighted by dental practitioners during stakeholder consultation as an area that required updating. The GDG agreed that the prevention of blood, bodily fluid contamination and transfer of pathogenic microorganisms were important outcomes for this clinical question.

What is the clinical and cost effectiveness of healthcare workers wearing plastic aprons or fluid repellent gowns vs. no aprons or gowns, gloves only or standard uniform on the reduction of blood, bodily fluid and pathogenic microorganism contamination?

17.5.1.1 Clinical evidence

Two observational studies investigating contamination of uniforms when disposable plastic aprons were worn were included for this review question[34,97], one of which was included in the previous 2003 guideline[34]. Two intensive care based, observational, before and after studies were included, comparing isolation procedures with gowns and gloves against isolation procedures with gloves alone in preventing the acquisition of vancomycin resistant enterococci (VRE)[214,243].

See Evidence Table G.3.2, Appendix G, Forest Plots in Figure 15-16, Appendix I.

Table 25: Disposable aprons vs. no aprons - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
MRSA contamination of uniform (Care assistants; aprons worn when washing and changing)[97]	1	Observational studies	Very serious[(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
MRSA contamination of uniform	1	Observational studies	Very serious[(a)]	No serious inconsistency	No serious indirectness	No serious imprecision

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Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
(Care assistants; aprons worn when washing, changing and for meal assistance)[97]						
MRSA contamination of uniform (Nurses; aprons worn for dressing)[97]	1	observational studies	Very serious[(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
MRSA contamination of uniform (Nurses; aprons worn for dressing and biological sampling)[97]	1	Observational studies	Very serious[(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
Bacterial contamination of uniform[34]	1	Observational studies	Very serious limitations [(c)]	No serious inconsistency	Serious indirectness[(d)]	No serious imprecision[(e)]
Bodily fluid contamination	0	RCT or observational				

(a) Study poorly reported. Not clear how the indications to wear aprons were allocated. Results were excluded for HCW who did not use aprons where indicated on more than 5 occasions per shift.
(b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(c) Study poorly reported. Study conducted in 2 wards but no baseline data reported regarding care activities for each ward, patient characteristics (including numbers) or staffing in the 2 wards.
(d) Study conducted in hospital population not primary or community care.
(e) No standard deviation reported so confidence intervals are unknown, therefore unknown whether effect is precise or not.

Table 26: Disposable aprons vs. no aprons - Clinical summary of findings

Outcome	Aprons	No aprons	Relative risk	Absolute effect	Quality
MRSA contamination of uniform (Care assistants; aprons worn when washing and changing)[97]	15/43 (34.9%)	5/16 (31.3%)	1.12 (0.48 to 2.57)	38 more per 1000 (163 fewer to 491 more)	VERY LOW
MRSA contamination of uniform (Care assistants; aprons worn when washing, changing and for meal assistance)[97]	7/80 (8.8%)	5/16 (31.3%)	0.28 (0.1 to 0.77)	225 fewer per 1000 (72 fewer to 281 fewer)	VERY LOW
MRSA contamination of uniform (Nurses; aprons worn for dressing)[97]	7/22 (31.8%)	7/16 (43.8%)	0.73 (0.32 to 1.66)	118 fewer per 1000 (298 fewer to 289 more)	VERY LOW
MRSA contamination of	2/20 (10%)	7/16	0.23	337 fewer per 1000	VERY

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Outcome	Aprons	No aprons	Relative risk	Absolute effect	Quality
uniform (Nurses; aprons worn for dressing and biological sampling)[97]		(43.8%)	(0.05 to 0.95)	(from 22 fewer to 416 fewer)	LOW
Bacterial Contamination of uniform[34]	Mean colony count in apron group: 59.40[(a)]	Mean colony count in no apron group 44.80a	N/R	N/R	VERY LOW

(a) Only results for mean colony counts were provided in the paper. No details about standard deviation of results were provided.

Table 27: Gowns and gloves vs. gloves alone- Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Vancomycin resistant enterococci (VRE) acquisition rate (cases per 100 days at risk)[243]	1	Observational	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision [(c)]
VRE acquisition rate (cases per 1000 MICU days)[214]	1	Observational	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	No serious imprecision [(c)]
Bodily fluid contamination	0	RCT or observational				

(a) Studies investigated impact of policy change over two consecutive periods of time. No blinding and so some bias due to changes in behaviour could have occurred.
(b) Study conducted in hospital population not primary or community care.
(c) No standard deviation reported so confidence intervals are unknown, therefore unknown whether effect is precise or not.

Table 28: Gowns and gloves vs. gloves alone - Clinical summary of findings

Outcome	Gowns and gloves	Gloves alone	Relative risk	Absolute effect	Quality
VRE acquisition rate (cases per 100 days at risk)	1.8[(a)]	3.78[(a)]	N/R	N/R	VERY LOW
VRE acquisition rate (cases per 1000 MICU days)	9.0[(b)]	19.6[(b)]	N/R	N/R	VERY LOW

(a) Results expressed as cases per 100 days at risk
(b) Results expressed as cases per 1000 MICU days

7.5.1.2 Cost-effectiveness evidence

Two economic studies were identified through the update search. One was excluded because it did not include any relevant outcomes, used a costing method that is incompatible with the NICE reference case , and as it was undertaken from a Turkish perspective, was considered a non-relevant setting by the GDG[20].

Update 2012

Results of a cost analysis by Puzniak et al (2004)[213] were presented to the GDG. The GDG were also presented with current UK gown and apron costs to inform decision making.

No economic studies were identified in the previous 2003 guideline.

Table 29: Gowns vs. No gowns – Economic study characteristics

Study	Limitations	Applicability	Other Comments
Puzniak 2004[213]	Potentially serious limitations[(a)]	Partial applicability[(b)]	ICU setting

(a) Based on a before and after trial designed to assess the impact of a policy change, difficult to isolate the effect of gowns as was part of an intervention package.
(b) USA hospital perspective; ICU isolation setting.

Table 30: Gowns vs. No gowns – Economic summary of findings

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Puzniak 2004[213]	Gowns cost £67 567 per year[(a)]	58 cases of VRE colonisation and 6 cases of VRE bacteraemia averted with use of gowns	Net benefit of £382 914 associated with gowns	Results were robust under exploratory analysis

(a) Annualised hospital-wide cost; cost of intervention included the healthcare worker time needed to don and doff gowns.

Table 31: Gown and apron costs

	Sterile fluid impervious gowns	Sterile standard gowns	Standard plastic apron
Cost per gown/apron (£)	2.10 (disposable)	1.80 (+laundry/autoclave)	0.10 (disposable)

Source/Note: Based on average NHS Supply Chain Catalogue[185] prices.

Update 2012

7.5.1.3 Evidence statements

Clinical

It is uncertain whether there is any difference in mean bacterial colony count on uniforms when wearing an apron compared with not wearing an apron. (VERY LOW QUALITY)

There is a statistically significant and clinically important reduction in MRSA contamination of care assistant uniforms when aprons were used for washing, and meal assistance in a long-term care facility compared with when no aprons were used. (VERY LOW QUALITY)

There is a statistically significant reduction of uncertain clinical importance in MRSA contamination of nurses uniforms when aprons were used for dressing changes and biological sampling compared with when no aprons were used. (VERY LOW QUALITY)

There was a statistically significant reduction of uncertain clinical importance in VRE acquisition when gowns and gloves were worn in isolation procedures compared to when gloves alone were worn. (VERY LOW QUALITY)

No studies were identified that reported bodily fluid contamination.

Economic

Wearing a gown or apron is likely to be cost-effective where there is a risk of infection transmission to the healthcare worker or between patients. (POTENTIALLY SERIOUS LIMITATIONS; PARTIALLY APPLICABLE)

No economic studies comparing gowns to aprons were identified.

7.5.1.4 Recommendations and link to evidence (2012)

Recommendations	**17. When delivering direct patient care:** • **wear a disposable plastic apron if there is a risk that clothing may be exposed to blood, body fluids, excretions or secretions, or** • **wear a full-body fluid-repellent gown if there is a risk of extensive splashing of blood, body fluids, excretions or secretions, onto skin or clothing. [2012]**
Relative values of different outcomes	The GDG agreed that prevention of blood, bodily fluid and pathogenic microorganism contamination were important outcomes for this clinical question.
Trade off between clinical benefits and harms	Wearing disposable aprons and gowns should protect healthcare workers from becoming contaminated whilst providing care and is also in line with health and safety legislation[1,3,4,116]. In turn, this should help prevent the spread of microorganisms to other patients. The GDG felt that potential clinical disadvantages may occur if the healthcare worker becomes reliant on the aprons to protect themselves and does not continue with other standard infection control best practice. The GDG considered that poor practice, such as not wearing a clean uniform or not wearing aprons for more than one patient care episode, should not occur.
Economic considerations	The cost of disposable aprons, cost of uniforms, cost of laundering uniforms, and consequences of infection were taken into consideration. The GDG agreed that the cost associated with apron use would likely be outweighed by the costs and consequences of not wearing an apron (staff time and resource use associated with changing and laundering soiled uniforms, and the risk of infection associated with exposure to blood, bodily fluid, excretions or secretions). The cost associated with fluid-repellent gown use should be considered relative to the risk of contamination associated with each episode of direct patient care. Where the risk of soiling or infection is high, the increased cost of a fluid-repellent gown is likely to be justified.
Quality of evidence	Four clinical studies were included. Two very low quality, poorly reported observational studies investigated uniform contamination when an apron was used compared to when no apron was used. Two very low quality comparative observational studies investigated the impact of changing isolation procedures in intensive care units on the acquisition of vancomycin resistant enterococci (VRE). Both studies reported lower VRE acquisition rates in the periods when gloves and gowns were used compared to the periods when gloves alone were used. The GDG agreed the changes to the recommendation by consensus.
Other considerations	The GDG noted that before any task is started an assessment of the risks should be undertaken to identify the risks of contamination to healthcare workers. They noted that appropriate PPE should be selected based on the task required. Employers are obliged to ensure that suitable PPE is available and that there are proper facilities for its storage and disposal in line with current legislation. The GDG thought that employees should be adequately instructed and trained in the safe use of PPE, which includes appropriate donning, doffing and disposal procedures. However, they did not feel it was necessary to make a recommendation in this area as this is covered in recommendation 5.3.1.1. The GDG noted that healthcare workers should be protected from contamination of bodily fluids that could cause infection. The level of protection (disposable apron or full gown) should depend on the extent of

Update 2012

	potential contamination. The recommendation from the previous guideline explicitly stated that aprons or gowns should be used to protect against body fluid contamination with the exception of sweat. The GDG decided to remove 'with the exception of sweat' as, although they acknowledged that microorganisms in sweat were unlikely to be pathogenic, the exception was confusing and unnecessary. In addition, the brackets included in the recommendation made in the previous guideline which provided the example of 'when assisting with child birth' were removed as it was felt by the GDG to be unnecessary and may limit the reader's interpretation of the recommendation.

Recommendations	**18. When using disposable plastic aprons or gowns:** • **use them as single-use items, for one procedure or one episode of direct patient care and** • **ensure they are disposed of correctly (see chapter 9). [2012]**
Relative values of different outcomes	The GDG agreed that prevention of blood and bodily fluid and pathogenic microorganism contamination were important outcomes for this clinical question.
Trade off between clinical benefits and harms	The GDG noted that wearing disposable aprons and gowns protect healthcare workers from becoming contaminated whilst providing care. This benefit is negated if bad practice is adopted such as wearing aprons or gowns between patients or wearing the same apron for different procedures on the same patient.
Economic considerations	The GDG agreed that any increased cost in apron and gown use associated with single-use of these items is outweighed by the cost and quality of life implications associated with infection transmission to healthcare workers and between patients.
Quality of evidence	The recommendation developed is in line with the available evidence which investigated the use of single use items which were discarded after each patient use. The evidence that showed the use of gowns reduced the acquisition of VRE in intensive care units, provided gowns that were not re-used between patients. It is unclear from consideration of the evidence reviewed whether the available gowns were disposable items.
Other considerations	The GDG updated the recommendation from the previous guideline to highlight that plastic aprons or gowns should be changed between 'individual episodes of patient care' in order to prevent disposable aprons used for a patient being re-donned when providing care for that same patient at a later time. Appropriate disposal of aprons and gowns is a legal requirement. The GDG decided to separate the section of the recommendation which required the healthcare worker to dispose of plastic aprons as 'healthcare waste' as this is now considered in a separate recommendation (see chapter 9).

Update 2012

7.6 When is a facemask, eye protection or other facial protection necessary?

Our previous systematic review failed to reveal any robust experimental studies that suggested any clinical benefit from wearing surgical masks to protect patients during routine ward procedures such as wound dressing or invasive medical procedures[209,210].

Personal respiratory protection is required in certain respiratory diseases, e.g., HIV-related or multiple drug-resistant tuberculosis[257] and where patients who are severely immunocompromised are at an increased risk of infection. In these instances, surgical masks are not effective protection and specialised respiratory protective equipment should be worn, e.g., a particulate filter mask[114,210,257].

Our previous systematic review indicated that different protective eyewear offered protection against physical splashing of infected substances into the eyes (although not on 100% of occasions) but compliance was poor[210]. Expert opinion recommends that face and eye protection reduce the risk of occupational exposure of healthcare practitioners to splashes of blood, body fluids, secretion or excretions[46,96,209].

7.6.1.1 Recommendations

19. Face masks and eye protection must[cc] be worn where there is a risk of blood, body fluids, secretions or excretions splashing into the face and eyes. [2003]

20. Respiratory protective equipment, for example a particulate filter mask, must[cc] be used when clinically indicated. [2003]

[cc] In accordance with current health and safety legislation (at the time of consultation on the guideline [July 2011]): Health and Safety at Work Act 1974, Management of Health and Safety at Work Regulations 1999, Health and Safety Regulations 2002, Control of Substances Harmful to Health Regulations 2002, Personal Protective Equipment Regulations 2002, and Health and Social Care Act 2008.

8 Standard principles for the safe use and disposal of sharps

8.1 Introduction

The updated review questions in this chapter are:

- choice of safety cannulae
- choice of safety needles.

The choice of safety cannulae and needles were prioritised for update to determine whether newer safety devices available since the publication of the previous guideline are effective at reducing needle stick injury and associated infection.

The evidence and text from the previous guideline that has been superseded by this update is included in Appendices D.6 and D.9.

No new review questions included in this chapter.

Sections not updated in this chapter are the safe handling of sharps (relating to the recommendation on sharps not being passed directly from hand to hand, and handling being kept to a minimum).

Specific recommendations on disposal of sharps are included in this chapter and have been updated following changes to legislation[65,67]. General waste disposal recommendations are in chapter 9. Waste disposal recommendations for personal protective equipment are in chapter 7.

Update 2012

This section discusses the evidence and associated recommendations for the safe use and disposal of sharps in community and primary care settings and includes minimising the risks associated with sharps use and disposal and the use of needle protection devices.

8.2 Sharps injuries – what's the problem?

The safe handling and disposal of needles and other sharp instruments should form part of an overall strategy of clinical waste disposal to protect staff, patients and visitors from exposure to blood borne pathogens[119]. The incidence of injuries caused by sharps varies across clinical settings and is difficult to compare due to different denominators for data collection. Audit data suggests that of the occupational injuries that occur in hospitals, 16% are attributable to sharps injuries[177]. National surveillance of occupational exposure to bloodborne viruses from 1997-2001 indicates that 68% of percutaneous exposures were caused by sharps. Of the exposures followed up at 6 weeks, 7 percent involved healthcare workers working in community and primary care settings[85]. In the first year of data collection the UK EpiNet sharps injury surveillance project provides data on 888 injuries occurring in 12 NHS Trusts identifying that 80% of injuries involve contaminated sharps, with 43% of injuries sustained by nursing staff and 24% by medical staff[221]. In general clinical settings, sharps injuries are predominantly caused by needle devices and associated with venepuncture, administration of medication via intravascular lines and recapping of needles during the disassembly of equipment[36]. All sharps injuries are considered to be potentially preventable.

The average risk of transmission of bloodborne pathogens following a single percutaneous exposure from a positive source has been estimated to be[212]:

- Hepatitis B Virus (HBV) 33.3 percent (1 in 3)

- Hepatitis C Virus (HCV) 3.3 percent (1 in 30)
- Human Immunodeficiency Virus (HIV) 0.31 percent (1 in 319)

National and international guidelines, are consistent in their recommendations for the safe use and disposal of sharp instruments and needles[38,87,189]. As with many infection prevention and control policies, the assessment and management of the risks associated with the use of sharps is paramount and safe systems of work and engineering controls must be in place to minimise any identified risks, e.g., positioning the sharps bin as close as possible to the site of the intended clinical procedure.[114] Any healthcare worker experiencing an occupational exposure to blood or body fluids needs to be assessed for the potential risk of infection by a specialist practitioner, e.g., physician, occupational health nurse and offered before testing, immunisation and post-exposure prophylaxis if appropriate[86].

8.2.1.1 Recommendations

21. Sharps should[dd] not be passed directly from hand to hand, and handling should be kept to a minimum. [2003, amended 2012]

Recommendations	**22. Used needles should not be recapped, bent or broken before disposal. If recapping or disassembly is unavoidable:** • **a risk assessment should be undertaken and** • **appropriate safety devices should be used. [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be prevention of needlestick injury, blood contamination and blood borne infection.
Trade off between clinical benefits and harms	The GDG considered recapping, bending and breaking used needles to put healthcare workers at risk from needlestick injuries and therefore the benefit of this recommendation is to prevent such injuries. The GDG were aware that a new EU Directive (2010/32/EU[49]) was introduced in the United Kingdom (UK) in May 2010 entitled: prevention of sharps injuries in hospitals and the healthcare sector. The UK will have until May 2013 to implement the Directive into national legislation. The GDG noted that the Directive aims to set up an integrated approach establishing policies in risk assessment, risk prevention, training, information, awareness raising and monitoring. The Directive states that "Where the results of the risk assessment reveal a risk of injuries with a sharp and/or infection, workers' exposure must be eliminated by taking the following measures, without prejudice to their order: the practice of recapping shall be banned with immediate effect...". Unavoidable situations for recapping, bending or breaking needles were brought to the attention of the GDG by dental colleagues during the stakeholder workshop. The GDG noted DH advice that some syringes used in dentistry are not disposable and needles should be re-sheathed using the needle guards provided[65].
Economic considerations	No relevant economic considerations were identified for this issue. Where avoidable, recapping and disassembly is not considered a valid alternative. Where unavoidable, 'appropriate safety devices', such as portable needle sheath holding devices, are likely to already be present in care settings where re-capping is routine and therefore implementation of this recommendation

Update 2010

[dd] The updated recommendation contains 'should' rather than 'must' (which is in the 2003 guideline) because the GDG considered that this is not covered by legislation (in accordance with the NICE guidelines manual, 2009).

	will be associated with minimal cost.
Quality of evidence	No clinical evidence was identified. Although a direct question was not asked about recapping, bending or breaking needles, the sharps literature search for other questions was considered to be wide enough to have captured this evidence. No major changes have been made to this recommendation since the last guideline, apart from the addition of situations where recapping or disassembling needles is unavoidable. GDG consensus was that in these cases a risk assessment should take place and appropriate safety devices (such as recapping devices) should be used. This was considered to be especially appropriate and in line with the EU directive noted above
Other considerations	Other considerations for the GDG included the training of all healthcare workers in the safe management of sharps regardless of type used to aid implementation of this recommendation, see also recommendation 26. In addition, they felt that training should include awareness of safety issues when sharps are kept in a patient's home.

Recommendations	**23. Used sharps must be discarded immediately into a sharps container conforming to current standards[ee] by the person generating the sharps waste. [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be prevention of needlestick injury, blood contamination and blood borne infection.
Trade off between clinical benefits and harms	GDG consensus was that the likelihood of needlestick injury is greatly reduced by the immediate disposal of sharps into an appropriate container. Failure to comply with this recommendation could result in legislative action. Further recommendations for waste disposal are in chapter 0.
Economic considerations	People generating sharps waste should already have access to sharps containers that conform to current standards. If not, then this recommendation will be associated with an implementation cost.
Quality of evidence	There was no clinical evidence review for this section. The GDG considered that it was important for any recommendation amendments to conform to the Safe Management of Healthcare Waste Guidelines[72] and the relevant EU and UK regulations and HTM-01-05 Decontamination in primary care dental practices [67]. The GDG were aware that the Royal College of Nursing had also published guidance in this area[222].
Other considerations	This recommendation has been updated to reflect current legislations and best practices. The GDG considered that this recommendation relates to patient safety and that the consequence of not implementing it mean that the risk of adverse events are so severe, that the use of the word 'must' is appropriate in line with the guidance from the NICE Guidelines Manual (2009)[180]. Clinical waste must be placed in the appropriate receptacle at source. This should always be performed by the person immediately involved in the generation of the waste. Passing used sharps from one person to another increases the risk of injury. The GDG also considered that to ensure that risk of injury was minimised it was important that the used sharps should be disposed of immediately after use and made the appropriate amendment to the existing recommendation to reflect this.

Update 2012

[ee] At the time of consultation on the guideline (July 2011): UN3291 and BS 7320.

1

Recommendations	**24.Sharps containers:** • **must[ff] be located in a safe position that avoids spillage, is at a height that allows the safe disposal of sharps, is away from public access areas and is out of the reach of children** • **must not[ff] be used for any other purpose than the disposal of sharps** • **must not[ff] be filled above the fill line** • **must[ff] be disposed of when the fill line is reached** • **should be temporarily closed when not in use** • **should be disposed of every 3 months even if not full, by the licensed route in accordance with local policy. [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be needlestick injury, blood contamination and blood borne infection.
Trade off between clinical benefits and harms	Compliance with this recommendation will reduce the risk of sharps injuries to healthcare workers, patients, carers and the public. Failure to comply with this recommendation could result in legislative action.
Economic considerations	Individuals and organisations generating sharps waste should already be compliant with this recommendation. If not, then this recommendation will be associated with an implementation cost.
Quality of evidence	There was no clinical evidence review for this section. The GDG noted that any amendments to the original recommendation should conform to the Safe Management of Healthcare Waste guidelines[72] and the relevant EU and UK regulations[65] and HTM-01-05 Decontamination in primary care dental practices[67]. They were also aware that the Royal College of Nursing have published guidance in this area[222].
Other considerations	Inappropriate disposal of sharps is an important cause of injury. This recommendation is a 'must' as it is covered by legislation detailed in the footnote in line with the NICE Guidelines Manual (2009)[180]. The GDG discussed and considered the following aspects when making the recommendations: • Patients cared for at home: The Safe Management of Healthcare Waste[72] document makes it clear that sharps containers should be prescribed for patients using sharps (injections/lancets) at home. It is important not to just involve the patient but also other relevant household members in training to ensure proper use of sharps and sharps bins. They felt that it would not be acceptable for this group to dispose of their sharps and lancets into the domestic waste stream e.g. household black bag. • Community nursing: For practicality reasons, community nurses may want to use just a single sharps receptacle

Update 2012

[ff] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/ Publications/PublicationsPolicyAndGuidance/DH_126345

8.3 Do safety cannulae reduce sharp injuries compared to standard cannulae?

8.3.1 Review question

This question was asked to determine whether newer safety devices available since the publication of the previous guideline are effective at reducing needle stick injury and associated infection.

What is the clinical and cost effectiveness of healthcare workers using safety needle cannulae vs. standard cannulae on compliance and user preference, infection related mortality and morbidity and sharps injuries?

8.3.1.1 Clinical evidence

Three RCTs were identified, two comparing active (requires pressing a button to trigger the withdrawal of the needle in to a plastic sleeve using a spring) and passive (with a protective shield that automatically covers the needlepoint during its withdrawal) safety cannulae to standard cannulae[16,211], and one RCT comparing active safeguarded needles with standard cannulae[48].

No studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.4.1, Appendix G, Forest Plots in Figure 17-19, Appendix I

Table 32: Active safety cannulae vs. standard cannulae - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury[16,211]	2	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
Catheterised on first attempt [16,48,211]	3	RCT	Serious limitations[(c)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
Blood contamination of patients or healthcare workers (HCWs) [16,48,211]	3	RCT	Serious limitation [(c)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
Infection related mortality and morbidity	0	RCT				
User preference	0	RCT				
Compliance	0	RCT				

(a) Lack of blinding and unclear randomisation and allocation in 1 study.
(b) Hospital setting rather than community.
(c) Lack of blinding and unclear randomisation in 2 studies.

Update 2012

Table 33: Active safety cannulae vs. standard cannulae - Clinical summary of findings

Outcome	Safety cannulae	Standard cannulae	Relative risk	Absolute effect	Quality
Needle stick injury	0/304 (0%)	0/304 (0%)	not pooled	not pooled	LOW
Catheterised on first attempt	426/515 (82.7%)	374/423 (88.4%)	RR 0.96 (0.91 to 1.01)	35 fewer per 1000 (80 fewer to 9 more)	LOW
Blood contamination of patients or HCWs	77/515 (15%)	32/423 (7.6%)	RR 1.94 (1.32 to 2.86)	71 more per 1000 (24 more to 141 more)	LOW

Table 34: Passive safety cannulae vs. standard cannulae - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury[16,211]	2	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
Catheterised on first attempt [16,211]	2	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	No serious imprecision
Blood contamination of patients or HCWs[16,211]	2	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Infection related mortality and morbidity	0	RCT				
User preference	0	RCT				
Compliance	0	RCT				

(a) Lack of blinding and unclear randomisation and allocation in 1 study.
(b) Hospital setting rather than community.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 35: Passive safety cannulae vs. standard cannulae - Clinical summary of findings

Outcome	Passive safety	Standard	Relative risk	Absolute effect	Quality
Needle stick injury	0/301 (0%)	0/304 (0%)	not pooled	not pooled	LOW
Catheterised on first attempt	278/301 (92.4%)	280/304 (92.1%)	RR 1 (0.96 to 1.05)	0 more per 1000 (37 fewer to 46 more)	LOW
Blood contamination of patients or HCWs	21/301 (7%)	20/304 (6.6%)	RR 1.06 (0.59 to 1.92)	4 more per 1000 (27 fewer to 61 more)	VERY LOW

8.3.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified.

No cost effectiveness evidence was identified in the previous 2003 guideline.

Update 2012

In the absence of any published cost-effectiveness evidence, estimates about the cost and quality of life associated with needle stick injury was obtained from several review articles[148-150] identified through the economic literature search and presented to the GDG to inform decision making. The GDG were also presented with the current UK cost of standard cannulae and safety cannulae.

Table 36: Cost of standard and safety IV cannulae

Type of cannula	Average cost (£)
Standard cannula	0.86 each
Active safety cannula	1.05 each
Passive safety cannula	2.10 each

Source/Note: Based on average 2010 Supply Chain[185] prices. Individual trusts may negotiate different contracts and prices with suppliers.

8.3.1.3 Evidence statements

Clinical

It is unlikely that there is any difference in success of cannulation on first attempt between active or passive safety cannulae compared to standard cannulae. (LOW QUALITY)

There were no sharps injuries for active or passive safety cannulae or standard cannulae. (LOW QUALITY)

There is a statistically significant and clinically important increase in blood contamination of patients or HCWs with active safety cannulae compared to standard cannulae. (LOW QUALITY)

It is uncertain whether there is any difference in blood contamination of patients or HCWs with passive safety cannulae compared to standard cannulae. (VERY LOW QUALITY)

No studies were identified that reported infection related mortality and morbidity, user preference or compliance.

Economic

No cost-effectiveness studies were identified.

8.3.1.4 Recommendations and link to evidence

The evidence for this review question was considered alongside the evidence for the following question and recommendations were made considering all the evidence. See recommendations at the end of this chapter 8.4.1.4.

Update 2012

8.4 Do safety needle devices reduce sharps injuries compared to standard needles?

8.4.1 Review question

This question was asked to determine whether newer safety devices available since the publication of the previous guideline are effective at reducing needle stick injury and associated infection.

What is the clinical and cost effectiveness of healthcare workers using safety needle devices (needle-free, retractable needles, safety re-sheathing devices) vs. standard needles on compliance and user preference, infection related mortality and morbidity and sharps injuries?

8.4.1.1 Clinical evidence

Five observational studies were identified. Three studies were before and after implementation studies of safety devices for phlebotomy procedures[39,168,219]. One study investigates the implementation of a disposable safety syringe for dentistry[283] compared to a non-disposable metal syringe. The final study investigates the implementation of a self-retracting glucometer lancet compared to a straight stick non-retracting lancet[196].

Three studies from the previous 2003 guideline met the inclusion criteria for this review question[39,196,283].

See Evidence Table G.4.2, Appendix G, Forest Plots in Figure 20-29, Appendix I.

Table 37: Safety devices for phlebotomy procedures vs. standard devices - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury[168(d)]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Needle stick injury[219]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Needlestick injury - Winged steel needle[39]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Needlestick injury - Bluntable vacuum tube[39]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Needlestick injury - Vacuum tube with recapping	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	Serious imprecision[(b)]

Update 2012

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
sheath[39]						
User preference[39]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
User preference[168](c)	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Blood borne infection	0	Observational studies				
Infection related mortality and morbidity	0	Observational studies				
Compliance	0	Observational studies				

(a) Hospital based rather than community.
(b) Wide confidence interval with low event number give a low confidence in the effect size.
(c) Taken from survey data, numbers given are those that preferred the safety needle, remaining respondents were assumed to prefer the standard needle.
(d) Denominator is the number total number of needles delivered to the department.

Table 38: Safety devices for phlebotomy procedures vs. standard devices - Clinical summary of findings

Outcome	Safety device	Standard device	Relative risk	Absolute effect	Quality
Needle stick injury	28/436180 (0%)	86/641282 (0%)	RR 0.48 (0.31 to 0.73)	0 fewer per 1000 (0 fewer to 0 fewer)	VERY LOW
Needle stick injury[(a)]	-	-	RR 0.62 (0.51 to 0.72)	-	VERY LOW
Needlestick injury - Winged steel needle	34/2540500 (0%)	53/1875995 (0%)	RR 0.47 (0.31 to 0.73)	0 fewer per 1000 (0 fewer to 0 fewer)	VERY LOW
Needlestick injury - Bluntable vacuum tube	2/501596 (0%)	14/523561 (0%)	RR 0.15 (0.03 to 0.66)	0 fewer per 1000 (0 fewer to 0 fewer)	VERY LOW
Needlestick injury - Vacuum tube with recapping sheath	5/628092 (0%)	19/895054 (0%)	RR 0.38 (0.14 to 1)	0 fewer per 1000 (0 fewer to 0 more)	VERY LOW
User preference	622/1939 (32.1%)	882/1939 (45.5%)	RR 0.71 (0.65 to 0.76)	132 fewer per 1000 (109 fewer to 159 fewer)	VERY LOW
User preference	199/536 (37.1%)	337/536 (62.9%)	RR 0.59 (0.52 to 0.67)	258 fewer per 1000 (207 fewer to 302 fewer)	VERY LOW

(a) Relative risk taken directly from paper. Total events and population not given for study period.

Update 2012

Table 39: Disposal safety syringe vs. non-disposable syringe - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury[283]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	No serious imprecision
Blood borne infection	0	Observational studies				
Infection related mortality and morbidity	0	Observational studies				
Compliance	0	Observational studies				

(a) Dental school setting rather than community.

Table 40: Disposal safety syringe vs. non-disposable syringe - Clinical summary of findings

Outcome	Safety syringe	Non-disposable	Relative risk	Absolute effect	Quality
Needle stick injury	0/1000 (0%)	21/1000 (2.1%)	RR 0.02 (0 to 0.38)	21 fewer per 1000 (13 fewer to 21 fewer)	VERY LOW

Table 41: Self-retracting glucometer lancet vs. straight stick non-retracting lancet - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury[196]	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness[(a)]	Serious imprecision[(b)]
Blood borne infection	0	Observational studies				
Infection related mortality and morbidity	0	Observational studies				
Compliance	0	Observational studies				

(a) The denominator used for needlestick injury was worker years rather than the actual number of lancets used.
(b) Wide confidence and low event number lead to low confidence in the effect size.

Table 42: Self-retracting glucometer lancet vs. straight stick non-retracting lancet - Clinical summary of findings

Outcome	Self-retracting	Non-retracting	Relative risk	Absolute effect	Quality
Needle stick injury	2/477 (0.4%)	16/954 (1.7%)	RR 0.25 (0.06 to 1.08)	13 fewer per 1000 (16 fewer to 1 more)	VERY LOW

Update 2012

8.4.1.2 Cost-effectiveness evidence

The update search conducted as part of this review identified two studies; neither met inclusion criteria. A cost analysis by Glenngard et al (2009)[104] was excluded because costs were presented nationally rather than individually and were considered specific to Sweden. A cost-effectiveness analysis from Madagascar[78] was excluded because neither the comparator nor the setting was relevant to this question.

One study identified by the clinical evidence review in the previous 2003 guideline met inclusion criteria for the update economic review. Peate and colleagues (2001)[196] conducted a basic cost analysis in their comparison of the use of self-retracting glucometer lancets to straight stick non-retracting lancets among emergency medical system workers in the United States.

Additional estimates of the cost and quality of life impact associated with needle stick injury were obtained from several review articles[148-150] identified through the economic literature search and presented to the GDG to inform decision making. The GDG were also presented with the current UK cost of various standard and safety needles.

Table 43: Self-retracting glucometer lancet vs. straight stick non-retracting lancet - Economic study characteristics

Study	Limitations	Applicability	Other Comments
Peate 2001[196]	Potentially serious limitations [(a)]	Partial applicability[(b)]	

(a) Resource use not reported, unit costs and cost source not reported, observational before-after study.
(b) USA setting.

Table 44: Self-retracting glucometer lancet vs. straight stick non-retracting lancet - Economic summary of findings

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Peate 2001[196]	Self-retracting lancets cost £363 more per year than non-retracting lancets (department-wide)	Self-retracting lancets resulted in fewer needlestick injuries (RR 0.25)	Self-retracting lancets resulted in a department-wide net savings of £14 014 due to averted treatment costs	N/R

Table 45: Cost of standard and safety needles

Type of needle	Average cost (£)
Hypodermic syringes	
Standard hypodermic syringe with standard needle	0.07 per 1ml syringe
Safety hypodermic syringe with retractable needle	0.17 per 1ml syringe
Safety hypodermic syringe with hinged shield needle	0.25 per 1ml syringe
Insulin syringes	
Standard insulin syringe with standard needle attached	0.08 per 1ml syringe
Safety insulin syringe with retractable needle	0.25 per 1ml syringe

Source/Note: Based on average 2010 Supply Chain[185] prices. Individual trusts may negotiate different contracts and prices with suppliers.

Update 2012

8.4.1.3 Evidence statements

Clinical

Phlebotomy devices

There is a statistically significant and clinically important reduction in needlestick injuries with the safety devices compared to standard devices. (VERY LOW QUALITY)

There is a statistically significant and clinically important increase in user preference with the safety devices compared to standard devices. (VERY LOW QUALITY)

Dental syringe

There is a statistically significant and clinically important reduction in needlestick injuries with the safety devices compared to standard devices. (VERY LOW QUALITY)

No studies were identified that reported blood borne infection, infection related mortality and morbidity, or compliance.

Safety lancet

It is uncertain whether there is any difference in needlestick injuries with the safety devices compared to standard devices. (VERY LOW QUALITY)

Economic

There is some evidence to suggest that safety lancets are more cost-effective than standard lancets in certain settings (POTENTIALLY SERIOUS LIMITATIONS AND PARTIAL APPLICABILITY). No other cost-effectiveness evidence was identified.

8.4.1.4 Recommendations and link to evidence

Update 2012

Recommendations	25. Use sharps safety devices if a risk assessment has indicated that they will provide safer systems of working for healthcare workers, carers and patients. [new 2012]
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be needlestick injury, success of cannulation on first attempt, blood contamination and blood borne infection.
Trade off between clinical benefits and harms	The GDG noted that active safety cannula devices caused more blood contamination of the surroundings, healthcare worker and/or the patient and therefore passive devices with a simpler design could be considered. However the GDG also noted that increased blood contamination was possibly related to previously unidentified training needs and unfamiliarity with the new devices. Risk assessment may require additional resources (time etc), but that the potential reduction in needlestick injuries outweighs this and provides a safer working environment for healthcare workers. Training is required to ensure safety devices are used correctly, and the evidence showed that if implemented correctly these devices do reduce needle stick injuries. The GDG were aware that there is anxiety amongst healthcare workers associated with taking a blood test to detect the presence of a blood borne virus' (for example, HIV, Hepatitis B and C). The GDG felt that minimising needlestick injury from such tests using safety devices would be an additional benefit.
Economic considerations	Safety devices are more costly than standard devices. However, given the high cost of investigation and treatment of needle stick injuries, the level of

	healthcare worker anxiety associated with these injuries, and the frequency with which they occur, the GDG agreed that the use of safety devices may prove cost-effective in high risk situations or situations where risk assessment has indicated their use.
Quality of evidence	Three RCTS were identified comparing safety cannulae with standard cannulae, which were all of low quality. Evidence from these studies was downgraded as the studies were all in hospital settings and data was of low or very low quality. No RCTs were identified for safety needle devices, but several observational studies were identified. Before and after implementation studies were identified; three for safety phlebotomy needles, one for safety lancet and one study for safety disposable dental syringes. These studies had several limitations and were all very low quality. In particular, the study implementing the disposable dental syringe [283] was sponsored by the manufacturer which introduced a large bias and excluded the first year of implementation from the analysis as the authors stated a lack of training. In addition the study implementing the safety lancet[196] which had one relevant outcome, needlestick injury, was downgraded for indirectness and imprecision.
Other considerations	The GDG were aware that there are problems obtaining accurate needlestick injury data due to under reporting of and possible reluctance to report injuries. They felt that further information could support the implementation of their recommendation and discussed what a risk assessment should include to determine the need for a safety device. The GDG considered the Health and Safety Executive document: Five Steps to Risk Assessment[117] and how it might contribute to supporting the implementation of risk assessment in the following areas: • the number of incidents and types of injuries • the procedure and the environment in which it is undertaken • the patient population's demographics • waste management and disposal • availability of alternative products • training.
Recommendations	**26. Train and assess all users in the correct use and disposal of sharps. [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be needlestick injury, blood contamination and blood borne infection.
Trade off between clinical benefits and harms	The GDG noted that incorrect use and unfamiliarity with a new safety device can lead to sharps injuries, as demonstrated by the clinical studies identified. The GDG were also aware from considering the evidence in review question 8.3.1 that poor familiarity with device operation may lead to increased blood contamination of the clinical area and healthcare workers. As shown by the evidence review above, implementation of safety devices did not lead to the complete elimination of sharps injuries. The GDG discussed the contribution that training, along with assessment, could have on healthcare workers in becoming familiar with the correct use of a device and correspondingly minimising the risk to themselves or patients. The GDG felt that training should also be available for those patients and carers who use sharps in the community.
Economic considerations	The GDG considered that training would be necessary in order to ensure that the potential cost-effectiveness or cost savings associated with safety devices is realised. When included as part of ongoing staff training programmes, implementation of this recommendation should not be associated with any additional cost.

Update 2012

Quality of evidence	Five observational implementation studies were identified and were all very low quality. The type of training varied across studies, for example hands on simulated insertions and annual training updates[168]; and training sessions and pamphlets in each ward[219].
Other considerations	In considering the poor quality of the evidence reviewed, the GDG used consensus to develop a recommendation on training. Training should be considered for new staff and when new devices are implemented for all users.

Update 2012

9 Waste disposal

Introduction

This chapter details general waste disposal recommendations and also lists the specific recommendations relating to waste disposal of personal protective equipment and sharps, which are described in more detail in chapters 7 and 8.

New legislation relating to waste disposal has been introduced since the previous guideline. The Department of Health have published a guidance document; Safe Management of Healthcare Waste version 1.0[72] as a best practice guide to the management of healthcare waste. Healthcare waste refers to any waste produced by, and as a consequence of, healthcare activities. The document replaces the Health Services Advisory Committee's (1999) guidance document "Safe Disposal of Clinical Waste" and HTM07-01 Safe Management of healthcare waste[65], which has revised and updated the previous documents to take into account the changes in legislation governing the management of waste, its storage, carriage, treatment and disposal, and health and safety.

Key changes since the 2006 update include: an update to statutory requirements; a focus on the waste hierarchy through procurement practices; a drive to address the carbon impact related to waste; the integration of new sector guides on GPs, dental practices, and community pharmacies; an emphasis on practical advice through case study examples (in particular on offensive waste streams), and more by way of staff training material; and, a review of terminology used for healthcare, clinical and non-clinical wastes.

Throughout the guideline, "healthcare waste" refers to any waste produced by, and as a consequence of, healthcare activities. "Clinical waste" is defined as ". . . any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it"[72].

Update 2012

9.1.1 Review questions

The clinical questions for this chapter are also in the personal protective equipment (PPE) chapter and the sharps chapter, see chapters 7 and 8. The two questions are:

Are there any changes in the legislations which affect the disposal of personal protective equipments in relation to patient care in the primary and community care settings?

Are there any changes in the legislations which affect the disposal of sharp instruments and needles in relation to patient care in the primary and community care settings?

9.1.2 Clinical evidence

A literature search was not performed for these questions as the objective was to review and update the current recommendations about the safe disposal of personal protective equipment and safe disposal of sharps in line with patient care and with the European Union (EU) and national legislations.

The Department of Health guidance; Safe Management of Healthcare Waste version 1.0[72] was reviewed.

9.1.1.3 Recommendations and link to evidence

Recommendations	27. Healthcare waste must be segregated immediately by the person generating the waste into colour-coded storage bags or containers, as defined by current national legislation[gg] and local policies. [new 2012]
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be the reduction in risks through the safe segregation and disposal of healthcare waste.
Trade off between clinical benefits and harms	Correct healthcare waste segregation and disposal into the correctly colour coded containers or bags is necessary to meet legislations. Failure to comply with this recommendation could result in legislative action.
Economic considerations	If healthcare organisations are currently improperly segregating, storing and disposing of clinical waste then compliance with this recommendation may be associated with implementation costs.
Quality of evidence	No clinical evidence review was conducted. This recommendation was developed based on the consideration of current best practice guidance from Department of Health; Safe Management of Healthcare Waste version 1.0[72] and the relevant EU and UK legislation.
Other considerations	The management of waste, its storage, carriage, treatment and disposal are governed by local policies and legislation at the national and European level. In addition to legislation specific to infection control and health and safety (e.g. Health and Safety Act), there are several transport, environmental, and waste disposal laws which are applicable to this question (e.g. Environment Protection Act). Complying with these recommendations is necessary to meet the requirements of local and national legislation. Therefore, this recommendation is a 'must'. This choice of wording is in line with guidance from the NICE Guidelines Manual (2009)[180]. The GDG discussed the importance of emphasising that the person generating the waste must segregate and dispose of it immediately into appropriate containers, rather than passing it on to another person to dispose of. The GDG also discussed the importance of ensuring that patients and healthcare workers caring for patients in their own homes are provided with appropriate receptacles for the disposal of clinical waste. See recommendations regarding sharps and waste disposal in chapters 7 and 8, respectively.

Update 2012

[gg] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

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Recommendations	28. Healthcare waste must be labelled, stored, transported and disposed of in accordance with current national legislation[hh] and local policies. [new 2012]
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be the reduction in risks through the safe disposal of healthcare waste.
Trade off between clinical benefits and harms	The correct segregation, storage, transport and disposal of healthcare waste is necessary to meet legislation. Failure to comply with this recommendation could result in legislative action.
Economic considerations	If healthcare organisations are currently improperly storing, transporting and disposing of clinical waste then compliance with this recommendation may be associated with implementation costs.
Quality of evidence	No clinical evidence review was conducted. Recommendation was developed based on the GDG's consideration of current best practice guidance from Department of Health; Safe Management of Healthcare Waste version 1.0[72] and the relevant EU and UK regulations.
Other considerations	The management of healthcare waste, its storage, carriage, treatment and disposal are governed by local policies and legislations at the national and European level. In addition to legislation specific to infection control and health and safety (e.g. Health and Safety Act), there are several transport, environmental, and waste disposal laws which are applicable to this question (e.g. Environment Protection Act). Complying with these recommendations is necessary to meet the requirements of local and national legislation. Therefore, this recommendation is a 'must'. This choice of wording is in line with guidance from the NICE Guidelines Manual (2009)[180].The GDG discussed the importance for trusts and healthcare providers to be aware of and compliant with specific local policies regarding waste segregation, storage, transport and disposal. For definitions of healthcare waste and clinical waste, see glossary. See recommendations regarding sharps and waste disposal in chapters 7 and 8, respectively.
Recommendations	**29. Educate patients and carers about the correct handling, storage and disposal of healthcare waste. [new 2012]**
Relative values of different outcomes	The GDG considered the most important outcomes for making this recommendation to be the reduction in risks through the safe handling, storage and disposal of healthcare waste.
Trade off between clinical benefits and harms	The correct segregation, storage, and disposal of healthcare waste is necessary to meet regulations; patients and carers need to be equipped with the knowledge to do this appropriately.
Economic considerations	If healthcare organisations are currently improperly storing, transporting and disposing of clinical waste then compliance with this recommendation may be associated with implementation costs.
Quality of evidence	No clinical evidence review was conducted. Recommendation was developed based on the GDG's consideration of current best practice guidance from Department of Health; Safe Management of

Update 2012

[hh] For guidance see (at the time of consultation on the guideline [July 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

	Healthcare Waste [72] and the relevant EU and UK regulations.
Other considerations	The GDG discussed the importance for trusts and healthcare providers to be aware of specific local policies regarding healthcare waste segregation, storage and disposal, and their role in helping patients cared for in their own homes to do so. The GDG discussed the importance of training and awareness of healthcare waste disposal policies among patients and carers. Healthcare waste covers both clinical and non-clinical waste. Most of the waste in the community setting is non-clinical waste such as packaging and offensive waste. The correct disposal of clinical waste begins with the appropriate segregation of healthcare waste into the appropriate categories. The GDG felt that patients and carers need information about how to handle, segregate and store clinical waste so that they can safely comply with local and national regulations. Also see recommendations regarding sharps and waste disposal in chapters 7 and 8, respectively.

Update 2012

Also see the other related recommendations in the sharps (see chapter 7) and PPE (see chapter 8) chapters.

9.1.2 Research recommendations

The GDG did not identify any research recommendations.

10 Long term urinary catheters

10.1 Introduction

The updated review questions in this chapter are:

- types of catheter
- bladder instillations and washouts
- antibiotic use when changing long-term indwelling catheters.

These review questions were prioritised as it was considered that new evidence had emerged since the 2003 guideline.

The evidence and text from the previous guideline that has been superseded by this update is included in Appendix D6. and D.9. No new review questions are included in this chapter.

Update 2012

Sections *not* updated in this chapter are:

- education of patients, carers and healthcare workers
- assessing the need for catheterisation
- catheter drainage options
- catheter insertion
- catheter maintenance (closed systems).

The GDG has prioritised four recommendations in this chapter as a key priority for implementation, see sections 10.5.1.4 and 10.5.2.5.

In the community and primary healthcare settings, long-term (>28 days) urinary catheterisation (LTC) is most commonly used in the management of the elderly and patients with neurological conditions. The prevalence of LTC in the United Kingdom (UK) has been estimated as 0.5 percent in those over 75 years old[135] and 4 percent in people undergoing domiciliary care.[99] Some patients may require continuous bladder drainage using urethral or suprapubic catheters. Alternatively, patients or carers may insert and remove urethral catheters at regular intervals (intermittent catheterisation).

Catheter care in the community is time consuming and expensive.[99,135,228] LTC should be regarded as a 'method of last resort' in the management of urinary problems as the burden both to the health service and to individual patients is high.[84] However, there will remain a group of patients for whom LTC is the best option.

The method of catheterisation will depend on each patient's individual requirements, available clinical expertise and services. Infection is a major problem in LTC although there are other non-infectious complications associated with LTC, including physiological/structural damage,[268] urological cancer[62] and psycho-social problems.[207] In selecting particular strategies to manage urinary problems, healthcare practitioners must take account of all of these complications. These guidelines focus on preventing infection. However, because infection has a complex inter-relationship with encrustation and blockage, these aspects of catheter management are also addressed.

These guidelines apply to adults and children and should be read in conjunction with the guidance on Standard Principles (see chapters 7 to 8). These recommendations are broad principles of best practice and are not detailed procedural protocols. They need to be adapted and incorporated into local practice guidelines. The recommendations are divided into five distinct interventions:

1. Education of patients, their carers and healthcare workers;

2. Assessing the need for catheterisation;
3. Selection of catheter type and system;
4. Catheter insertion;
5. Catheter maintenance.

The systematic review process is described in Appendix D.1.

10.2 Education of patients, carers and healthcare workers

Given the prevalence of LTC and the associated risk of clinical urinary tract infection, it is important that everyone involved in catheter management is educated about infection prevention. As many people, including children, will manage their own catheters, they must be confident and proficient in the procedure, aware of the signs and symptoms of clinical infection and how to access expert help when difficulties arise.[79,98,140,280]

10.2.1.1 Recommendations

30. Patients and carers should be educated about and trained in techniques of hand decontamination, insertion of intermittent catheters where applicable, and catheter management before discharge from hospital. [2003]

31. Community and primary healthcare workers must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance. [2003]

32. Follow-up training and ongoing support of patients and carers should be available for the duration of long-term catheterisation. [2003]

10.3 Assessing the need for catheterisation

Catheterising patients increases the risk of acquiring a urinary tract infection. The longer a catheter is in place, the greater the danger.

The highest incidence of healthcare-associated infection is associated with indwelling urethral catheterisation.[244] Many of these infections are serious and lead to significant morbidity. In acute care facilities, 20-30% of catheterised patients develop bacteriuria, of whom 2-6 percent develop symptoms of urinary tract infection (UTI).[244] The risk of acquiring bacteriuria is approximately 5 percent for each day of catheterisation,[93,95] and therefore most patients with LTC are bacteriuric after 20 days of catheterisation.[269]

A study of patients in long-term care facilities demonstrated significantly higher morbidity and mortality in catheterised patients than in matched non-catheterised controls.[140] Duration of catheterisation is strongly associated with risk of infection, i.e., the longer the catheter is in place, the higher the incidence of UTI.[244]

Best practice emphasises that all procedures involving the catheter or drainage system and the related batch codes of these devices are recorded in the patient's records.[280] Patients should be provided with adequate information in relation to the need, insertion, maintenance and removal of their catheter by the person planning their care.[280]

10.3.1.1 Recommendations

33. **Indwelling urinary catheters should be used only after alternative methods of management have been considered. [2003]**

34. **The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible. [2003]**

35. **Catheter insertion, changes and care should be documented. [2003]**

10.4 Catheter drainage options

10.4.1 How to select the right system

Choosing the right system for any given patient will depend on a comprehensive individual patient assessment.

Our search identified one systematic review[236] concerning the approaches to catheterisation. This reported a higher rate of infection associated with indwelling rather than intermittent catheterisation. This finding is reflected in a recent position paper[187] on urinary tract infections in long-term care facilities by the Society for Healthcare Epidemiology of America (SHEA) who recommended that "where clinically appropriate, intermittent catheterisation should be used for urinary drainage rather than a chronic indwelling catheter."

Two studies were identified in our search which compared catheter options.[125,255] The first focussed on the risk of Meticillin-resistant *Staphylococcus aureus* (MRSA) colonisation and infection in nursing home patients.[255] This study concluded that indwelling catheters posed a greater risk of infection than intermittent catheters. The second studied men with prostatic enlargement and reported a significantly lower rate of infection in those with suprapubic rather than urethral catheters, despite the former being used for two weeks longer.[125] A non-comparative study of patients with neuropathic bladder demonstrated a low rate of infection (6 percent) associated with the use of long-term suprapubic catheters.[237] However, 30% of patients in this study reported other catheter-related complaints. Economic opinion suggests that if staff and resource use are the same, suprapubic catheterisation is more cost effective.[227,237]

Eight studies were identified which focussed exclusively on the use of intermittent catheterisation. The study populations encompassed a wide range of patient groups and ages.[17-19,43,79,172,198,271] One theme emerging from these studies was that the prevalence of bacteriuria is equal between men and women[17,18] though the incidence of clinical UTI appears to be higher in women.[18,19] There is also some evidence that bacteriuria rates are similar between adults and children.[58]

Generally, large studies indicated that the rates of infection associated with intermittent catheterisation were low,[198,271] 1 per 87 months,[271] and that hydrophilic catheters were associated with a further reduction in infection risk.[19,43]

A possible alternative to indwelling and intermittent catheterisation is the penile sheath (condom catheter). Whilst our systematic review did not include a specific question related to the use of penile sheath catheters, there is evidence that this type of device may be preferable in men who are able to empty their bladder and are unlikely to manipulate the system.[58,227] To date there are no controlled studies comparing penile sheaths with indwelling devices.

10.4.1.1 Recommendations

36. Following assessment, the best approach to catheterisation that takes account of clinical need, anticipated duration of catheterisation, patient preference and risk of infection should be selected. [2003]

37. Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient. [2003]

10.5 Types of long-term catheters

Long-term urinary catheterisation is considered an important area where updated guidance is required. New types of catheters with silver or antibacterial coating/impregnation have been introduced. Manufacturers claim these might reduce catheter-related infection and blockage but they may be more expensive so it is important to ascertain the clinical and cost-effectiveness of these new products.

10.5.1 Review question

What is the clinical and cost effectiveness of different types of long-term indwelling urinary catheters (non-coated silicone, hydrophilic coated, or silver or antimicrobial coated/impregnated) on urinary tract infections, bacteraemia, frequency of catheter change, encrustations and blockages, mortality, and patient preference?

10.5.1.1 Clinical evidence

One study was identified, which investigated hydrophilic catheters compared to silicone elastomer catheters[32]. None of the studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.5.2, Appendix G, Forest Plots in Figure 30-32, Appendix I

Table 46: Hydrophilic coated vs. silicone catheters for long term indwelling catheterisation – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Mean catheter time in situ [32]	1	RCT	Serious limitations[(a)]	No serious inconsistency	No serious indirectness	No serious imprecision
Encrustations leading to catheter change [32]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
Catheter related adverse events [32]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
Symptomatic UTI	0	RCT				
Bacteraemia	0	RCT				
Frequency of catheter change	0	RCT				
Mortality	0	RCT				
Patient	0	RCT				

Update 2012

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
preference and comfort						

(a) Unclear allocation concealment and selective outcome reporting where full data is not provided.
(b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 47: Hydrophilic coated vs. silicone catheters for long term indwelling catheterisation - Clinical summary of findings

Outcome	Hydrophilic	Silicone	Relative risk	Absolute effect	Quality
Mean catheter time in situ (days)	36	33	-	MD 32.91 higher (15.14 to 50.68 higher)	MODERATE
Encrustations leading to catheter change	11/36 (30.6%)	9/33 (27.3%)	RR 1.12 (0.53 to 2.36)	33 more per 1000 (128 fewer to 371 more)	LOW
Catheter related adverse events	1/36 (2.8%)	7/33 (21.2%)	RR 0.13 (0.02 to 1.01)	185 fewer per 1000 (208 fewer to 2 more)	LOW

10.5.1.2 Cost-effectiveness evidence

Update 2012

No cost-effectiveness evidence was identified in the update search.

No cost-effectiveness evidence was identified in the previous 2003 guideline.

In the absence of any published cost-effectiveness analyses, current UK catheter and infection-related costs were presented to the GDG to inform decision making. The GDG were also presented with the costs and quality of life associated with UTI and UTI-associated complications (see economic model in Appendix J and K).

Table 48: Cost of long-term indwelling urinary catheters

Foley catheter type	Product description	Average cost (£)
PTFE coated latex	Self-retaining 2-way long-term PTFE coated latex connected to 2 litre drainage bag	3.87
Non-coated silicone	Self-retaining 2-way long-term silicone connected to 2 litre drainage bag	4.87
Hydrophilic coated silicone	Self-retaining 2-way long-term hydrogel coated silicone connected to 2 litre drainage bag	4.95
Silver coated silicone	Self-retaining 2-way long-term silicone hydromer coated silver connected to 2 litre drainage bag	7.17

Source: Based on average 2010 Supply Chain[185] prices.

Abbreviations: PTFE = polytetrafluoroethylene

10.5.1.3 Evidence statements

Clinical	There is a statistically significant and clinically important increase in mean catheter time *in situ* for hydrophilic catheters compared to silicone catheters for long-term indwelling catheterisation. (MODERATE QUALITY)
	It is uncertain whether there is any difference in encrustations leading to catheter change for hydrophilic catheters compared to silicone catheters for long-term indwelling catheterisation. (LOW QUALITY)
	It is unlikely that there is any difference in catheter related adverse events for hydrophilic catheters compared to silicone catheters for long-term indwelling catheterisation. (LOW QUALITY)
	No studies identified reported symptomatic urinary tract infections, bacteraemia, frequency of catheter change, mortality or patient preference and comfort.
Economic	No relevant economic studies were identified.

10.5.1.4 Recommendations and link to evidence

Recommendations	**38. Select the type and gauge of an indwelling urinary catheter based on an assessment of the patient's individual characteristics, including:** • **age** • **any allergy or sensitivity to catheter materials** • **gender** • **history of symptomatic urinary tract infection** • **patient preference and comfort** • **previous catheter history** • **reason for catheterisation. [new 2012]**
Relative values of different outcomes	Prevention of urinary tract infections was considered the most important outcome. Encrustations and blockages were also seen as an important outcome.
Trade off between clinical benefits and harms	The GDG considered the trade off in time involved in selecting an appropriate catheter and the benefit of increased patient satisfaction. The GDG also considered the risk of infection of choosing an inappropriate catheter balanced against the need for patient comfort and choice. The GDG discussed the clinical and economic evidence, but felt that there was not sufficient evidence to recommend one type of catheter over another. The GDG discussions centred around the key factors that would influence choice of catheter in practice and chose to make a recommendation based on a consensus agreement of these factors, which are discussed under other considerations.
Economic considerations	In the absence of high-quality evidence of effectiveness, there is little on which to assess the relative cost-effectiveness of different types of long-term indwelling catheters.
Quality of evidence	Only one RCT was identified for types of indwelling catheters. The evidence was of low to moderate quality. There were serious study limitations (unclear allocation concealment and selective outcome reporting, where full data was not provided).

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Other considerations	Healthcare workers must be competent to assess the need for catheterisation (see Assessing the need for catheterisation) and select the appropriate catheter. The factors within the current recommendation are listed in alphabetical order rather than by order of priority and should not be considered an exhaustive list. This list was largely made by GDG consensus and the reasoning behind the inclusion of each factor is discussed below: • Age – The length and gauge of the catheter should be appropriate for the patient. For example, the size should be appropriate for the age or size of the child. • Catheter material sensitivity/ allergy – latex-containing catheters are inappropriate for patients with latex allergies. • Gender – Males and females require catheters of different length. • History of symptomatic UTI – a previous history of a symptomatic UTI with a certain type of catheter may influence selection. • Patient preference/comfort –Many patients find that a small catheter gauge is more comfortable than a large gauge. A larger catheter gauge may be used if the patient has a specific catheter need. • Previous catheter history - a previous history of catheter related complications (discomfort or blockage) with a certain type of catheter may influence selection. • Reason for catheterisation – the type of catheter should be based on clinical reason for catheterisation, such as bladder cancer or chronic retention. The GDG have prioritised this recommendation as a key priority for implementation as they considered that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes, leads to a more efficient use of NHS resources, promotes patient choice and means that patients reach critical points in the care pathway more quickly.

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10.5.2 Review questions

The following two questions both address the clinical and cost effectiveness of intermittent self catheterisation. They were addressed independently for the clinical evidence review, but incorporated into the same economic model.

1. What is the clinical and cost effectiveness of different types of long-term intermittent urinary catheters (non-coated, hydrophilic or gel reservoir) on symptomatic urinary tract infections, bacteraemia, mortality, and patient preference?

2. In patients performing intermittent catheterisation, what is the clinical and cost effectiveness of non-coated catheters reused multiple times compared to single use on urinary tract infections, bacteraemia, mortality, and patient preference?

10.5.2.1 Clinical evidence

Question 1. Non-coated vs. hydrophilic vs. gel reservoir catheters:

Six studies were identified, five of which investigated hydrophilic catheters compared to non-coated catheters[35,60,191,251,262] and one that compared non-hydrophilic gel reservoir catheters to non-coated catheters[100]. None of the studies from the previous 2003 guideline met the inclusion criteria for this review question.

The non-coated catheters were used as a single use product in Cardenas et al., 2009 [35], as a multi use product (reused up to 5 times a day, with a new catheter used each day) in Vapnek et al., 2003[262] and

Pachler et al., 1999[191] and not stated in Giantonni et al., 2001[100] and Sutherland et al., 1996[251] and DeRidder et al., 2005[60]. In order to allow accurate incorporation of the data from these studies into the economic model, the authors of these studies were contacted for clarification. Dirk de Ridder replied that the catheters used in the study were single use. No reply was obtained from Giantonni et al. and Sutherland et al; it was assumed that these studies also used single use non-coated catheters.

See Evidence Table G.5.2, Appendix G, Forest Plots in Figure 33-40, Appendix I

Table 49: Hydrophilic coated vs. non-coated catheters for long term intermittent self catheterisation – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Mean monthly urinary tract infection - 12 months[262]	1	RCT	Serious limitations[(a)]	No serious inconsistency	No serious indirectness	No serious imprecision
Total urinary tract infections - 1 year [35]	1	RCT	Serious limitations [(b)]	No serious inconsistency	No serious indirectness	No serious imprecision
Patients with ≥1 urinary tract infection – 1 year[35,60]	2	RCT	Serious limitations [(b),(d)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Patients/helpers very satisfied with the catheter – 6 months [60]	1	RCT	Serious limitations [(d)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Patients/helpers very satisfied with the catheter – 1 year [60]	1	RCT	Serious limitations [(d)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Patient satisfaction [251](visual analogue scale, 10 = least favourable)	1	RCT	Serious limitations [(e)(g)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Problems introducing catheter[191]	1	RCT	Serious limitations [(f)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Burning sensation when introducing the catheter[191]	1	RCT	Serious limitations [(f)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Pain when introducing the catheter[191]	1	RCT	Serious limitations [(f)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Burning sensation or pain after removal of the catheter[191]	1	RCT	Serious limitations [(f)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Bacteraemia	0	RCT				
Mortality	0	RCT				

(a) Method of randomisation not stated. Number of urinary tract infections at baseline is higher in intervention compared to the control. Catheters re-used up to 5 times a day for control, where as intervention did not reuse catheters

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(b) Method of randomisation not stated and unclear allocation concealment. Higher number of women in control group compared to the intervention [35].
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(d) High dropout rate in DeRidder et al., 2005[60] (54%) due to restored urinary function and thus no further need for catheterisation, change of bladder management to an indwelling catheter and withdrawal of consent.
(e) Sutherland et al., 1996 [251]- population is all male mean age 12 years old.
(f) Unclear allocation concealment.
(g) Crossover study. Not details of allocation concealment or assessor blinding.

Table 50: Hydrophilic coated vs. non-coated catheters for long term intermittent self catheterisation - Clinical summary of findings

Outcome	Hydro-philic	Non-coated	Relative risk	Absolute effect	Quality
Mean monthly urinary tract infection - 12 months	31	31	-	MD 0.01 lower (0.11 lower to 0.09 higher)	MODERATE
Total urinary tract infections at 1 year	22	23	-	MD 0.18 higher (0.5 lower to 0.86 higher)	MODERATE
Patients with 1 or more urinary tract infection – 1 year	51/83 (61.4%)	65/85 (76.5%)	RR 0.8 (0.65 to 0.99)	153 fewer per 1000 (8 fewer to 268 fewer)	LOW
Patients/helpers very satisfied with the catheter – 6 months	10/55 (18.2%)	6/59 (10.2%)	RR 1.79 (0.7 to 4.59)	80 more per 1000 (31 fewer to 365 more)	LOW
Patients/helpers very satisfied with the catheter – 1 year	9/55 (16.4%)	7/59 (11.9%)	RR 1.38 (0.55 to 3.45)	45 more per 1000 (53 fewer to 291 more)	LOW
Patient satisfaction (visual analogue scale, 10 = least favourable)	17	16	-	MD 0.6 lower (2.36 lower to 1.16 higher)	LOW
Problems introducing catheter	1/32 (3.1%)	2/32 (6.3%)	RR 0.5 (0.05 to 5.24)	31 fewer per 1000 (59 fewer to 265 more)	LOW
Burning sensation when introducing the catheter	2/32 (6.3%)	1/32 (3.1%)	RR 2 (0.19 to 20.97)	31 more per 1000 (25 fewer to 624 more)	LOW
Pain when introducing the catheter	3/32 (9.4%)	2/32 (6.3%)	RR 1.5 (0.27 to 8.38)	31 more per 1000 (46 fewer to 461 more)	LOW
Burning sensation or pain after removal of the catheter	2/32 (6.3%)	2/32 (6.3%)	RR 1 (0.15 to 6.67)	0 fewer per 1000 (53 fewer to 354 more)	LOW

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Table 51: Gel reservoir vs. non-coated catheters for long term intermittent self catheterisation – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Patients with ≥1 urinary tract infection – 7 weeks[100]	1	RCT	Very serious[(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(c)]
Patient comfort (visual analogue scale, low = more comfortable)[100]	1	RCT	Very serious[(b)]	No serious inconsistency	No serious indirectness	No serious imprecision
Bacteraemia	0	RCT				
Mortality	0	RCT				

(a) Crossover study, the outcomes measured 3 times per patient and reported for 3x the number of total patients in the group i.e. 54 instead of 18. Not details of allocation concealment or assessor blinding.
(b) Crossover study. Not details of allocation concealment or assessor blinding. Small number of patients in each arm.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 52: Gel reservoir vs. non-coated catheters for long term intermittent self catheterisation - Clinical summary of findings

Outcome	Gel reservoir	Non-coated	Relative risk	Absolute effect	Quality
Patients with 1 or more urinary tract infection – 7 weeks (visual analogue scale, low = more comfortable)	4/54 (7.4%)	12/54 (22.2%)	RR 0.33 (0.11 to 0.97)	149 fewer per 1000 (7 fewer to 198 fewer)	VERY LOW
Patient comfort	18	18	-	MD 2.39 higher (1.29 to 3.49 higher)	VERY LOW

Question 2. Single-use non-coated vs. multiple-use non-coated catheters (see section Review questions 10.5.2):

Two RCTs were identified for inclusion comparing multi use non-coated catheters to single use catheter for intermittent catheterisation, where the multi-use arm had new catheters once a week[79] or every 24 hours[134]. None of the studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.5.2, Appendix G, Forest Plots in Figure 41-42, Appendix I.

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Table 53: Non-coated catheters reused multiple times vs. single use – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI[79,134]	2	RCT	Serious limitations[(a)]	No serious inconsistency	No serious indirectness	No serious imprecision
Frequency of catheterisations per day [79]	1	RCT	Serious limitations[(a)]	No serious inconsistency	No serious indirectness	Serious imprecision[(b)]
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				

(a) Unclear randomisation, allocation concealment and blinding. The length of follow up varied from 1-107 days.
(b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 54: Non-coated catheters reused multiple times vs. single use - Clinical summary of findings

Outcome	Reused	Single use	Relative risk	Absolute effect	Quality
Symptomatic UTI	34/61 (55.7%)	38/65 (58.5%)	RR 0.98 (0.77 to 1.25)	12 fewer per 1000 (134 fewer to 146 more)	MODERATE
Frequency of catheterisations per day	38	42	-	MD 0.2 higher (0.28 lower to 0.68 higher)	LOW

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10.3.2.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified in the update search.

No cost-effectiveness studies were identified in the previous 2003 guideline.

This question was identified as a high priority area for economic modelling and an original cost-utility model was developed to inform the cost-effectiveness evidence for this question.

10.3.2.3 Cost-effectiveness evidence – original economic model

Methods

A cost-utility analysis was undertaken to evaluate the cost-effectiveness of different types of intermittent catheters. A Markov model was used to estimate the lifetime quality-adjusted life years (QALYs) and costs from a UK NHS and personal social services perspective. Both costs and QALYs were discounted at a rate of 3.5% per annum in line with NICE methodological guidance. The model was built probabilistically to take into account uncertainty surrounding each of the model input parameters.

Population & comparators

The population evaluated in the base case analysis was people with bladder dysfunction caused by spinal cord injury (SCI). This population was chosen for the base case as it most closely matched the population considered by the majority (4/5) of the RCTs included in the clinical review and because this group of patients is one of the largest users of intermittent catheters. The average age of the

population entering the model was 40 years and 80% were assumed to be male; this is the average age at injury and gender composition of the UK population of people with SCI.

A similar model exploring the cost-effectiveness of intermittent catheterisation in patients with bladder dysfunction not due to SCI was considered as part of the sensitivity analysis.

The comparators selected for the model were the types of intermittent catheter available to patients living or being cared for in the community:

- Single use hydrophilic catheters
- Single use gel reservoir catheters
- Single use non-coated catheters
- Clean multiple use non-coated catheters

The GDG indicated that there may be situations in which it would not be practical or advisable for patients to wash and reuse catheters (such as when facilities are not available or patients are unable to wash and dry catheters, or if patients are catheterised by others). Therefore, two models were constructed; they varied only in the inclusion/exclusion of clean multiple use non-coated catheters as a comparator.

The GDG also noted that in children and young people (≤ 16 years old), symptomatic UTI can cause progressive renal scarring which may lead to renal failure later in life. Renal failure carries a high risk of mortality and morbidity, is associated with very high cost and decreased quality of life. The most recent NICE guideline for Urinary Tract Infection in Children[179] concluded that it was not possible to estimate the true risk of renal failure as a result of childhood UTI, did not identify any quality of life values for children with UTI, and did not consider economic modelling a valid option in this population. The current GDG agreed with this decision and noted that none of the studies included in the clinical review which contained symptomatic UTI as an outcome were conducted in children. Given the uncertain risk of harm as a result of symptomatic UTI in childhood, the GDG decided to employ the precautionary principle in their approach to intermittent self catheterisation (ISC) in children. Therefore, only single use catheters were considered an option for ISC in children and modelling was not explicitly undertaken in this population.

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Approach to modelling

Symptomatic UTI was considered the most important outcome for evaluating the efficacy of different types of intermittent catheters. The GDG also considered the costs and consequences arising from antimicrobial resistant UTIs and catheter-associated bacteraemia to be an important factor to include when assessing the downstream effects of symptomatic UTI. In the absence of any comparative clinical evidence, in the base case analysis it was assumed that urethral complications do not vary between catheter types. This assumption was explored in sensitivity analysis.

The main simplifying assumption of the model was that the probability of antibiotic resistance does not change over time. This assumption was necessary due to a lack of available data about current and historical resistance rates, the complexity of forecasting antibiotic resistance trends over time and within populations, and a lack of examples on which to base methodological approaches [50]. Different rates of resistance were explored in sensitivity analysis.

Results

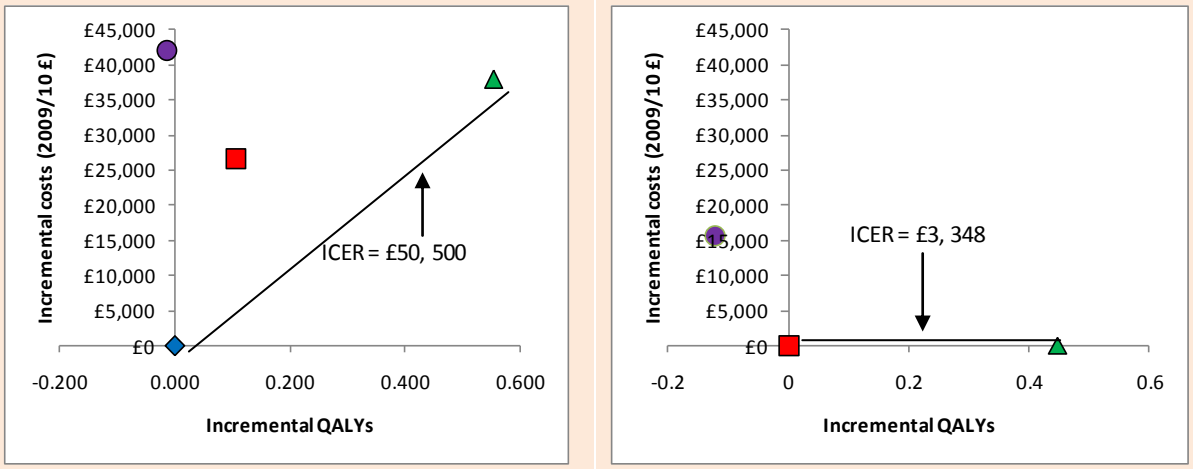
This analysis found that clean multiple-use non-coated catheters are the most cost-effective type of intermittent catheter. Although gel reservoir catheters were found to be slightly more effective than clean non-coated catheters, they were associated with a much greater cost. Dividing the incremental cost by the incremental effectiveness results gives a cost-effectiveness ratio of £50,500 per QALY gained. This value far exceeds the £20,000 per QALY threshold set by NICE. By taking into account the

standard error of each model input, probabilistic analysis revealed that clean multiple-use non-coated catheters are the most cost-effective option in 99.5% of model iterations.

In patients who are unable to use clean non-coated catheters, gel reservoir catheters were found to be the most cost-effective option, at approximately £3, 350 per QALY gained. Compared to hydrophilic catheters, gel reservoir catheters are most cost-effective in 84.8% of model iterations.

In both scenarios, hydrophilic catheters were found to be slightly less effective than gel reservoir catheters. They are also less costly, although their incremental cost is still much greater than the cost of clean non-coated multiple-use catheters. Therefore, hydrophilic catheters are excluded from the further considerations due to extended dominance. Single-use non-coated catheters were found to be slightly less effective and more costly than multiple-use non-coated catheters. They are therefore said to be 'dominated' by the more effective, less costly alternatives under consideration.

Figure 2: Base case analysis results (probabilistic)



Legend: Non-coated catheter used multiple times; Non-coated catheter used once only; Hydrophilic catheter; Gel reservoir catheter.

Results for each subgroup are plotted on the incremental cost-effectiveness ratio axis. The non-coated multi-use catheter is the least costly strategy and has been used as the baseline comparator. Therefore, it is plotted at the axis. The slope of the line is the ICER.

Table 55: Base case analysis results (probabilistic)

Catheter	Total cost	Total QALYs	Incremental cost*	Incremental QALYs*	ICER	Probability CE
In cases where non-coated catheters can be washed and reused						
Non-coated used multiple times	£13, 816	11.893	Baseline	Baseline	Baseline	99.55%
Hydrophilic	£40, 319	12.000	£26, 503	0.107	ED	0.00%
Gel reservoir	£41, 819	12.448	£28, 003	0.555	£50, 500	0.55%
Non-coated used once only	£55, 893	11.879	£42, 077	-0.015	D	0.00%
In cases where non-coated catheters cannot be washed and reused						
Hydrophilic	£40, 319	12.000	Baseline	Baseline	Baseline	15.21%
Gel reservoir	£41, 819	12.448	£1,500	0.448	£3, 348	84.79%
Non-coated used once only	£55, 893	11.879	£15, 574	-0.121	D	0.00%

The health gain to individuals using ISC is presented in terms of total and incremental QALYs. Cost is presented as total and incremental cost per catheter strategy. These values are used to calculate the ICER. Because single-use non-coated catheters are less effective and more expensive than non-coated catheters used multiple times, they are said to be dominated and are

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*eliminated from further analysis. Similarly, hydrophilic catheters are excluded by extended dominance. QALYs = quality adjusted life years; ICER = incremental cost-effectiveness ratio; ED = extended dominated; D = dominated; CE = cost-effective at a threshold of £20,000.*Incremental costs and QALYs are calculated compared to the option with the lowest cost – non-coated multiple use catheters and hydrophilic catheters, respectively.*

Scenario and sensitivity analyses

Intermittent self catheterisation (ISC) in patients with bladder dysfunction not due to spinal cord injury

A separate set of probabilities and utilities was collected in order to run a scenario analysis for patients with bladder dysfunction that is not caused by SCI. Assuming that each type of catheter exhibits the same relative efficacy in this population, the conclusion of this scenario analysis is the same as that for patients with SCI: Where it is possible to wash and re-use non-coated catheters (in this population gel reservoir catheters are associated with a cost of £148, 788 per QALY gain and so do not represent an efficient use of NHS resources); however, when re-use of non-coated catheters is not an option, gel reservoir catheters represent the most cost-effective option. In both cases, single-use non-coated catheters are excluded from the analysis by dominance and hydrophilic catheters by extended dominance.

Urethral complications

When the relative risk of urethral complications associated with each type of coated catheter is reduced to zero and the cost of complications is doubled (i.e. hydrophilic catheters prevent 100% of urethral complications and those that occur with the use of other catheter types are twice as expensive as assumed in the base case), the conclusion of the analysis is unchanged. This is true regardless of whether or not multiple-use non-coated catheters are considered an option.

Antimicrobial resistance

The conclusions of the model were robust to simultaneously varying the probability of the risk of treatment failure and multidrug resistant UTI to the upper limit of each input's 95% confidence interval. This shows that given current understanding of the scope of antibiotic resistance, multiple use non-coated catheters are the most cost cost-effective option for ISC.

This analysis did not take into account the dynamic and extremely complex nature of antimicrobial resistance. Although the GDG sought to use the most current, relevant estimates to inform this analysis, data about the prevalence and mortality associated with antibiotic resistant UTIs is limited and it is impossible to predict the future of this phenomenon. If the prevalence, clinical and economic impact of antimicrobial resistance increases beyond the extreme values used in this model, then the cost-effectiveness of clean intermittent catheterisation in this population may have to be re-visited.

Number of non-coated catheters used

The number of clean non-coated catheters used per year was varied between an average of 60 per year (average 5 per *month*) and 1825 per year (average 5 per *day*) in a threshold analysis. Clean ISC ceases to be the most cost-effective option when an average of 785 non-coated catheters is used per year; this equivalent to approximately 15 catheters per week or 2.2 per day.

Interpretation and limitations

This analysis combines the best available evidence about the costs and consequences of each type of catheter used for intermittent catheterisation. Based on the results of the model, we can conclude that the small decrease in symptomatic infections associated with single-use gel reservoir and hydrophilic catheters is not enough to justify the large increase in the cost of these catheters

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compared to multiple use non-coated catheters. As a result, clean multiple use non-coated catheters represent the most cost-effective type of catheter for ISC. This conclusion was robust to a wide range of sensitivity analyses, including the increased probability of urethral complications that may be associated with the use of non-coated catheters. However, multiple use non-coated catheters cease to be the most cost-effective choice when patients use *an average* of more than two catheters per day. Compliance and behaviour are therefore important factors for healthcare workers to consider when prescribing an ISC regime.

Healthcare workers must also consider other patient-specific situations when deciding which catheter to prescribe. Under the current decision rule, the recommended treatment is identified as that with the highest ICER that falls below the cost-effectiveness threshold. Preferences are incorporated into the cost-utility analysis through the values that are attached to each health state; these values represent the average weight attached to each health state by the general population and are assumed to be independent of factors related to the health care process.

The use of societal values creates the potential for conflict where individual patients hold a strong preference for a particular treatment that is not reflected in the decision made at the societal level[26]. It has been suggested that one way to incorporate individual patient preference into cost-effectiveness decisions would be to adopt a two-part decision process which gives the patient the choice of the most cost-effective treatment plus all cheaper options[77].

Of the five RCTs included in our review of clinical efficacy, three included a measure of patient preference and comfort; none found any difference between catheter types. Nevertheless, it is still possible that patients may find one type of catheter more comfortable or easier to use than another and therefore derive a benefit from the catheter that is not captured in the model[76]. When deciding between gel reservoir and hydrophilic catheters for patients who cannot use multiple non-coated catheters, the GDG did not wish to force the consumption of more costly gel reservoir catheters. If a patient has a strong preference for hydrophilic catheters then the GDG agreed that they should be able to choose this less costly option.

It is important to note that under this rule patients should not be given a choice of therapies that are more expensive and more costly than the most cost-effective treatment[77]. In other words, this line of reasoning *cannot* be extended to patients who are able to use clean multiple use non-coated catheters but prefer not to, nor to patients who prefer single use non-coated catheters to single use gel reservoir or hydrophilic catheters.

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10.3.2.4 Evidence statements

Clinical

Question 1. Non-coated vs. hydrophilic vs. gel reservoir catheters

It is unlikely that there is any difference in mean monthly urinary tract infections or total urinary tract infections at 1 year for hydrophilic coated catheters compared to non-coated catheters for long-term intermittent catheterisation. (MODERATE QUALITY)

It is uncertain whether there is any difference in patient/helper satisfaction with catheters and catheter preference for hydrophilic coated catheters compared to non-coated catheters for long-term intermittent catheterisation. (LOW QUALITY)

There is a statistically significant decrease of uncertain clinical importance in the number of patients with 1 or more urinary tract infection(s) at 1 year with hydrophilic coated catheters compared to non-coated catheters for long-term intermittent catheterisation. (LOW QUALITY)

There is a statistically significant decrease of uncertain clinical importance in the number of patients with 1 or more urinary tract infection(s) at 7 weeks for gel

	reservoir catheters compared to non-coated catheters for long-term intermittent catheterisation. (VERY LOW QUALITY)
	There is a statistically significant increase of uncertain clinical importance in patient comfort for gel reservoir catheters compared to non-coated catheters for long-term intermittent catheterisation. (VERY LOW QUALITY)
	No studies were identified that reported bacteraemia or mortality.
	Question 2. Single-use non-coated vs. multiple-use non-coated catheters
	It is unlikely that there is any difference in symptomatic urinary tract infections with clean vs. sterile uncoated catheters for long-term intermittent catheterisation (MODERATE QUALITY).
	It is uncertain whether there is any difference in frequency of catheterisations per day with clean vs. sterile non-coated catheters for long-term intermittent catheterisation (LOW QUALITY).
	No studies were identified that reported bacteraemia, mortality or patient preference and comfort.
Economic	New economic analyses comparing single use hydrophilic, single-use gel reservoir, single use non-coated, and clean multiple use non-coated catheters found that washing and re-using non-coated catheters is the most cost-effective option for intermittent self catheterisation. In situations where it may not be feasible or appropriate to wash and reuse non-coated catheters, gel reservoir catheters appear to be the most cost-effective catheter type. However, if patients prefer hydrophilic catheters to gel reservoir catheters, they may also be considered cost-effective. Single use non-coated catheters are never a cost-effective option for intermittent self catheterisation. The conclusion was robust to a wide range of scenario and sensitivity analyses, including varying the probability and cost of urethral complications (MINOR LIMITATIONS AND DIRECTLY APPLICABLE).

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10.5.2.5 Recommendations and link to evidence

Recommendations	39. Offer non-coated intermittent catheters for multiple use[ii] to patients[jj] except in the following circumstances, when a choice of single use hydrophilic or gel reservoir catheters should be offered: • if the patient is unable to wash and dry catheters • if no suitable facilities to wash, dry and store catheters are readily available • if catheterisation is performed by a healthcare worker or anyone else other than the patient or a close family member. [new 2012]
Relative values of different outcomes	The GDG considered the most important outcomes to be symptomatic UTIs (recurrent and total) and mortality. Other outcomes also searched for were allergic reactions, bacteraemia, and patient preference/comfort.
Trade off between clinical benefits and harms	Based on the evidence included in the clinical review, different types of intermittent catheters are associated with slightly different rates of symptomatic urinary tract infection. Although some of these differences are statistically significant, all are associated with wide and overlapping confidence intervals, conferring a degree of uncertainty whether the effect is of clinical significance. Although there was a statistically significant increase of scores for comfort gel reservoir catheters compared to single-use non-coated catheters, it is uncertain if this is important. No difference was reported between hydrophilic and single-use non-coated catheters; and there was no evidence for single-use non-coated compared to multiple-use non-coated catheters for patient and comfort or preference. The GDG considered that the combination of uncertain significance of the reduction in urinary tract infections and the excessive cost per QALY of single use hydrophilic or gel reservoir catheters prevented them being recommended for first-line use. The GDG considered that there may be situations in which it is difficult for patients to wash, dry and store multiple-use non-coated catheters, for example patients with communal washing facilities. On this basis, the GDG agreed that there are situations in which it is not appropriate for patients to use multiple-use non-coated catheters.
Economic considerations	Based on the results of the original economic model developed for this update review, gel reservoir catheters are associated with an incremental cost per QALY gain of £50, 500. Because this exceeds the NICE cost-effectiveness threshold of £20, 000 (and given that hydrophilic catheters and single-use non-coated catheters are excluded by extended dominance and dominance, respectively), clean multiple use non-coated catheters are the most cost-effective type of intermittent catheter. This conclusion was robust to a wide range of sensitivity analyses. In situations where multiple-use non-coated catheters are not considered a valid option, gel reservoir catheters may be most cost-effective with an incremental cost per QALY gain of £3, 348 compared to hydrophilic catheters. However, not all patients find gel reservoir suitable so flexibility is needed to allow the use of hydrophilic catheters in this situation.

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[ii] Refer to the manufacturer's instructions for advice on the use, cleaning and storage of catheters. See also recommendation 59 about cleaning of reusable intermittent catheters.

[jj] Do not offer multiple-use catheters for use in children or young people of 16 years or under (see recommendation 40)

Quality of evidence	Two RCTs were identified investigating single-use versus multiple-use non-coated catheters that were of low to moderate quality. These studies varied in length of follow up between patients and had unclear randomisation, allocation concealment and blinding. Five RCTs and one crossover trial looked at hydrophilic coated or gel reservoir catheters versus single-use non-coated catheters for intermittent catheterisation. The quality of the evidence is low to moderate. Several of the outcomes for this recommendation were imprecise and although, for example there is a statistically significant decrease in number of patients with 1 or more urinary tract infection at 1 year with hydrophilic coated catheters compared to non-coated catheters, there is uncertainty whether this is clinically important because of the wide confidence intervals for this outcome. The 95% confidence interval of the reduction of number of patients with 1 or more urinary tract infection ranged from 6 to 268 fewer in the hydrophilic catheter group. It was difficult to interpret the meaning of the increase in patient comfort score because invalidated tools were used. For example, it is unclear what it means for patients when the score for patient comfort increased 2.39 points, 95% CI of 1.29 to 3.49) for non-hydrophilic gel reservoir catheter compared to non coated catheters, and whether this is of clinical importance.
Other considerations	The GDG were aware that the majority of non-coated intermittent catheters bear a symbol on their packaging indicating that they are single-use devices. According to the MHRA, this symbol means that the manufacturer: • Intends the device to be used once and then discarded • Considers that the device is not suitable for use on more than one occasion • Has evidence to confirm that re-use would be unsafe. However, the GDG considered this to be contradictory for several reasons: • Some manufacturers provide instructions for cleaning non-coated catheters, which may be taken to imply that the manufacturer intends for them to be used more than once. • There is no evidence to suggest that re-use of non-coated catheters is unsafe. On the contrary, the evidence suggests that single-use non-coated catheters are associated with a non-significant increase in symptomatic urinary tract infections compared to multiple-use non-coated catheters. • The NHS Drug Tariff states that non-coated catheters can be re-used for up to one week. The GDG did not feel that there was any further evidence that would support a recommendation on the guidance of frequency of change of multiple use catheters outside of the existing drug tariff. Upon further investigation, it was understood that the MHRA interpretation of the single-use symbol is applicable in healthcare settings or where care is delivered by healthcare workers (such as care homes or community hospitals). In community settings (e.g. in patient's homes), the Drug Tariff recommendations apply and catheters are considered to be single-patient-use devices. Therefore, in all healthcare settings or where care is delivered by healthcare workers, multiple-use catheters are not a valid alternative and coated catheters must be used. For patients who perform intermittent self catheterisation in the community, washing and re-using non-coated catheters is a valid method of catheterisation. It is more effective than using single-use non-coated catheters and more cost-effective than using coated catheters. Under no circumstances should the same catheter be used by more than one patient.

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	The GDG felt it important to consider privacy and dignity issues when recommending a type of intermittent catheter. In addition to the situations outlined above, they felt there may be other circumstances (such as shared toilets in work places or other public spaces) in which patients may not feel comfortable washing and drying non-coated catheters. In these cases, a coated catheter should be recommended. This update did not compare different methods for cleaning intermittent catheters as it was outside the scope of the guideline. The GDG felt that for information about cleaning non-coated catheters patients could refer to manufacturer's instructions. Patients may require education on how to clean catheters if they are unable to read or understand the manufacturers' instructions. The GDG did not feel it was appropriate to make a recommendation regarding the frequency of change of multiple use catheters as this was likely to be influenced by other factors such as comfort or efficacy which would be routinely discussed as part of the normal patient-clinician interaction. Furthermore no evidence was reviewed in this area. The GDG have prioritised this recommendation as a key priority for implementation as they considered that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes, leads to a more efficient use of NHS resources, promotes patient choice and means that patients reach critical points in the care pathway more quickly. See section 4.1.

1

Recommendations	**40.Do not offer multiple use catheters for use in children or young people of 16 years or under. [new 2012]**
Relative values of different outcomes	The GDG considered symptomatic UTI and the risk of long-term complications as a result of childhood UTI as the most important outcome for this question. Mortality, bacteraemia, and patient preference/comfort were also considered relevant outcomes.
Trade off between clinical benefits and harms	Symptomatic UTI in childhood carries the risk of serious kidney damage. In light of the absence of evidence related to the use of single- vs. multiple- use non-coated catheters in children, and the uncertainty surrounding the real lifetime risk of established renal failure as a result of childhood UTI, the GDG decided to adopt a precautionary approach when making this recommendation.
Economic considerations	The NICE guideline 'Urinary Tract Infection in Children'[179] concluded that it is currently impossible to accurately establish the risk of long-term complications as a result of childhood UTI. The GDG considered that given the current level of understanding of the long-term risks of childhood UTI and the lack of evidence about quality of life in children with UTI, it would be invalid to attempt to model this process. The current GDG agreed with this decision and noted that none of the studies included in the clinical review which contained symptomatic UTI as an outcome were conducted in children. Given the uncertain risk of harm as a result of symptomatic UTI in childhood, the GDG decided to employ the precautionary principle in their approach to ISC in children. Therefore, only single use catheters were considered an option for ISC in children and modelling was not explicitly undertaken in this population.
Quality of evidence	No clinical evidence was found for multiple versus single use catheters in children and adolescents. UTIs were not reported in the single study identified in children[251] which investigated hydrophilic catheters versus non-coated PVC catheters in children (mean age 12 years)[251]. This study did suggest that there is no difference in patient satisfaction between the catheter types;this evidence was low quality.

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	In the absence of evidence, the GDG developed this recommendation by consensus.
Other considerations	Urinary tract infection in childhood may carry special significance, as discussed in the Urinary Tract Infection in Children guideline[179]. This includes the risks of acute clinical deterioration and long-term renal damage. Although the vast majority of children who have a urine infection recover promptly and do not have any long-term complications, there is a small subgroup at risk of significant morbidity, including children with congenital abnormalities of the urinary tract. The GDG also considered the social impact upon children and young people of non-coated catheters for multiple use. Children and young people requiring intermittent self-catheterisation may have difficulties accessing adequate facilities to wash, dry and store their catheters. The GDG recognised the difficulties in ensuring privacy and dignity where shared toilet facilities are used, such as in schools and colleges. Even where these facilities are provided and accessed, issues such as peer pressure and embarrassment in schools could have an adverse impact on the child or young person's self-esteem, and potentially reduce compliance with intermittent catheterisation and appropriate hygiene and storage of the catheter.

10.5.3 Is one catheter better than another?

There is some evidence that the balloon material on all silicone Foley catheters has a greater tendency to "cuff" on deflation than latex catheters, particularly when used suprapubically. Cuffing can cause distress and injury to patients when the catheter is removed.[165] Our systematic review showed that smaller gauge catheters (12-14 Ch) with a 10 ml balloon minimise urethral trauma, mucosal irritation and residual urine in the bladder, all factors which predispose to catheter-associated infection.[218,227] A non-systematic review of the literature confirmed this.[245] For suprapubic catheterisation, a 16 Ch gauge catheter is usually preferable to avoid blockage.[162] Where there is no difference in the quality of the catheter, the least expensive option should be used.[73]

One study[277] identified by our systematic review compared the use of catheter valves with a standard drainage system and found no significant difference in urinary tract infection but a patient preference for the catheter valve. The Medical Device Agency suggests patients need to be assessed for their mental acuity, manual dexterity, clothing preferences and use of night drainage bags when considering using catheter valves.[164]

10.5.4 Recommendations

41. In general, the catheter balloon should be inflated with 10 ml of sterile water in adults and 3-5 ml in children. [2003]

42. In patients for whom it is appropriate, a catheter valve can be used as an alternative to a drainage bag. [2003]

10.6 Asepsis

The following question was asked as this was not included in the previous guideline and it was highlighted by stakeholders during the scoping consultation that where aseptic techniques were referred to in recommendations that the terminology may be out-of-date. Asepsis is also covered in the PEG and VAD chapters (see chapter 11 and 12).

10.6.1 Review question

What is the most clinically and cost effective technique (aseptic technique, non-touch, aseptic non touch technique or a clean technique) when handling long-term urinary catheters to reduce colony forming units, urinary tract infections, compliance, MRSA or *C. diff* reduction and mortality?

Update 2012

10.6.1.1 Clinical evidence

No clinical evidence was identified. No clinical evidence was identified in the previous 2003 guideline.

10.6.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline.

10.6.1.3 Recommendations

The GDG decided not to make any new recommendations or to change any other specific recommendations in this chapter relating to aseptic or clean techniques. Also see recommendations in section 10.7.1.1 below.

10.7 Catheter Insertion

10.7.1 Catheterisation is a skilled procedure

Principles of good practice, clinical guidance[267,281] and expert opinion[74,75,131,141,244] agree that urinary catheters must be inserted using sterile equipment and an aseptic technique. Expert opinion indicates that there is no advantage in using antiseptic preparations for cleansing the urethral meatus prior to catheter insertion.[94,139] Urethral trauma and discomfort will be minimised by using an appropriate sterile, single-use lubricant or anaesthetic gel. The insertion of urinary catheters by healthcare workers who are competent in the procedure will minimise trauma, discomfort and the potential for catheter-associated infection.[75,94,141,267]

With regard to self-catheterisation, our systematic review found that in a study examining the safety of clean versus sterile intermittent catheterisation in male adults aged 36-96 years, no significant differences were found in infection rates, time to first infection or number of episodes.[79] A systematic review identified three controlled trials regarding the benefits of sterile or “non-touch techniques” for intermittent catheterisation vs. conventional clean intermittent catheterisation.[236] Data “neither supports nor refutes the need to utilize sterile, as opposed to clean, intermittent catheterisation.” Economic analysis suggests that clean intermittent catheterisation is unlikely to lead to additional infections and the additional cost of sterile catheterisation is unlikely to be justified.[79,271]

10.7.1.1 Recommendations

43. All catheterisations carried out by healthcare workers should be aseptic procedures. After training, healthcare workers should be assessed for their competence to carry out these types of procedures. [2003]

44. Intermittent self-catheterisation is a clean procedure. A lubricant for single-patient use is required for non-lubricated catheters. [2003]

45. For urethral catheterisation, the meatus should be cleaned before insertion of the catheter, in accordance with local guidelines/policy. [2003]

46. An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection. [2003]

10.8 Catheter Maintenance

10.8.1 Leave the closed system alone!

Maintaining a sterile, continuously closed urinary drainage system is central to the prevention of catheter-associated infection.[75,102,141,258,267,281] The risk of infection reduced from 97% with an open system to 8-15% when a sterile closed system was employed as standard practice.[94,101,139] However, breaches in the closed system such as unnecessary emptying of the urinary drainage bag or taking a urine sample increase the risk of catheter-related infection and should be avoided.[139,206,267] Hands must be decontaminated and healthcare workers should wear clean, non-sterile gloves before manipulation.

Reflux of urine is associated with infection and, consequently, best practice suggests catheters are secured to avoid trauma and drainage bags should be positioned in a way that prevents back-flow of urine.[75,267] Expert opinion also recommends that urinary drainage bags should be supported in such a way that prevents contact with the floor.[139] For night drainage, a link system should be used to maintain the original closed system, i.e., a bag attached to the end of the day system.[246]

Drainable urinary drainage bags should be changed in line with the manufacturer's recommendations, generally every 5-7 days, or sooner if clinically indicated, e.g. malodorous or damaged. Bags that are non-drainable should be used once, e.g., overnight, and emptied before disposal.

10.8.1.1 Recommendations

47. Indwelling catheters should be connected to a sterile closed urinary drainage system or catheter valve. [2003]

48. Healthcare workers should ensure that the connection between the catheter and the urinary drainage system is not broken except for good clinical reasons, (for example changing the bag in line with manufacturer's recommendations). [2003]

49. Healthcare workers must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves. [2003]

50. **Patients managing their own catheters, and their carers, must be educated about the need for hand decontamination[kk] before and after manipulation of the catheter, in accordance with the recommendations in the standard principles section (chapter 6.). [2003, amended 2012]**

51. **Urine samples must be obtained from a sampling port using an aseptic technique. [2003]**

52. **Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor. [2003]**

53. **A link system should be used to facilitate overnight drainage, to keep the original system intact. [2003]**

54. **The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated. [2003]**

10.8.2 Appropriate maintenance minimises infections

10.8.2.1 Meatal cleansing with antiseptic solutions is unnecessary

One systematic review considered six acceptable studies that compared meatal cleansing with a variety of antiseptic/antimicrobial agents or soap and water.[209] No reduction in bacteriuria was demonstrated when using any of these preparations for meatal care compared with routine bathing or showering. Expert opinion[75,139,281] and another systematic review[227] support the view that vigorous meatal cleansing is not necessary and may increase the risk of infection. Washing the meatus with soap and water during daily routine bathing or showering is all that is needed.

10.8.3 Recommendation

55. **The meatus should be washed daily with soap and water. [2003]**

[kk] The highlighted text replaces 'Carers and patients managing their own catheters must wash their hands…' in the 2003 guideline. This has been amended to reflect input from the NICE Patient and Public Involvement Programme: recommendations cannot be made directly about what patients and carers must do.

10.9 Do bladder instillations or washouts reduce catheter associated symptomatic urinary tract infections?

The terminology regarding bladder instillations, irrigations and washouts can be confusing. Bladder irrigation refers to the continuous introduction of a sterile fluid into the bladder for the purpose of draining blood and debris; bladder instillation refers to the introduction of a sterile fluid into the bladder and leaving it there for a variable period of time in order to dissolve encrustations, alter bladder pH, or suppress bacterial growth; bladder washout refers to the introduction of a sterile fluid which is allowed to drain immediately for the purpose of diluting bladder contents or unblocking an obstruction. Bladder irrigation is not performed in primary and community settings and is therefore outside the scope of this guideline. However, in the literature the term 'irrigation' is sometimes used to refer to what is actually an instillation. Therefore, the term 'irrigation' was included as a search term to ensure that studies in which the terminology may have been confused were identified. These papers were also reviewed by a GDG member to ensure that only studies reporting on bladder instillations were included.

10.9.1 Review question

What is the clinical and cost effectiveness of bladder instillations or washouts on reduction of catheter associated symptomatic urinary tract infections and encrustations and blockages?

Update 2012

10.9.1.1 Clinical evidence

Four studies were identified. The terms instillations, washouts and irrigations were not defined or used consistently in the studies. The studies have been categorised into those that compare one type of washout to another and those that compare a washout to no washout.

One randomised crossover trial, which was included in the previous guideline, compared saline, Solution G (active ingredients: citric acid, magnesium oxide and sodium bicarbonate) and Solution R (active ingredients: citric acid, magnesium carbonate and gluconolactone)[133] instillations/washouts twice a week. One RCT compared saline and acetic acid instillations/washouts twice a week[266]. One RCT compared Solution G and saline instillations/washouts once a week to no instillation/washout[171]. One randomised crossover trial compared saline to no instillation/washout[174].

Only one study from the previous 2003 guideline met the inclusion criteria for this review question [133].

See Evidence Tables G.5.3, Appendix G, Forest Plots in Figure 43-59, Appendix I.

Comparison of solutions for instillation/washout

Table 56: Solution G vs. saline – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter Blockage [133]	1	RCT	Serious limitations[(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Partially Blocked Catheter [133]	1	RCT	Serious limitations[(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Catheters Not Encrusted [133]	1	RCT	Serious limitations[(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Catheter Removal/ Replacement [133]	1	RCT	Serious limitations[(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Symptomatic UTI	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				

(a) Crossover trial. Allocation concealment and blinding not reported
(b) Randomised catheters rather than patients, therefore patients were included in the study more than once.
(c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

Table 57: Solution G vs. saline- Clinical summary of findings

Outcome[(a)]	Solution G	Saline	Relative risk	Absolute effect	Quality
Catheter Blockage	14/29 (48.3%)	18/44 (40.9%)	RR 1.18 (0.7 to 1.98)	74 more per 1000 (123 fewer to 401 more)	LOW
Partially Blocked Catheter	12/29 (41.4%)	14/44 (31.8%)	RR 1.3 (0.71 to 2.4)	95 more per 1000 (92 fewer to 445 more)	LOW
Catheters Not Encrusted	3/29 (10.3%)	12/44 (27.3%)	RR 0.38 (0.12 to 1.23)	169 fewer per 1000 (240 fewer to 63 more)	LOW
Catheter Removal/ Replacement	14/84 (16.7%)	16/84 (19%)	RR 0.88 (0.46 to 1.68)	23 fewer per 1000 (103 fewer to 130 more)	LOW

(a) Catheters outcomes reported per number of catheters rather than number of study participants

Update 2012

Table 58: Solution R vs. saline – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter Blockage [133]	1	RCT	Serious limitations (a),(b)	No serious inconsistency	No serious indirectness	Serious imprecision(c)
Partially Blocked Catheter[133]	1	RCT	Serious limitations (a),(b)	No serious inconsistency	No serious indirectness	Serious imprecision(c)
Catheters Not Encrusted[133]	1	RCT	Serious limitations (a),(b)	No serious inconsistency	No serious indirectness	Serious imprecision(c)
Catheter Removal/ Replacement[133]	1	RCT	Serious limitations (a),(b)	No serious inconsistency	No serious indirectness	Serious imprecision(c)
Symptomatic UTI	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				

(a) Crossover trial. Allocation concealment and blinding not reported.
(b) Randomised catheters rather than patients, therefore patients were included in the study more than once.
(c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

Table 59: Solution R vs. saline - Clinical summary of findings

Outcome(a)	Solution R	Saline	Relative risk	Absolute effect	Quality
Catheter Blockage	7/27 (25.9%)	18/44 (40.9%)	RR 0.63 (0.31 to 1.31)	151 fewer per 1000 (from 282 fewer to 127 more)	LOW
Partially Blocked Catheter	10/27 (37%)	14/44 (31.8%)	RR 1.16 (0.6 to 2.24)	51 more per 1000 (from 127 fewer to 395 more)	LOW
Catheters Not Encrusted	10/27 (37%)	12/44 (27.3%)	RR 1.36 (0.68 to 2.7)	98 more per 1000 (from 87 fewer to 464 more)	LOW
Catheter Removal/ Replacement	14/84 (16.7%)	16/84 (19%)	RR 0.88 (0.46 to 1.68)	23 fewer per 1000 (from 103 fewer to 130 more)	LOW

(a) Catheters outcomes reported per number of catheters rather than number of study participants.

Update 2012

Table 60: Solution G vs. solution R – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter Blockage[133]	1	RCT	Serious [(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Partially Blocked Catheter[133]	1	RCT	Serious [(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Catheters Not Encrusted[133]	1	RCT	Serious [(a),(b)]	No serious inconsistency	No serious indirectness	No serious imprecision
Catheter Removal/ Replacement[133]	1	RCT	Serious [(a),(b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Symptomatic UTI	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				

(a) Crossover trial. Allocation concealment and blinding not reported.
(b) Randomised catheters rather than patients, therefore patients were included in the study more than once.
(c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

Table 61: Solution G vs. solution R - Clinical summary of findings

Outcome[(a)]	Solution G	Solution R	Relative risk	Absolute effect	Quality
Catheter Blockage	14/29 (48.3%)	7/27 (25.9%)	RR 1.86 (0.89 to 3.9)	223 more per 1000 (29 fewer to 752 more)	LOW
Partially Blocked Catheter	12/29 (41.4%)	10/27 (37%)	RR 1.12 (0.58 to 2.15)	44 more per 1000 (156 fewer to 426 more)	LOW
Catheters Not Encrusted	3/29 (10.3%)	10/27 (37%)	RR 0.28 (0.09 to 0.91)	267 fewer per 1000 (33 fewer to 337 fewer)	LOW
Catheter Removal/ Replacement	14/84 (16.7%)	14/84 (16.7%)	RR 1 (0.51 to 1.97)	0 fewer per 1000 (82 fewer to 162 more)	LOW

(a) Catheters outcomes reported per number of catheters rather than number of study participants.

Update 2012

Table 62: Acetic acid vs. saline – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI[266]	1	RCT	Serious limitations[(a, b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Adverse effects[266]	1	RCT	Serious limitations [(a, b)]	No serious inconsistency	No serious indirectness	Serious imprecision[(c)]
Encrustations and blockages	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				
Encrustations and blockages	0	RCT				

(a) Randomised non-controlled trial. Sequence generation not clear and allocation concealment not reported.
(b) Blinding not clear.
(c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

Table 63: Acetic acid vs. saline - Clinical summary of findings

Outcome	Acetic acid	Saline	Relative risk	Absolute effect	Quality
Symptomatic UTI	6/30 (20%)	1/29 (3.4%)	RR 5.8 (0.74 to 45.26)	166 more per 1000 (9 fewer to 1526 more)	LOW
Adverse effects	1/30 (3.3%)	0/29 (0%)	RR 2.9 (0.12 to 68.5)	0 more per 1000 (0 fewer to 0 more)	LOW

Update 2012

Table 64: Solution G vs. saline washout – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI[171]	1	RCT	Very serious limitations (a)(b)	No serious inconsistency	No serious indirectness	Very serious imprecision[(c)]
Mean time to first catheter change (weeks)[171]	1	RCT	Very serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision [(c)]
Encrustations and blockages	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				
Encrustations and blockages	0	RCT				

(a) Open label study - blinding not possible due to nature of sterile packaging.

(b) 2-3 patients in each group did not complete data collection due to self reported UTI and initiation of antibiotic treatment, but none met study criteria for symptomatic UTI.
(c) Very low number of patients in each study arm, likely to be underpowered.

Table 65: Solution G vs. saline washout - Clinical summary of findings

Outcome	Solution G	Saline	Relative risk	Absolute effect	Quality
Symptomatic UTI	0/17 (0%)	0/16 (0%)	not pooled	N/A	VERY LOW
Mean time to first catheter change (weeks)	17	16	-	MD 0.43 lower (2.32 lower to 1.46 higher)	VERY LOW

Comparison of solutions for instillation/washout vs. no instillation/washout

Table 66: Solution G vs. no washout– Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI [171]	1	RCT	Very serious limitations [(a)]	No serious inconsistency	No serious indirectness	Very serious imprecision [(b)]
Mean time to first catheter change (weeks) [171]	1	RCT	Very serious limitations [(a)]	No serious inconsistency	No serious indirectness	Very serious imprecision [(b)]
Encrustations and blockages	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				

(a) Open label study - blinding not possible due to nature of sterile packaging
(b) Very low number of patients in each study arm, likely to be underpowered.

Table 67: Solution G vs. no washout- Clinical summary of findings

Outcome	Solution G	No washout	Relative risk	Absolute effect	Quality
Symptomatic UTI	0/17 (0%)	0/20 (0%)	not pooled	not pooled	VERY LOW
Mean time to first catheter change (weeks)	17	20	-	MD 0.2 higher (1.58 lower to 1.98 higher)	VERY LOW

Update 2012

Table 68: Saline washout (once a week) vs. no washout – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI[171]	1	RCT	Very serious limitations (a)(b)	No serious inconsistency	No serious indirectness	Very serious imprecision(c)
Mean time to first catheter change (weeks) [171]	1	RCT	Very serious limitations (a)	No serious inconsistency	No serious indirectness	Very serious imprecision (c)
Encrustations and blockages	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and comfort	0	RCT				
Encrustations and blockages	0	RCT				

(a) Open lable study - blinding not possible due to nature of sterile packaging.
(b) 2-3 patients in each group did not complete data collection due to self reported UTI and initiation of antibiotic treatment, but none met study criteria for symptomatic UTI.
(c) Very low number of patients in each study arm, likely to be underpowered.

Table 69: Saline washout (once a week) vs. no washout - Clinical summary of findings

Outcome	Saline washout	No washout	Relative risk	Absolute effect	Quality
Symptomatic UTI	0/16 (0%)	0/20 (0%)	not pooled	N/A	VERY LOW
Mean time to first catheter change (weeks)	16	20	-	MD 0.63 higher (1.28 lower to 2.54 higher)	VERY LOW

Table 70: Saline washout (once a day) vs. no washout – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter replacement per 100 days of catheterisation [174]	1	RCT	Serious limitations(a, b, c)	No serious inconsistency	No serious indirectness	Serious imprecision (d)
Encrustations and blockages	0	RCT				
Bacteraemia	0	RCT				
Mortality	0	RCT				
Patient preference and	0	RCT				

Update 2012

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
comfort						
Encrustations and blockages	0	RCT				
Symptomatic UTI	0	RCT				

(a) Crossover trial. Sequence generation and allocation concealment not clear.
(b) 23 patients participated in full duration of trial, but 32 patients (crossover and partial crossover patients) included in analysis.
(c) Blinding not reported.
(d) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

Table 71: Saline washout (once a day) vs. no washout - Clinical summary of findings

Outcome	Saline	No washout	Relative risk	Absolute effect	Quality
Catheter replacement per 100 days of catheterisation	5.5 N = 32	4.7 N = 32	N/A[(a)]	N/A[(a)]	LOW

(a) Value not estimated as SD not reported.

10.9.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified.

No cost-effectiveness evidence was identified in the previous 2003 guideline.

In the absence of any published cost-effectiveness analyses, the current UK cost of bladder instillations and washouts, nurse time, and catheter-related infections were presented to the GDG to inform decision making.

Table 72: Cost of bladder instillation and washout solutions

Solution	Dose	Average cost (£)
3.23% Citric Acid	100 ml	3.35
6.00% Citric Acid	100 ml	3.35
0.9% Saline	100 ml	3.26
Sterile water	100 ml	3.30

Source: NHS Drug Tariff 2010[184]; Infection-related costs – see economic model in Appendix J. Acetic acid (used in the included clinical trials) was not identified in either the BNF or NHS Drug Tariff and was therefore not included in this table.

10.9.1.3 Evidence statements

Clinical

It is uncertain whether there is any difference between saline, Solution G or Solution R for catheter encrustations, symptomatic UTIs and mean time to first catheter change. (LOW QUALITY)

It is uncertain whether there is any difference between saline and acetic acid for symptomatic UTIs or adverse effects. (LOW QUALITY)

It is uncertain whether there is any difference between saline and no washout in the number of catheter replacements, mean time to first catheter change or catheter 'obstruction'. (VERY LOW QUALITY)

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It is uncertain whether there is any difference between Solution G and no washout for mean time to first catheter change. (LOW QUALITY)

No studies were identified that reported bacteraemia or mortality.

Economic

No evidence of the cost-effectiveness of instillations or washouts was identified.

There is little cost difference between different types of solutions. It is more expensive (in terms of solution cost and nurse time) to use an instillation or washout than to not use an instillation or washout.

10.3.1.4 Recommendations and link to evidence

Recommendations	**56. To minimise the risk of blockages, encrustations and catheter-associated infections for patients with a long-term indwelling urinary catheter:** • **develop a patient-specific care regimen** • **do not use bladder instillations or washouts** • **consider approaches such as reviewing the frequency of planned catheter changes and increasing fluid intake** • **document catheter blockages. [new 2012]**
Relative values of different outcomes	The number of symptomatic UTIs was considered the primary outcome of interest. Catheter replacement/ frequency of catheter change, encrustations, and blockages were also considered important outcomes.
Trade off between clinical benefits and harms	The GDG considered a trade off between the potential for instillations/washouts to reduce the incidence of blockages and encrustations and the increased risk of infection associated with breaking a closed system. The GDG also considered the potential for increased fluid intake to reduce encrustations, blockages and UTIs, and the risk of fluid overload (i.e. excessive fluid consumption) that may occur as a result of patients being encouraged to increase fluid intake.
Economic considerations	The GDG considered the cost of bladder instillation and washout solutions as well as the nurse time needed to perform these procedures. They also took into account the cost and QALY loss associated with UTIs, risk of fluid overload, and the resource use associated with catheter changes resulting from encrustations and blockages. The GDG thought that performing bladder instillations and washouts is likely to lead to an increase in infections due to the risk associated with breaking a closed system. It is also more expensive to administer an instillation or washout than to not administer an instillation or washout. Instillations and washouts are therefore very unlikely to be cost-effective. The GDG thought that taking the time to develop patient-specific care plans, reviewing the frequency of planned catheter changes, and encouraging an increase in fluid intake would likely be a more cost-effective use of nurse time.
Quality of evidence	This recommendation was based on GDG consensus, as the evidence was deemed poor quality due to study limitations and inconclusive outcomes.
Other considerations	The GDG considered approaches other than instillations and washouts which could be effective in reducing blockages, encrustations and catheter associated infections. These approaches included the development of patient specific care regimens, reviewing the frequency of planned catheter changes, and encouraging increased fluid intake. The GDG considered these approaches to be good practice for the care of patients using long-term indwelling catheters. The GDG acknowledged that therapeutic intervention, such as instillations for

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	patients undergoing chemotherapy, was an area beyond the scope of the guideline. Patient preference and quality of life were considered important.

10.9.2 Changing catheters

There is no definitive evidence as to the optimal interval for changing catheters in patients undergoing long-term urinary drainage via either the urethral or suprapubic route. Our search identified a study which suggested that a higher rate of infection was associated with frequent catheter changes, though evidence is not definitive.[274] Expert opinion suggests changing the catheter according to the clinical needs of the patient or as recommended by the catheter manufacturer (usually every 12 weeks).[267,281] Our systematic review identified a study that showed if catheter blockage occurs within a shorter interval, catheters should be changed more frequently to avert a future clinical crisis.[98] An economic analysis suggested that there may be a cost saving in changing a catheter at six weeks when there is an increased likelihood of blockage (>50%).[183]

10.9.3 Recommendations

57. Catheters should be changed only when clinically necessary, or according to the manufacturer's current recommendations. [2003]

10.10 Use of antibiotics when changing long-term urinary catheters

Antibiotic use when changing indwelling catheters is considered an area of disparity and associated with mixed views regarding antibiotic resistance and patient safety. This update aims to determine the need for prophylactic antibiotics and their impact on the reduction of urinary tract infections.

10.10.1 Review question

In patients with long-term urinary catheters (more than 28 days), what is the clinical and cost effectiveness of prophylactic antibiotics (single dose or short course) use during catheter change on reduction of urinary tract infections?

10.10.1.1 Clinical evidence

One RCT conducted in elderly patients using an open urinary collecting catheter system and silicone coated catheters was identified[90]. No studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.5.1, Appendix G, Forest Plots in Figure 60-62, Appendix I.

Table 73: Antibiotic prophylaxis vs. control - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Antibiotic resistance[90]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Very serious imprecision [(c)]
Mortality[90]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Very serious imprecision [(c)]
Bacteraemia[90]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Very serious imprecision [(c)]
Symptomatic	0	RCT				

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Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
UTI						
Upper UTI (pylonephritis)	0	RCT				
Patient preference	0	RCT				

(a) Randomisation allocation and concealment method not reported. Not double blinded.
(b) The patients in the study were elderly in a home, and used an open urinary collecting catheter system; the antibiotic prophylaxis used was meropenem. Meropenem is a broad spectrum antibiotic normally reserved as a second line treatment in the UK. It is highly uncertain whether this evidence is applicable to prophylaxis in the community for UK patients.
(c) Sparse data and confidence intervals crossed MID. Sample size was too small to detect statistical significance for rare events.

Table 74: Antibiotic prophylaxis vs. control - Clinical summary of findings

Outcome	Alpha blocker	Placebo	Relative risk	Absolute effect	Quality
Antibiotics resistance	0/36 (0%)	0/34 (0%)	Not estimable	0 fewer per 1000 (0 fewer to 0 fewer)	VERY LOW
Mortality	1/36 (2.8%)	2/34 (5.9%)	RR 0.47 (0.04 to 4.97)	31 fewer per 1000 (56 fewer to 234 more)	VERY LOW
Bacteraemia	0/36 (0%)	0/34 (0%)	Not estimable	0 fewer per 1000 (0 fewer to 0 fewer)	VERY LOW

10.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost effectiveness evidence was identified in the previous 2003 guideline.

From an economic perspective, questions surrounding the use of antibiotic prophylaxis are very complex. A recent Health Technology Assessment performed a literature search in order to develop a conceptual evaluative framework for the economic evaluation of policies against MRSA[50]. Many of the considerations discussed within this review were relevant to the current question and provided a useful background for GDG discussions related to the cost-effectiveness of antibiotic prophylaxis for changing long-term indwelling urethral catheters.

The GDG were also presented with current UK antibiotic and infection-related costs (see economic model in Appendix J).

Table 75: Cost of antibiotics commonly used for prophylaxis when changing long-term indwelling urinary catheters

Antibiotic	Standard prophylactic dose	Cost per dose (£)
Gentamicin	80mg intramuscular	1.48
Ciprofloxacin	20mg x 2 per oral	0.22
Nitrofuratonin	50mg x 4 per oral	0.38
Trimethoprim	200mg x 2 per oral	0.02

Source: Drug and dosing data based on expert advice; costs obtained from the NHS Drug Tariff[184] prices.

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10.10.3 Evidence statements

Clinical

It is uncertain whether there are any differences between providing single dose antibiotics vs. not providing antibiotics in mortality, bacteraemia and antibiotic resistance when changing urinary catheters. (VERY LOW QUALITY)

No studies were identified that reported symptomatic lower UTI, symptomatic upper UTI, or patient preference.

Economic

No evidence comparing the cost-effectiveness of providing antibiotic prophylaxis vs. not providing prophylactic antibiotics while changing urinary catheters was identified.

10.10.4 Recommendations and link to evidence

Recommendations	**58. When changing catheters in patients with a long-term indwelling urinary catheter:** • **do not offer antibiotic prophylaxis routinely** • **consider antibiotic prophylaxis[ll] for patients who:** **i. have a history of symptomatic urinary tract infection after catheter change or** **ii. experience trauma[mm] during catheterisation. [new 2012]**
Relative values of different outcomes	Prevention of symptomatic UTI was considered the most important outcome. UTI-associated mortality, bacteraemia and pylonephritis or upper UTIs were also considered important outcomes.
Trade off between clinical benefits and harms	Symptomatic UTI carries the risk of serious complications such as bacteraemia and death. There is a clear clinical benefit to be gained from the prevention of symptomatic UTI in patients with long-term indwelling catheters. However, the risk of using antibiotics as a form of prophylaxis is that it may lead to an increase in resistance to that drug which, in turn, may reduce the available treatments for patients with clinical infections in the future. Antibiotics also carry a risk of adverse reaction in individual patients. The recommendation was based on GDG consensus as the strength of evidence was insufficient to indicate an overall benefit from routine antibiotic prophylaxis.
Economic considerations	Assessing the cost-effectiveness of antibiotic prophylaxis is very complex. Within the past decade there has been a large increase in the prevalence of multi-drug resistant UTIs in the community. The use of antibiotics is undoubtedly a factor in this phenomenon. There is a need to consider the potential economic consequences across the patient population rather than simply considering the cost-effectiveness for individuals. However, predicting the development of antibiotic resistance within individuals and between populations is an area characterised by extreme uncertainty. The GDG thought that is likely that the effect of antibiotic prophylaxis on antibiotic resistance will depend on the extent of usage. Given the high cost and QALY loss associated with UTI and UTI-associated complications, the GDG thought that among patients at higher risk of UTI during catheter change, and the low cost of a single dose of antibiotics, prophylactic antibiotic use for indwelling catheter change would likely be cost-effective. Given the long-term

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[ll] At the time of consultation (July 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented.

[mm] The GDG defined trauma as frank haematuria after catheterisation or two or more attempts of catheterisation.

	risks to the patient and the population associated with antibiotic resistance, the GDG decided that the routine use of antibiotic prophylaxis would likely represent an inefficient use of resources.
Quality of evidence	The evidence was of very low quality; any estimates of effect sizes obtained were highly uncertain. Only one small RCT conducted in elderly patients using an open urinary collecting catheter system and silicone coated catheters was identified. This study had serious limitations. There was serious imprecision and indirectness of the population (i.e. applicability to the guideline population), type of intervention used (meropenem, which is normally a second-line therapy antibiotic) and type of catheterisation used in the study. This recommendation is based on GDG consensus and input of expert advisors on the interpretation of the evidence. No cost-effectiveness evidence was identified.
Other considerations	The GDG considered the opinion of the microbiologist expert advisor who worked with the GDG to interpret the evidence and provide advice on the current practices in this area. Although there was no evidence of effectiveness for short course/single dose antibiotic prophylaxis, the GDG thought that antibiotics may be considered in certain groups (where there is a high risk of UTI or the consequences of complications from UTI are particularly high). The GDG felt that in these groups, the potential benefit of risk reduction from antibiotic prophylaxis may outweigh the potential disadvantages associated with its use. • Both groups are at an increased risk of getting UTI during catheter change. The numbers needed to treat in order to prevent infections in this group may be lower if their baseline risks are higher. This would tip the balance of benefits vs. harms to favour considering antibiotics. • Prophylactic antibiotics are normally offered as a single dose (and very rarely, as a short course). Adequate efforts to ensure appropriate use and good adherence may be helpful to minimise the risk of bacterial resistance. For these groups, the concerns about patient safety were paramount. There is no existing widely accepted definition of “trauma” from repeated or difficult catheterisation. The definition provided (frank haematuria following catheterisation or two or more attempts of catheterisation) is formed by GDG consensus, with expert input, and intended to capture the concern that traumatic catheterisation led to tissue damage which could increase the risk of infection becoming systemic. The choice of antibiotics has not been specified because resistance patterns could vary based on locality and over time. It is assumed that clinicians will follow local guidance and prescribe an effective antibiotic with the lowest acquisition cost unless otherwise indicated. None of the antibiotics are licensed for single dose or short course prophylaxis of urinary tract infections when changing long-term urinary catheter. It is important to fully inform patients about the advantages and disadvantages of using antibiotics for their individual circumstances, and the importance of fully adhering to the antibiotic prophylaxis regimen to reduce the risk of bacterial resistance. Patients should be asked their preference and to consent on the course of antibiotic prophylaxis prescribed. Other linked recommendations: Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures CG 64 (http://guidance.nice.org.uk/CG64). The GDG have also made a research recommendation in this area, see section 10.12.

	The GDG have prioritised this recommendation as a key priority for implementation as they consider that it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes and leads to a more efficient use of NHS resources, see section 4.1.

10.10.5 Re-use of intermittent catheters

Many people use disposable single-use catheters for intermittent catheterisation. Reusable single patient use catheters need to be cleaned after use. Our systematic review identified two crossover studies of young people with neurogenic bladders which indicated that cleaning catheters with soap and water results in acceptably low rates of bacteriuria when compared with the use of sterile catheters.[170,172] However, manufacturer's recommendations advise against using soap as soap residues may cause urethral irritation. Catheters should be stored in a clean and dry condition, which is least likely to promote the growth of contaminating microorganisms.

10.10.5.1 Recommendation

59. Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. [2003]

10.11 Areas for Further Research

In developing the recommendations we identified several areas that were inadequately addressed in the literature. The following recommendations for research are therefore made.

Assessing the need for catheterisation

Epidemiological studies of the prevalence and incidence of bacteriuria/clinical urinary tract infection during long-term catheterisation in different populations and different care settings. These should at least encompass the predominant populations; older people and those with neurological deficits in both institutional and domiciliary settings. There needs to be clear definition of the 'cases' and the populations from which they are drawn.

Catheter drainage options

Randomised controlled trials of different approaches to urinary drainage. These should compare urethral indwelling catheterisation with and without a drainage bag (i.e., a valve); urethral intermittent catheterisation; suprapubic catheterisation; penile sheath drainage and incontinence pads in appropriate populations. Outcome measures need to include rates of bacteriuria/clinical UTI; tissue damage; patient/carer satisfaction; and cost-benefit.

Randomised controlled trials of the efficacy of antimicrobial impregnated urethral catheters for long-term use.

Catheter maintenance

Randomised controlled trials of strategies to reduce/prevent/manage encrustation and blockage. These need to determine whether catheter maintenance solutions (washouts/installations) are effective in reducing encrustation; blockage; urethral trauma; frequency of catheter replacement; and interventions/visits by healthcare practitioners. The rates of these complications when catheter valves are used in place of drainage bags also needs to be compared.

Cohort studies to determine whether monitoring of urinary pH can be used to predict time to blockage. These need to be undertaken in defined and representative groups.

Randomised controlled trials to establish the optimum time interval between changing equipment. There is a particular need to determine whether the frequency of changing leg bags or catheter valves influences the rates of bacteriuria/clinical UTI.

10.12 Research Recommendations

3. For patients using long-term indwelling urinary catheters, what is the clinical and cost effectiveness of impregnated versus hydrophilic versus silicone catheters in reducing symptomatic urinary tract infections, encrustations and/or blockages?

Why is this important?

Long-term indwelling catheters are commonly used in both hospital and community care settings. Long-term catheterisation carries a significant risk of symptomatic urinary tract infection, which can lead to more serious complications. Several different types of impregnated and hydrophilic long-term indwelling catheters on the market claim to be more effective than non-coated catheters, but are also more expensive.

The clinical evidence review for the guideline revealed an absence of evidence for the effectiveness of indwelling catheters over the long term. A comparison of impregnated (for example, with silver) catheters, hydrophilic catheters and silicone catheters id needed. The primary outcome measures should be symptomatic urinary tract infections, encrustations, blockages, cost/resource use and quality of life. Secondary outcome measures should include the mean number of days the catheter remains in situ (mean dwell time) and patient comfort.

4. When recatheterising patients who have long-term indwelling urinary catheters, what is the clinical and cost effectiveness of single-dose antibiotic prophylaxis in reducing symptomatic urinary tract infections in patients with a history of urinary tract infections associated with catheter change?

Why is this important?

The immediate clinical and economic impact of urinary tract infection is so great that patients at risk of infection are sometimes offered the option to receive prophylactic antibiotics. However, the widespread use of antibiotics, including their prophylactic use, has been identified as a major factor in the increasing levels of antibiotic resistance observed across England and Wales. There is currently an absence of evidence about the short-term and long-term effects of prophylactic antibiotic use during catheter change. The GDG identified this as an important area for research to establish the benefits and harms of this practice in order to develop future guidance (the recommendation on this topic in the current guideline was based on GDG consensus).

A randomised control trial or cohort trial to compare single-dose antibiotic prophylaxis with selected major antibiotic groups is needed. The primary outcome measures should be symptomatic urinary tract infection, cost and quality of life. This is an important area for patients as it could minimise the inappropriate use of antibiotics.

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11 Enteral Feeding

11.1 Introduction

The updated review questions in this chapter are:

- aseptic techniques
- care of the enteral feeding tube.

Asepsis was considered as a priority to be included in this update as this area was not included in the previous guideline. The previous guideline did refer to aseptic techniques in the recommendations, but the terminology was considered to be incorrect or out-of-date by the scoping group. This area was also highlighted many times by various stakeholders during the consultation as an area that should be included in the scope. The use of syringes (single use syringes vs. single patient use (reusable) syringes) was also highlighted during the scoping phase as an area for update.

No new evidence was found, however changes were made to recommendations in section 11.4.2.3 and 11.5.2.4.

The evidence and text from the previous guideline that has been superseded by this update is included in Appendices D.6 and D.9.

No new review questions are included in this chapter.

Sections not updated in this chapter are:

- preparation of storage feeds
- administration of feeds
- care of the insertion site.

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Once enteral feeding (EF) in hospital became common practice in the late 1980s, it was inevitable that those requiring prolonged feeding would continue this treatment at home. Enteral feeding is usually prescribed for patients in hospital requiring artificial nutrition support (ANS) for 7-10 days and long-term feeding / home enteral tube feeding (HETF) may be considered for patients needing ANS for more that 30 days.[8] HETF has expanded rapidly and by the end of 2000, 11,817 adult patients receiving HETF were registered with the British Artificial Nutrition Survey (BANS).[82] Of these, 46.5% were over 70 years of age. Over 60% of the patients were receiving tube feeds because of disorders of the central nervous system, of which cerebral vascular accident accounted for 34%. It was reported that over half the adult patients and virtually all children starting home enteral feeding lived in their own home and 40% of adults lived in nursing homes.

Nutrition Support Teams (NST) are recommended to support patients receiving artificial nutrition.[82] However, only 22% of NST stated that they were responsible for HETF and 47% stated that they were never responsible.[82] In addition, only one third felt that they had sufficient time to train patients on HETF prior to discharge from hospital. It is therefore not surprising that enteral feeding places a growing workload on community healthcare workers[158] and an audit of patients on HETF highlighted a need for continuing support.[142] Contamination of feeds is a key concern in HETF as it has been found that more than 30% of feeds in hospital and home are contaminated with a variety of microorganisms, largely due to the preparation or administration of feeds,[10] and this has been linked to serious clinical infection.[201] The rates of contamination are highest in home settings and reinforces the need for infection prevention guidelines.[10]

Despite searching for infection prevention measures associated with nasogastric and jejunostomy feeding, most of the evidence related to gastrostomy or percutaneous endoscopic gastrostomies (PEG feeds). Although these guidelines have been developed for gastrostomy feeding, the Guideline Development Group felt that most of these principles could also be applied to other feeding systems.

These guidelines apply to adults and children over 1 year old and should be read in conjunction with the guidance on Standard Principles. These recommendations are broad principles of best practice and are not detailed procedural protocols. They need to be adapted and incorporated into local practice guidelines. The recommendations are divided into four distinct interventions:

1. Education of patients, their carers and healthcare workers;
2. Preparation and storage of feeds;
3. Administration of feeds;
4. Care of insertion site and enteral feeding tube.

11.2 Education of patients, carers and healthcare workers

Although not a specific question for our systematic review, it has become evident from our research that the responsibility for preparing and administering HETF lies usually with the patient, their carers and in some cases, community healthcare workers. An audit of the nursing knowledge of percutaneous endoscopic gastrostomy (PEG)[126] of hospital nurses in a district general hospital identified gaps in their knowledge and management of enteral feeding systems and a similar situation was noted in the community.[273] The BANS survey noted the less than optimum support people on HETF receive[82] despite expert opinion stressing the need for education and training.[2,166] Given that nutrition is a key Department of Health patient-focused benchmark for healthcare practitioners,[64] it is of concern that this does not include those receiving artificial nutrition and consequently support and preparation for these patients is not widely available.

A system known as Hazard Analysis and Critical Control Point (HACCP) is employed widely in the food industry to highlight areas where food safety may be at risk. The Parenteral & Enteral Nutrition Group of the British Dietetic Association supports the use of HACCP in enteral feeding to increase safety and as an educational tool.[9]

11.2.1.1 Recommendations

60. Patients and carers should be educated about, and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital. [2003]

61. Healthcare workers should be trained in enteral feeding and management of the administration system.[2003]

62. Follow-up training and ongoing support of patients and carers should be available for the duration of home enteral tube feeding. [2003]

11.3 Preparation and storage of feeds

11.3.1 Select the right system

Our systematic review identified two randomised controlled trials, which demonstrated that closed systems (i.e., sterile prefilled ready-to-use feeds that do not expose feed to the air during assembly) as available from all major manufacturers, have lower contamination rates than open systems.[120,265]

The design of the system is also important in order to minimise handling.[22,161,272]

11.3.1.1 Recommendations

63. Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution.[2003]

64. The system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube.[2003]

11.3.2 Hygienic preparation of feeds is essential

Hand hygiene is critical and hand decontamination is discussed more fully in Standard Principles (chapter 6). The International Scientific Forum on Home Hygiene has also published comprehensive guidance on food preparation and cleanliness in the home.[233] Our systematic review identified three studies[11,12,147] concerned with feed preparation. The evidence on the use of gloves is contradictory. Two studies[11,12] suggested that gloves were preferable and one suggested bare hands if properly decontaminated were acceptable.[147] However all three studies linked contamination to the amount of manipulation a system required and reinforces the guidance above.

Standard principles stress the importance of hand decontamination and expert opinion[9,166,239] stresses the need to prepare the work surface and, where necessary the equipment for reconstituting or diluting the feed. Equipment used for either opening sterile feeds or preparing feeds should be dedicated for enteral feeding use only. It should be cleaned in a dishwasher or washed with hot soapy water, rinsed and then dried and stored covered until required. Cooled boiled water or freshly opened sterile water should be used to prepare feeds in the home.[9,275]

11.3.2.1 Recommendations

65. Effective hand decontamination must be carried out before starting feed preparation.[2003]

66. When decanting, reconstituting or diluting feeds, a clean working area should be prepared and equipment dedicated for enteral feed use only should be used.[2003]

67. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-touch technique.[2003]

11.3.3 Store feeds safely

Expert opinion[239] and manufacturers[5,92] advise that ready-to–use, prepackaged feeds should be stored in a clean environment, protected from extremes of temperature. Stock should be rotated to avoid feeds exceeding their best before date.

Where feeds need to be reconstituted or diluted they can be made up for 24 hours. All feeds not required for immediate use must be stored in a refrigerator at a temperature not exceeding 4 degrees Celsius and discarded after 24 hours.[5,92]

11.3.3.1 Recommendations

68. Feeds should be stored according to manufacturer's instructions and, where applicable, food hygiene legislation.[2003]

69. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a refrigerator, and used within 24 hours.[2003]

11.4 Administration of feeds

11.4.1 Minimal handling reduces risk

Four reports,[109,147,160,195] which studied enteral feeds delivered in a variety of settings, demonstrated that the risk of contamination is related to the manipulation of the system and the system design. This reinforces earlier guidance about selecting a system that requires minimal handling.

When assembling the system, first assess the condition of the connection. A no-touch technique should be used to connect the feed container to the administration set using the minimum number of connectors possible. Contact with the patient's clothes should be avoided when attaching the administration set to the enteral feeding tube.[9]

Administering feeds for the maximum time possible reduces handling to a minimum. Sterile ready-to-hang feeds can be left for a maximum time 24 hours and non-sterile (reconstituted) feeds for 4 hours.[9,225] However even closed systems can become contaminated if hands are not adequately decontaminated.[195]

Bacterial contamination has been associated with the re-use of feed bags and administration sets.[8] One study in a long-term care facility[109] suggested that administration set changes could be left up to 72 hours but other studies[83,136,225,230] suggested that 24 hours is the maximum time acceptable. Three experimental, in vitro studies[13,110,241] considered the re-use of equipment but none identified a satisfactory system for disinfecting equipment that might be acceptable in practice. As evidence suggests re-use is not advisable, the administration system should be considered single use only and discarded after each session.

Currently there appears to be a debate on the re-use of single use syringes used to flush enteral feeding tubes. Our systematic review found no evidence to either support or refute the reuse of syringes. The Medical Device Agency's current guidance is that items labelled single use must not be reused under any circumstances and the reuse of such items has legal implications.[166]

11.4.2 Review question

The following question was asked to determine which technique should be used when handling PEGs as this was identified as an area where there is confusion in terminology. The GDG identified diarrhoea, vomiting, peritonitis and gastrostomy site infection as the primary outcomes of interest.

What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non touch technique or a clean technique) when handling PEGs to reduce healthcare-associated infections?

11.4.2.1 Clinical evidence

No clinical evidence was identified. No clinical evidence was identified in the previous 2003 guideline.

11.4.2.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline.

11.4.2.3 Recommendations

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Recommendations	70. Use minimal handling and a no-touch technique to connect the administration system to the enteral feeding tube. [new 2012]
Relative values of different outcomes	The GDG considered diarrhoea, vomiting, peritonitis and gastrostomy site infection the most important outcomes for this question. However, no evidence was identified which reported these outcomes.
Trade off between clinical benefits and harms	The GDG recognised the potential for contamination when assembling a feeding system. Consequently adopting a no-touch technique when assembling the equipment was considered the most important practice, regardless of how this is achieved. An example of this is that no open part of the enteral feeding delivery system, feed or enteral tube should be in contact with the hands, clothes, skin or other non-disinfected surface.
Economic considerations	The GDG did not think that adopting a no-touch technique would be associated with any additional time or resource requirements.
Quality of evidence	No clinical or economic evidence was identified.
Other considerations	A minor change was made during the update in that the term 'aseptic' was removed. The GDG noted that there are many terms used interchangeably for an aseptic technique, but that essentially they mean the same thing. This inconsistency in terminology can cause confusion. The GDG chose the term 'no-touch technique' as its preferred option for describing this approach. See also the sections on asepsis discussed in LTC (section 0) and VAD (section 12.3) chapters.

71. Ready-to-use feeds can be given for a whole administration session, up to a maximum of 24 hours. Reconstituted feeds should be administered over a maximum 4-hour period. [2003]

72. Administration sets and feed container are for single use and must be discarded after each feeding session. [2003]

11.5 Care of insertion site and enteral feeding tube

11.5.1 Keep the tube clear

Our systematic review searched for evidence regarding the stoma site as a source of infection. Although some evidence related to infection immediately after insertion of the first tube, we have found no evidence relating to infections in a healed stoma.[137,250] However, after the stoma site has healed, usually 10-12 days after placement, no dressings are necessary. Instead the site should be inspected and cleaned daily, and dried thoroughly. The tube should be rotated 360 degrees regularly to avoid infections related to 'buried bumper syndrome'. [239]

11.5.1.1 Recommendations

73. The stoma should be washed daily with water and dried thoroughly. [2003]

11.5.2 Review question

The following recommendation was prioritised for update to determine the most suitable type of syringe for flushing enteral tubes. The GDG identified the most important outcomes for the question as the number of blockages/ tube occlusions and fungal colonisation.

What is the clinical and cost effectiveness of single vs. reusable syringes used to flush percutaneous endoscopic gastrostomy tubes on reduction of tube blockages, diarrhoea, fungal colonisation, gastrostomy site infection, peritonitis and vomiting?

11.5.2.1 Clinical evidence

No clinical evidence was identified. No clinical evidence was identified in the previous 2003 guideline.

11.5.2.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline.

In the absence of any published cost-effectiveness analyses, current UK syringe and infection-related costs were presented to the GDG to inform decision making.

Table 76: Cost of single use and single patient use (reusable) enteral syringes

Healthcare professional	Cost per syringe (£)	Approximate cost per week (£)[(a)]
Single patient use (reusable) syringe	0.22	0.22
Single use syringe	0.16	5.60

(a) Estimate only - Based on the assumption that each reusable syringe is used for up to one week and five single use syringes are used per day.

Source: Based on average 2010 NHS Drug Tariff[184] prices.

Possible infections arising from PEG tubes include: fungal colonisation, gastrostomy site infection, and peritonitis, with symptoms ranging from vomiting and diarrhoea to bloodstream infection and sepsis. Cost and quality of life implications are potentially large.

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11.3.2.3 Evidence statements

3	Clinical	No clinical studies were identified
4	Economic	No economic studies were identified

11.5.2.4 Recommendations and link to evidence

Recommendation	**74. To prevent blockages, flush the enteral feeding tube before and after feeding or administering medications using single use syringes or single patient use (reusable) syringes according to the manufacturer's instructions. Use:** • **fresh tap water for patients who are not immunosuppressed** • **either cooled freshly boiled water or sterile water from a freshly opened container for patients who are immunosuppressed.[new 2012]**
Relative values of different outcomes	The number of blockages/ tube occlusions and fungal colonisation were considered to be the key outcomes. Diarrhoea, vomiting, peritonitis and gastrostomy site infection were also considered to be important outcomes by the GDG.
Trade off between clinical benefits and harms	Single use syringes and single patient use syringes are both deemed feasible to use in primary and community care, provided use is in accordance with manufacturer's instructions. Although the use of oral/entral syringes is associated with a risk of infection, the GDG did not consider there to be a greater risk associated with one type of syringe compared to the other. In order to address concerns over immunosuppresed patients, the GDG decided to highlight the importance of using cooled freshly boiled water or sterile water from a freshly opened container to reduce the risk of infection in this highly susceptible group.
Economic considerations	The GDG considered the difference in cost between single use syringes and single patient use (reusable) syringes. The cost and quality of life associated with acquiring an infection was also considered. Because there is an absence of evidence related to the infection rate associated with each type of oral/enteral syringe, it is not possible to evaluate which type of syringe is most cost effective. If both are equally effective, then the question becomes one of cost minimisation and the least costly option should be chosen.
Quality of evidence	No clinical or economic evidence was identified. The recommendation was formulated using GDG expert opinion.
Other considerations	Since March 2007 the National Patient Safety Agency (NPSA)[182] has advised the use of clearly labelled 'oral/enteral syringes' (popularly known as purple syringes due to their purple coloured plungers or syringe barrels) for the oral/enteral administration of liquids to reduce the risk of accidental parenteral administration. Oral/enteral syringes can be sterile or non sterile devices and may be for single use or single patient use. In the absence of evidence for any of the outcomes for the use of single and single patient use oral/enteral syringes, the GDG felt that individual patient characteristics would play a role in this decision and that the choice of syringe should be assessed on an individual basis taking into account susceptibility to infection and patient care setting. The GDG did not think that the type of solution that the tubes were flushed with should change from the recommendation in the previous guideline. The GDG considered the wording of the recommendation in the previous

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	infection control guideline and felt that restructuring the recommendation would make the advice for immunosuppressed patients clearer.

11.6 Areas for Further Research

In developing the recommendations we identified several areas that were inadequately addressed in the literature. The following recommendations for research are therefore made.

Although comprehensive data is available on the use of HETF in the United Kingdom, very little information is documented about enteral feeding practices. Anecdotal reports suggest a wide variation in practice that may or may not be safe. The use of risk assessment, including HACCP has been reported as a means of reducing risks but little is known about healthcare workers's knowledge and use of risk assessment tools.

Descriptive studies of enteral feeding practices in a range of primary care trusts. This should include healthcare workers, patients and carers, their preparation to undertake enteral feeding and ongoing support, availability and use of equipment. Data should also be collected on the incidence of stoma site infections.

A qualitative study of healthcare practitioners' understanding and use of risk assessment in practice. Ideally this should be a series of interviews with a range of healthcare workers about their knowledge of risk assessment and the tools they use. This could be applied to other areas where risk assessment is used.

Randomised control trials to assess the effectiveness of HACCP in reducing the incidence of enteral feeding related infection. These should focus on HETF in a variety of settings and involving a range of patients and healthcare workers.

11.6.1 Preparation and storage of feeds

Epidemiological studies of the incidence of clinical infection associated with reconstituting enteral feeds for different populations and in different care settings. These should at least encompass the predominant populations - older people and those with neurological deficits in both institutional and domiciliary settings and children. There needs to be clear definition of the 'cases' and the populations from which they are drawn.

11.6.2 Administration of feeds

Randomised controlled trials of single use, single patient use and reusable syringes. Outcome measures need to include rates of clinical infection, patient/carer satisfaction and cost effectiveness.

Randomised controlled trial comparing the use of cooled boiled water versus sterile water to flush enteral feeding tubes. Outcome measures need to include rates of clinical infection; patient/carer satisfaction, and cost effectiveness.

12 Vascular access devices

12.1 Introduction

The updated review questions in this chapter are:

- aseptic techniques
- types of dressings
- frequency of dressing change
- decontamination of skin when changing dressings (central and peripheral vascular access devices (VADs))
- decontamination of inserted catheter ports and hubs before access (central and peripheral VADs).

The evidence and text from the previous guideline that has been superseded by this update is included in Appendices D.6 and D.9.

New review questions included in this chapter are:

- skin decontamination prior to insertion of peripheral VADs
- single versus multiuse vials.

Sections not updated in this chapter are:

- in line filters
- antibiotic lock solutions
- system anticoagulation.

Community based infusion therapy is an increasingly viable option as technology, treatment regimes and healthcare policy advances. The various vascular access devices; peripheral cannulae (VAD inserted into an extremity whereby the catheter tip does not sit in a centrally located vein), midline catheters and central venous access devices (the catheter sits within a centrally located vein with the tip residing in the vena cava) provide options that can meet the clinical and lifestyle requirements of patients. Furthermore, in the community the insertion of peripheral VAD such as cannulae and midlines is rising. Central lines are not inserted in community settings and therefore have not been included in the review of evidence for skin decontamination prior to insertion. However, patients in the community may have long-term central VADs, and therefore all other questions related to vascular catheter management, such as skin decontamination during dressing changes and type of dressing and frequency of dressing change, have been updated to reflect this. As a result, the care and management of both peripheral and central VADs is pertinent.

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VADs are one of the most important causes of healthcare acquired infection. Millions of vascular catheters are used each year, putting large numbers of patients at risk of phlebitis and catheter-related blood stream related infection. The attributable mortality of catheter-related blood stream infections is approximately 15%, and catheter-related bloodstream infections have been associated with significant costs[157,263]. The aim of this chapter was to review the clinical and cost-effectiveness evidence for several strategies that have been found to decrease the incidence of catheter-associated infections. The GDG has prioritised two recommendations in this chapter as a key priority for implementation, see section 12.4.1.4.

Two recommendations from the 2003 version of this guideline have been removed in this update (see Appendix D.10). These deleted recommendations are already covered by recommendations in the hand hygiene (see 6.3) and PPE (see 7.4) chapters.

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12.1.1 Expert review of evidence

These guidelines are primarily based upon an expert review of evidence-based guidelines for preventing intravascular device-related infections developed at the Centers for Disease Control and Prevention (CDC) in the United States of America by the Healthcare Infection Control Practices Advisory Committee (HICPAC).[40,188] Using a validated guideline appraisal instrument developed by the AGREE collaboration,[256] three experienced appraisers independently reviewed these guidelines, taking into consideration supplementary information provided by HICPAC at our request (see Appendix D.5). We concluded that the development processes were valid and that the guidelines were: evidence-based; categorised to the strength of the evidence examined; reflective of current concepts of best practice; and acknowledged as the most authoritative reference guidelines currently available. They were subsequently recommended as the principal source of evidence for developing the guidance below.

12.2 Education of patients, carers and healthcare professionals

To improve patient outcomes and reduce healthcare costs, it is essential that everyone involved in caring for patients with CVCs is educated about infection prevention. Healthcare workers, patients and their carers need to be confident and proficient in infection prevention practices and to be equally aware of the signs and symptoms of clinical infection and how to access expert help when difficulties arise. Well-organised educational programmes that enable healthcare workers to provide, monitor, and evaluate care and to continually increase their competence are critical to the success of any strategy designed to reduce the risk of infection. Evidence reviewed by HICPAC consistently demonstrated that the risk for infection declines following the standardisation of aseptic care and increases when the maintenance of intravascular catheters is undertaken by inexperienced healthcare workers[188].

12.2.1.1 Recommendations

75. Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a vascular access device[nn]. [2003, amended 2012]

76. Healthcare workers caring for a patient with a vascular access device[nn] should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline. [2003, amended 2012]

77. Follow-up training and support should be available to patients with vascular access devices[nn] and their carers. [2003, amended 2012]

[nn] The updated recommendation contain 'vascular access device' rather than 'central venous catheter'. This change has been made because peripherally inserted catheters were included in the scope of the guideline update.

12.3 Aseptic technique

Asepsis was considered as a priority to be included in this update as this area was not included in the previous guideline. The previous guideline did refer to aseptic techniques in the recommendations, but the terminology was considered to be incorrect or out-of-date by the scoping group. This area was also highlighted many times by various stakeholders during the consultation as an area that should be included in the scope.

12.3.1 Review question

What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling vascular access devices to reduce infection related bacteraemia, phlebitis, compliance, MRSA or *C. diff* reduction and mortality?

12.3.1.1 Clinical evidence

No clinical evidence was identified. No clinical evidence was identified in the previous 2003 guideline.

12.3.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline.

12.3.1.3 Recommendations

Recommendations	78. Hands must be decontaminated before accessing or dressing a vascular access device. [new 2012]
Relative values of different outcomes	As stated in the hand hygiene recommendation regarding when to wash your hands (see section 6.3) the GDG considered the most important outcomes to be healthcare-associated infections and colony forming units (CFUs).
Trade off between clinical benefits and harms	There is no direct evidence for this recommendation and therefore this recommendation is based on GDG consensus. Hand decontamination may reduce the risk of infection. There are no obvious clinical harms to the patient for conducting this step. The evidence in section 6.3 shows that there is an increase in hand hygiene compliance before patient contact with the implementation of the WHO 5 moments and with the implementation of the CDC 2002 guideline. Catheter associated UTIs and nosocomial infections per 1000 bed days were shown to decrease with the implementation of the CDC 2002 and APIC guidelines, respectively.
Economic considerations	Vascular catheter-related infections are associated with a large cost, decreased quality of life, and high risk of mortality. The GDG agreed that the prevention of vascular catheter-associated infections is likely to offset the marginal increase in staff time and product cost associated with compliance to hand hygiene guidance.
Quality of evidence	The evidence is reviewed in section 6.3 of the hand hygiene chapter for when to decontaminate hands. Four very low quality cohort studies were identified. The population is indirect (not in community settings) and one study is based in a low income country[7]. In section 6.3, three very low to low quality RCTs were identified comparing alcohol rubs to hand washing with soap and water. All of these studies were downgraded for indirectness as they are hospital based and not in community

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	settings. These studies all had relatively small sample sizes and an imprecise estimate of effect.
Other considerations	The GDG considered that this recommendation relates to patient safety and that the consequence of not implementing it means that the risk of adverse events are so severe, that the use of the word 'must' is appropriate in line with the guidance from the NICE Guidelines Manual (2009)[180]. The GDG decided to update this recommendation to be consistent with the evidence reviewed in the hand hygiene chapter and to emphasise the importance of hand hygiene for VAD management. The GDG have removed 'either by washing with an antimicrobial liquid soap and water, or by using an alcohol handrub' from the original recommendation. Although no search was performed for this recommendation, the review questions in the hand hygiene chapter (see section 6.3) are directly relevant to this recommendation. The hygiene product that should be used to decontaminate hands is discussed in recommendation 6.3 of the hand hygiene chapter. Please refer to the hand hygiene chapter for a detailed explanation of products to use for hand decontamination. This recommendation is in line with the recommendations in the hand hygiene chapter and is included in the VAD chapter to emphasise the importance of hand hygiene. This recommendation is consistent with the 'when to wash your hands' recommendation (see section 6.3), which states 'decontaminate hands immediately before every episode of direct patient contact or care'. This recommendation is also consistent with the WHO 5 moments of hand hygiene and the potential benefit of this recommendation is the prevention of infection. A recommendation from the earlier guideline (CG02) was removed following this update: "Following hand antisepsis, clean gloves and a no-touch technique or sterile gloves should be used when changing the insertion site dressing'. The GDG considered that this recommendation was no longer required as it is already captured in the existing recommendations.

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Recommendations	**79. An aseptic technique, such as Aseptic Non Touch Technique (ANTT) must be used for vascular access device catheter site care and when accessing the system. [new 2012]**
Relative values of different outcomes	The GDG considered bacteraemia, phlebitis and MRSA and *C. diff* reduction as the most important outcomes.
Trade off between clinical benefits and harms	None of the outcomes identified as important were reported in the literature. The aim of all aseptic techniques is to prevent infection. To date, there is no evidence (RCT or cohort) that one aseptic technique is more clinically or cost-effective than another.
Economic considerations	The GDG considered the cost of staff time, training, equipment, and infections when making this recommendation. The GDG agreed that any increase in cost associated with an aseptic technique would likely be outweighed by the prevention of catheter-associated infections. The GDG thought that the difference in staff time and resource use between different aseptic techniques is likely to be minimal. Therefore, the most effective technique will also certainly be the most cost-effective.
Quality of evidence	No clinical or economic evidence was identified.
Other considerations	The GDG considered that this recommendation relates to patient safety and that the consequence of not implementing it mean that the risk of adverse events are so severe, that the use of the word 'must' is appropriate in line with the guidance from the NICE Guidelines Manual (2009)[180].

	Minor changes to this recommendation have been made during this update based on GDG consensus. The term 'vascular access device' has been inserted to avoid confusion as urinary catheters are also discussed in the guideline. This addition ensures that this recommendation can be read as a standalone recommendation. ANTT (www.antt.org.uk) was also added to this recommendation as a possible aseptic technique for VAD maintenance. It was the opinion of the GDG that standardisation of aseptic techniques would reduce confusion among healthcare workers and lead to better training about the principles of asepsis. The GDG considered that ANTT is widely used in acute and community settings and represents a possible framework for establishing aseptic guidance. The GDG felt that protocols for aseptic technique could be established in organisational policies to support this approach but did not feel that a separate recommendation was required. See also recommendations regarding asepsis discussed in the Long term urinary catheters and Enteral Feeding chapters.

12.4 Skin decontamination prior to insertion of peripheral vascular access devices

This is a new section added to the guideline as peripheral VADs are inserted in the community. Central VADs are not inserted in the community and therefore are not within the remit of this guideline. Care of VAD sites (such as changing dressings), both peripheral and central is included in section 12.5.

The following review question was prioritised for update to determine the most effective decontamination solution for skin decontamination prior to insertion of peripheral vascular access devices, as it was felt there are more types of decontamination products are available since 2003. In particular, stakeholders highlighted uncertainty regarding what is the most appropriate concentration for chlorhexidine gluconate (CHG).

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12.4.1 Review question

What is the most clinical and cost effective product or solution for decontamination of the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia, local or soft tissue infection and phlebitis?

12.4.1.1 Clinical evidence

Three RCTs were found comparing the effectiveness of different antiseptic solutions for the insertion of peripheral VADs [47,61,240]. These studies provide different levels of details about the type of antiseptic used, and the descriptions used in this section reflect the information provided in the papers. For examples, in some comparisons, the type and concentration of alcohol used is specified whereas others just noted "alcohol".

See Evidence Table G.7.5, Appendix G, Forest Plots in Figure 63-64, Appendix I

2% Iodine in 70% alcohol vs. 70% alcohol

Table 77: 2% Iodine in 70% alcohol vs. 70% alcohol – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Directness	Imprecision
VAD related phlebitis[61]	1	RCT	No serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision [(c)]
Infection related mortality	0	RCT				
Septicaemia	0	RCT				
VAD related bacteraemia	0	RCT				
VAD related local infection	0	RCT				
Catheter tip colonisation	0	RCT				
VAD line removal	0	RCT				

(a) Open label study, but randomisation and allocation concealment methods were clearly reported.
(b) Downgrading for indirectness (population among hospitalised COPD patients receiving prednisolone).
(c) Confidence intervals crossed MIDs.

Table 78: **2% Iodine in 70% alcohol vs. 70% alcohol - Clinical summary of findings**

Outcomes	2% iodine in 70% alcohol	70% alcohol	Relative risk (95% CI)	Absolute risk	Quality of evidence
VAD related phlebitis	12/54 (22.6%)	6/55 (10.6%)	2.04 (0.82, 5.04)	113 more per 1000 (20 fewer to 441 more)	LOW

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0.5% chlorhexidine gluconate(CHG) vs. povidone iodine(PVP-I) and 70% alcohol

Table 79: 0.5% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. povidone iodine (PVP-I) and alcohol – Clinical study characteristics

Outcomes	No of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related phlebitis[47]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision [(c)]
Catheter tip colonisation [47]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision [(c)]
Infection related mortality	0	RCT				
VAD related local infection	0	RCT				
Septicaemia	0	RCT				
VAD related bacteraemia	0	RCT				
VAD line removal	0	RCT				

(a) Number of patients analysed or lost to follow up not reported. Study not blinded because interventions are physically different.
(b) Large proportion of hospitalised patients in study; actual proportion of inpatients in the study not reported.
(c) Actual numbers of patients with an outcome and number of patients analysed not reported. Only the P values were reported in for some outcomes and 95% confidence intervals were not available.

Table 80: 0.5% chlorhexidine gluconate(CHG) vs. povidone iodine(PVP-I) and 70% alcohol - Clinical summary of findings

Outcome	0.5% CHG in 70% IPA	70% alcohol followed by PVP-I	PVP-I followed by 70% alcohol	Relative risk (95% CI)	Absolute effect
Catheter tip colonisation	N/R	N/R	N/R	N/R	P=0.62 (reported by authors)
VAD related phlebitis	1.2%	12.5%	9.88%	N/R	P=0.008 overall (reported by authors)

2% Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl alcohol (IPA)

Table 81: 2% Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl alcohol (IPA) - Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Directness	Precision
Infection related mortality [240]	1	RCT	Serious [(a),(b)]	No serious inconsistency	Serious indirectness[(c)]	Serious imprecision [(d)]
VAD related blood bacteraemia[240]	1	RCT	Serious [(a),(b)]	No serious inconsistency	Serious indirectness[(c)]	Serious imprecision [(d)]
VAD related local infection [240]	1	RCT	Serious [(a),(b)]	No serious inconsistency	Serious indirectness[(c)]	Serious imprecision [(d)]
Catheter tip colonisation[240]	1	RCT	Serious [(a),(b)]	No serious inconsistency	Serious indirectness[(c)]	No serious imprecision
VAD line removal[240]	1	RCT	Serious [(a),(b)]	No serious inconsistency	Serious indirectness[(c)]	Serious imprecision [(d)]
VAD related phlebitis	0					
Septicaemia	0	RCT				

(a) Methods of randomisation and allocation concealment not reported. Studies not blinded because interventions are physically different.

(b) The paper reported "no evidence of infection found". Communication with authors clarified that they looked for VAD related blood stream infection but there were no cases.

(c) Patients were hospitalised and undergoing elective cardiology interventions.

(d) Small sample size – not powered to detect a difference that reaches the minimal important difference.

Table 82: 2%Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl alcohol (IPA)- Clinical summary of findings

Outcomes	2% CHG in 70% IPA	70% IPA	Relative risk (95% CI)	Absolute risk or mean difference	Quality of evidence
Infection related mortality	0/91(0%)	0/79 (0%)	Not estimable	Not estimable	VERY LOW
VAD related bacteraemia	0/91(0%)	0/79 (0%)	Not estimable	Not estimable	VERY LOW
VAD related local infection	0/91(0%)	0/79 (0%)	Not estimable	Not estimable	VERY LOW
Catheter tip colonisation	18/91(19.8%)	39/79(49.4%)	0.40 (0.25, 0.64)	296 fewer (178 to 370 fewer)	LOW
VAD line removal	2.3 days (range 1-6 days) N=91	2.2 days (range 1-4 days) N=79	Not applicable	0.1 day	VERY LOW

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12.4.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified in the previous 2003 guideline related to this topic.

One cost-effectiveness analysis by Chaiyakunapruk and colleagues (2003)[41] was identified in this update. However, the majority of the studies used to inform clinical effectiveness parameters in this model had evaluated central VADs; the remainder were either unpublished posters or conference abstracts. Therefore, this study was excluded.

In the absence of any economic evidence which met inclusion criteria, current UK decontamination product costs and estimated infection-related costs and quality of life data were presented to the GDG to inform decision making.

Table 83: Skin decontamination product costs

Decontamination product	Average cost
7% Povidone Iodine in aqueous solution	£2.50 (per 500ml) + sterile gauze
10% Povidone Iodine in aqueous solution	£2.50 (per 500ml) + sterile gauze
0.5% Chlorhexidine in 70% isopropyl alcohol	£0.98 (per 100 6cm x 3cm wipes)
2.0% Chlorhexidine in 70% isopropyl alcohol	£90.47 (per 25 10.5ml preparations)

Source/Note: NHS Supply Catalogue 2010 [185]

Table 84: Peripheral vascular catheter infection-related costs estimates

VAD-related infection	Cost estimate	Note	Source
Catheter tip colonisation	£7	Based on the cost of a laboratory culture.	NHS Reference Costs[71]
Site infection/phlebitis	£30 to ≥ £1 000	Includes the cost of a GP consultation and course of antibiotics. In some cases a line change may be necessary, which would incur a hospital visit and possible inpatient admission.	PSSRU 2010[54], NHS Drug Tariff[184], expert opinion
Vascular catheter related blood stream infection	≥ £3 000	Based on the cost of an inpatient admission for septicaemia with intermittent complications plus the estimated cost of a line change.	NHS Reference Costs[71], expert opinion

Source/Note: The resource use used to calculate cost estimates was based on the input of the GDG and co-opted expert advisors.

Table 85: Vascular catheter infection-related quality of life estimates

Health state	Utility estimate	Note	Source
Full health	0.80	Quality of life assigned to patients with VADs in the only identified cost-utility analysis for venous access devices.	Marciante 2003[157]
Site infection/phlebitis	NR	No estimates of quality of life in people with VAD site infection or phlebitis were identified.	NR
Vascular catheter related blood stream infection	0.66	Based on an estimate of catheter-related blood stream infection/sepsis identified in the quality of life review undertaken as part of the intermittent urinary	Halton 2009[113]

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Health state	Utility estimate	Note	Source
		catheter model.	

Source/Note: *These values were presented to the GDG as rough estimates only and were not identified systematically.*

12.4.1.3 Evidence statements

Clinical

It is uncertain whether there is any difference between 2% iodine in 70% alcohol compared to 70% alcohol in VAD related phlebitis (LOW QUALITY).

None of the studies identified reported infection related mortality, septicaemia, VAD related bacteraemia, VAD related local infection, VAD line removal and catheter tip colonisation for 2% iodine in 70% alcohol compared to 70% alcohol.

There was no statistically significant difference in the number of catheter tip colonisation between 0.5% chlorhexidine gluconate(CHG) in 70% isopropyl alcohol (IPA) compared to povidone iodine (PVP-I) and alcohol applied one after another (VERY LOW QUALITY).

There were statistically significant fewer VAD related phlebitis for 0.5% CHG in 70% IPA compared to PVP-I and alcohol applied one after another (VERY LOW QUALITY).

None of the studies identified reported infection related mortality, septicaemia, VAD related bacteraemia, and VAD related local infection and VAD line removals for 0.5% CHG in 70% IPA compared to PVP-I and alcohol applied one after another.

There is a statistically significant and clinically important reduction in catheter tip colonisation among patients receiving 2% CHG in 70% IPA compared to 70% IPA.

It is uncertain whether there were any difference in infection related mortality, VAD related blood stream infection, VAD related location infections and VAD related line removal between 2% CHG in 70% IPA compared to 70% IPA.

None of the studies identified reported septicaemia, VAD related bacteraemia and VAD related phlebitis for 2% CHG compared to 70% IPA.

Economic

No economic studies were included.

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12.4.1.4 Recommendations and link to evidence

Recommendations	**80. Decontaminate the skin at the insertion site with chlorhexidine gluconate in 70% alcohol before inserting a peripheral vascular access device or a peripherally inserted central catheter. [new 2012]**
Relative values of different outcomes	The GDG considered VAD related phlebitis, infection related mortality, septicaemia and soft tissue, skin or local infections as the most important and relevant outcomes to patients. The frequency of VAD line removal and clinician time involved are also important outcomes.
Trade off between clinical benefits and harms	Reducing the risk of infections was considered the priority, balanced against the very small risk of chlorhexidine hypersensitivity. Compared to alcohol on its own or povidone iodine applied before or after 70% alcohol, the percentage of patients with phlebitis seemed to be lower for patients who used chlorhexidine gluconate in 70% alcohol. Compared to alcohol on its own, there were significantly less catheter tip colonisations for 2% chlorhexidine gluconate in alcohol. Hypersensitivities were not reported in any of the studies identified.
Economic considerations	The GDG considered the greater cost of chlorhexidine solution compared to alcohol and povidone iodine solution. The GDG agreed based on the limited clinical evidence and consensus that chlorhexidine is the most effective solution for the decontamination of skin prior to insertion of peripheral VADs and agreed that the cost savings and quality of life gain associated with preventing VAD-related infections would outweigh the incrementally greater cost of alcoholic chlorhexidine.
Quality of evidence	The amount of evidence available is very limited. For each comparison, one small RCT with low or very low quality evidence was identified. These studies had serious methodological limitations. In addition, data were collected from hospitalised patients, and may not be applicable to the community setting. The GDG reached the recommendation through analysis of the limited and low quality evidence and consensus. Although the level of uncertainty in the evidence found was high and it is difficult to conclude that one particular antiseptic solution is better than another, the trend in the evidence suggests that chlorhexidine gluconate in alcohol may be more effective than alcoholic povidone iodine solutions. There is no RCT evidence comparing different concentrations of chlorhexidine gluconate in alcohol.
Other considerations	In the absence of direct comparisons between different concentrations of chlorhexidine in alcohol it is unclear which is the most optimal concentration for the best balance of efficacy versus potential risk of chlorhexidine hypersensitivity. The GDG noted that this recommendation is consistent with current best practices of using chlorhexidine gluconate in alcohol. They also noted that the reduction of microorganisms and residual effect is higher at higher concentrations of chlorhexidine gluconate. However, the GDG chose not to specify the concentration of chlorhexidine gluconate in alcohol in this recommendation having considered the lack of specific evidence about concentrations. At the time of the development of the guidance, the GDG were aware that the American Healthcare Infection Control Practices Advisory Committee (HICPAC) guidance (available from: http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html) had previously described an effective concentration as above 0.5% for preparing skin before insertion of central and peripheral venous catheters and during dressing changes. However, the GDG felt that the evidence reviewed as part of this guideline development process did not allow for a more robust recommendation about concentration to be made at this time. The GDG

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Recommendations	80. Decontaminate the skin at the insertion site with chlorhexidine gluconate in 70% alcohol before inserting a peripheral vascular access device or a peripherally inserted central catheter. [new 2012]
	recognised this remains a pertinent issue for clinical practice and as such made a research recommendation (see section 12.11). The correct technique and volume of decontamination solution was considered critical to achieve skin decontamination, see section 6.6. The GDG also considered the practicality of the different options for skin decontamination presented by the evidence. Iodine preparation for the purpose of disinfection is usually in the form of aqueous solution. Therefore, iodine was considered as not practical in the community because it takes a longer time to dry than chlorhexidine, has residual staining and there are risks associated with iodine absorbed through the skin. The expert advisor (microbiologist) to the GDG noted that iodine preparations stain the skin, and that this staining may obscure clinical signs of infection present at the catheter site. The GDG clinical experience was that this staining may obscure the Visual Infusion Phlebitis (VIP) score, and this would be unsatisfactory clinically as evidence of infection could be missed. The GDG noted that in practice, it is important to recommend the same type of disinfectant solutions for both decontaminating the skin and also the ports and hubs. They noted that this could reduce the chance of confusion of which to solution to use. The GDG have prioritised this recommendation as a key priority for implementation as it has a high impact on outcomes that are important to patients, has a high impact on reducing variation in care and outcomes and mean patients reach critical points in the care pathway more quickly.

Update 2012

12.5 Types of vascular access device dressing

Dressings for peripherally and centrally inserted vascular access devices have been highlighted as an area for updating as it was considered that more types of dressings are now available for use, since 2003. The following question aims to determine which types of dressing for peripherally or centrally inserted vascular access device sites is the most effective at preventing healthcare-associated infections.

12.5.1 Review question

What is the clinical and cost effectiveness of dressings (transparent semipermeable, impregnated or gauze and tape) covering peripherally or centrally inserted vascular access device insertion sites, including those that are bleeding or oozing, on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and phlebitis?

12.5.1.1 Clinical evidence

Four RCTs were identified for peripherally inserted VADs [51,124,154,259]. Three studies investigated transparent semipermeable membrane (TSM) dressing vs. gauze and tape, and one study compared TSM dressings with iodophor antiseptic adhesive vs. gauze and tape [154]. No studies from the previous 2003 guideline met the inclusion criteria for this review question.

Five RCTs were identified for centrally inserted VADs [25,146,200,238,276]. One study was identified comparing highly permeable transparent membrane dressings with gauze and tape [25]. One study was identified comparing highly permeable transparent membrane dressings with TSM dressings [276].

Three studies were identified comparing TSM dressings vs. gauze and tape [146,200,238]. No studies from the previous 2003 guideline met the inclusion criteria for this review question.

No evidence was found relating to insertion sites that were bleeding or oozing.

See Evidence Table G.7.1-G.7.2, Appendix G, Forest Plots in Figure 65-76, Appendix I.

Clinical evidence for peripherally inserted VADs

Table 86: Transparent semi permeable membrane vs. gauze and tape – Clinical study characteristics; peripherally inserted VADs

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter tip colonisation [51,124]	2	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Phlebitis [124,154,259]	3	RCT	Serious limitations[(d)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Frequency of dressing change	0	RCT				
Mortality	0	RCT				
Bacteraemia	0	RCT				

(a) Unclear allocation concealment and blinding. Craven 1985 randomised catheter sites rather than patients, therefore patients were included in the study up to 8 times.
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(d) Unclear allocation concealment and blinding. Maki 1987 randomised catheter sites rather than patients, therefore patients were included in the study more than once.

Table 87: Transparent semi permeable membrane vs. gauze and tape - Clinical summary of findings; peripherally inserted VADs

Outcome	Transparent dressing	Gauze and tape	Relative risk	Absolute effect	Quality
Catheter tip colonisation	42/562 (7.5%)	34/645 (5.3%)	RR 1.46 (0.94 to 2.26)	24 more per 1000 (3 fewer to 66 more)	VERY LOW
Phlebitis	64/881 (7.3%)	67/889 (7.5%)	RR 0.96 (0.69 to 1.34)	3 fewer per 1000 (23 fewer to 26 more)	VERY LOW

Table 88: Transparent semi permeable membrane with iodophor antiseptic vs. gauze and tape – Clinical study characteristics; peripherally inserted VADs

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Phlebitis [154]	1	RCT	Serious limitations[(a)]	no serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Catheter tip colonisation	0	RCT				
Frequency of dressing change	0	RCT				
Mortality	0	RCT				

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Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Bacteraemia	0	RCT				

(a) Randomised catheter sites rather than patients, therefore patients were included in the study more than once.
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 89: Transparent semi permeable membrane with iodophor antiseptic vs. gauze and tape - Clinical summary of findings; peripherally inserted VADs

Outcome	Transparent + antiseptic	Gauze and tape	Relative risk	Absolute effect	Quality
Phlebitis	49/498 (9.8%)	50/544 (9.2%)	RR 1.07 (0.74 to 1.56)	6 more per 1000 (24 fewer to 51 more)	VERY LOW

Clinical evidence for centrally inserted VADs

Table 90: Highly permeable transparent membrane vs. gauze and tape – Clinical study characteristics; centrally inserted VADs

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter related sepsis [25]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Exit site infection [25]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Bacteraemia/fungaemia [25]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Catheter tip colonisation	0	RCT				
Frequency of dressing change	0	RCT				
Mortality	0	RCT				

(a) Unclear randomisation, allocation concealment and blinding.
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 91: Highly permeable transparent membrane vs. gauze and tape - Clinical summary of findings; centrally inserted VADs

Outcome	Highly permeable	Gauze and tape	Relative risk	Absolute effect	Quality
Catheter related sepsis	5/48 (10.4%)	1/53 (1.9%)	RR 5.52 (0.67 to 45.59)	85 more per 1000 (6 fewer to 841 more)	VERY LOW
Exit site infection	4/48 (8.3%)	2/53 (3.8%)	RR 2.21 (0.42 to 11.52)	46 more per 1000 (22 fewer to 397 more)	VERY LOW
Bacteraemia/ fungaemia	3/48 (6.3%)	6/53 (11.3%)	RR 0.55 (0.15 to 2.09)	51 fewer per 1000 (96 fewer to 123 more)	VERY LOW

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Table 92: Highly permeable transparent membrane vs. transparent semi permeable membrane – Clinical study characteristics; centrally inserted VADs

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter related sepsis [276]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Catheter tip colonisation	0	RCT				
Frequency of dressing change	0	RCT				
Mortality	0	RCT				
Skin infection	0	RCT				

(a) Unclear randomisation, allocation concealment and blinding.
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 93: Highly permeable transparent membrane vs. transparent semi permeable membrane - Clinical summary of findings; centrally inserted VADs

Outcome	Highly permeable	Semipermeable	Relative risk	Absolute effect	Quality
Catheter related sepsis	1/51 (2%)	3/50 (6%)	RR 0.33 (0.04 to 3.04)	40 fewer per 1000 (58 fewer to 122 more)	VERY LOW

Table 94: Transparent semi permeable membrane vs. gauze and tape – Clinical study characteristics; centrally inserted VADs

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter related sepsis[238]	1	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
Exit-site infection [146,200,238]	3	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Bacteraemia[146]	1	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision [(c)]
Catheter tip colonisation	0	RCT				
Frequency of dressing change	0	RCT				
Mortality	0	RCT				

(a) Unclear allocation concealment, blinding and randomisation
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.
(d) Unclear allocation concealment and blinding.

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Table 95: Transparent semi permeable membrane vs. gauze and tape - Clinical summary of findings; centrally inserted VADs

Outcome	Transparent	Gauze and tape	Relative risk	Absolute effect	Quality
Catheter related sepsis	1/51 (2%)	0/47 (0%)	RR 2.77 (0.12 to 66.36)	0 more per 1000 (0 fewer to 0 more)	VERY LOW
Exit-site infection	6/87 (6.9%)	3/83 (3.6%)	RR 1.81 (0.54 to 6.1)	29 more per 1000 (17 fewer to 184 more)	VERY LOW
Bacteraemia	1/29 (3.4%)	2/29 (6.9%)	RR 0.5 (0.05 to 5.21)	34 fewer per 1000 (66 fewer to 290 more)	VERY LOW

12.5.1.2 Cost-effectiveness evidence for peripherally inserted VADs

No economic evidence was identified in the update search. No studies from the previous 2003 guideline met the inclusion criteria for this review question.

This topic was originally identified as a high-priority area for original economic modelling. However, after reviewing the clinical evidence it was decided that there was insufficient comparative clinical evidence to inform a cost-effectiveness model. In addition, the GDG did not consider each of the dressings to represent true alternatives; certain dressings were considered to be more appropriate for certain clinical indications than others.

In the absence of cost-effectiveness evidence, the GDG were presented with current UK dressing costs and estimates of infection-related costs (see Table 84) to inform decision making.

Update 2012

Table 96: Cost of dressings for centrally and peripherally inserted VADs

	Sterile gauze	Transparent	Chlorhexidine
Cost per dressing (£)[(a)]	0.06	0.97	4.38
Number of dressings per box	5	50	10
Dispensing fee per box (£)	1.95	1.95	1.95

(a) For mid-size dressings measuring approximately 10cm x 12cm (transparent, gauze) or 2.4cm in diameter (chlorhexidine).

Source: Based on average 2010 NHS Drug Tariff [184] and Supply Chain [185] prices

12.5.1.3 Cost-effectiveness evidence for centrally inserted VADs

Three studies were identified in the update search. One study was a cost analysis by Crawford et al (2004)[52] comparing chlorhexidine dressings to 'standard' dressings in patients with central venous catheters. The other two were RCTs comparing the use of TSM dressings and gauze dressings in patients undergoing bone marrow transplant[238] and haemodialysis[146].

For a list of excluded studies and reasons for exclusion, refer to Appendix L.

No studies from the previous 2003 guideline met the inclusion criteria for this review question.

Table 97: Chlorhexidine dressing vs. transparent semi permeable membrane dressing - Economic summary of findings; centrally inserted VADs

Study	Limitations	Applicability	Other Comments
Crawford 2004 [52]	Potentially serious [(a)]	Partially applicable [(b)]	Central line dressing Hospital setting

(a) Clinical evidence based on an unpublished, industry funded trial which is not publicly available, time horizon is unclear, risk of mortality from CRBSI is not accounted for, costs not reported incrementally
(b) Hospital based setting (specific ward and patient population not reported), definition of 'standard' dressing unclear and assumed to refer to transparent dressings, USA hospital perspective, industry funded study.

Table 98: Transparent semi permeable membrane dressing vs. gauze dressing - Economic summary of findings; centrally inserted VADs

Study	Limitations	Applicability	Other Comments
Shivnan 1991 [238]	Potentially serious [(a)]	Partially applicable [(b)]	Central line dressing Bone marrow transplant patients
Le Corre 2003 [146]	Potentially serious [(c)]	Partially applicable [(d)]	Central line dressing Haemodialysis

(a) Cost of infection not accounted for, industry funded study.
(b) Hospital based setting, USA hospital perspective.
(c) Cost of infection not accounted for, industry funded study.
(d) Hospital based setting, Canadian healthcare system perspective.

Table 99: Chlorhexidine vs. transparent - Economic summary of findings; centrally inserted VADs

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Crawford 2004[52]	N/R [(a)]	Chlorhexidine dressings were associated with fewer site infections (28.14% vs. 45.24%) and catheter-related BSI (2.37% vs. 6.12%)	N/R	Based on a series of scenario analyses, it was estimated that chlorhexidine dressings were associated with £327 to £965 cost savings due to decreased infection [(b)]

(a) Cost of transparent dressing not reported, therefore it was not possible to analyse costs incrementally.
(b) Note that cost of transparent dressings is not reported, therefore it is not possible to determine true incremental costs; costs adjusted to 2009/10 GBP; four scenario analyses were run in which the cost of treating a blood stream infection was alternated

Table 100: Transparent vs. gauze - Economic summary of findings; centrally inserted VADs

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Shivnan 1991[238]	Transparent dressings were £137 less costly in terms of dressing materials and nurse time (per patient per 30 days)	Transparent dressings were associated with a small increase in local infection (3.9% vs. 2.1%) and bacteraemia (1.9% vs. 0.0%)	N/A	N/A
Le Corre 2003[146]	Transparent dressings were £3.11 less costly (per patient per week)	Transparent dressings were associated with a decrease in local infection (3.5% vs. 10.3%) and bacteraemia (3.5% vs 7%)	Transparent dressings were the dominant intervention	N/A

Update 2012

Table 101: Central vascular catheter infection-related costs estimates

VAD-related infection	Cost estimate	Note	Source
Catheter tip colonisation	£7	Based on the cost of a laboratory culture.	NHS Reference Costs[71]
Site infection/phlebitis	£3 000	Based on GDG estimate of the cost of a central line change, antibiotics and inpatient potential admission.	Expert opinion
Vascular catheter related blood stream infection	£9 148	Estimate of the cost of central venous catheter blood stream infection identified in a recent HTA	Hockenhull 2008[123]

Source/Note: The resource use used to calculate cost estimates was based on the input of the GDG and co-opted expert advisors.

12.5.1.4 Evidence statements

Clinical

It is uncertain whether there is any difference in catheter tip colonisation or phlebitis with transparent semipermeable membrane dressing compared to gauze and tape for peripherally inserted VADs. (VERY LOW QUALITY)

It is uncertain whether there is any difference in phlebitis with transparent semipermeable membrane with iodophor antiseptic in the adhesive compared to gauze and tape for peripherally inserted VADs. (VERY LOW QUALITY)

It is uncertain whether there is any difference in catheter related sepsis, exit site infection, bacteraemia/fungaemia with highly permeable transparent membrane compared to gauze and tape for centrally inserted VADs. (VERY LOW QUALITY)

It is uncertain whether there is any difference in catheter related sepsis with highly permeable transparent membrane compared to transparent semipermeable membrane dressings for centrally inserted VADs. (VERY LOWQUALITY)

It is uncertain whether there is any difference in catheter related sepsis, exit site infection or bacteraemia with transparent semipermeable membrane compared to gauze for centrally inserted VADs. (VERY LOW QUALITY)

No studies were identified that reported frequency of dressing change or VAD related mortality.

Economic

No studies were identified for peripherally inserted VADs

In patients with centrally inserted VADs, transparent semipermeable membrane dressings appear to be cost-saving in terms of materials and nursing time (POTENTIALLY SERIOUS LIMITATIONS AND PARTIAL APPLICABILITY).

Chlorhexidine dressings may be cost-effective compared to transparent semipermeable membrane dressings (POTENTIALLY SERIOUS LIMITATIONS AND PARTIAL APPLICABILITY).

Update 2012

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12.3.1.5 Recommendations and link to evidence

Recommendations	81. Use a sterile, transparent semipermeable membrane dressing to cover the vascular access device insertion site. [new 2012]
Relative values of different outcomes	Catheter tip colonisation, infection-related mortality, septicaemia, VAD related bacteraemia, phlebitis and skin infections were considered to be the most important outcomes by the GDG.
Trade off between clinical benefits and harms	Although the review did not provide evidence of any significant difference in clinical outcomes, the GDG thought that transparent semipermeable membrane dressings (TSM) dressings provide a more secure fix compared to gauze and tape, allowing them to be kept in place for longer, whilst also allowing staff to inspect the VAD insertion site for signs of infection without removing the dressing. The GDG noted that gauze dressings provide absorbency, but do not provide visibility or maintain sterility of the VAD insertion site. From an equalities perspective, the GDG noted that TSM dressings are well tolerated in clinical care, including paediatrics and elderly patients.
Economic considerations	The GDG considered the cost of dressings, staff time, and consequences of infections associated with peripheral and centrally inserted VADs. The GDG agreed that TSM dressings appear to be less costly and more effective compared to gauze dressings. In the absence of any evidence to the contrary, the GDG did not think that compared to TSM dressings, chlorhexidine dressings would be sufficiently effective to justify the greater cost of these dressings in routine care in the community (the economic study identified for this question was considered to be of very low quality and not directly relevant to the community care setting).
Quality of evidence	The identified studies were of very low quality. They were downgraded due to: limitations in study design; indirectness as no community data was identified; and imprecision due to wide confidence intervals and low event numbers. No clinical evidence was identified for dressings on bleeding or oozing VAD insertion sites. No clinical evidence was identified for silver- or chlorhexidine-impregnated dressings. Cost-effectiveness evidence from two low quality studies was considered. Neither study included all relevant comparators, costs, or outcomes.
Other considerations	Dressing adherence and water resistance were considered important issues in community settings as patients place a high value on being able to conduct their daily tasks, such as showering and washing. The GDG considered that a recommendation to use TSM dressings addressed these concerns

Update 2012

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4

Recommendations	82. Only consider a sterile gauze dressing covered with a sterile, transparent semipermeable membrane dressing if the patient has profuse perspiration, or if the vascular access device insertion site is bleeding or oozing. If a gauze dressing is used: • change it every 24 hours, or sooner if it is soiled and • replace it with a transparent semipermeable membrane dressing as soon as possible. [new 2012]
Relative values of different outcomes	The GDG considered VAD related phlebitis as the most important outcome. They also considered dressing change or frequency of dressing change, infection-related mortality, septicaemia, VAD related bacteraemia, phlebitis and skin infections as important outcomes.
Trade off between clinical benefits and harms	The advantage of a gauze dressing is its absorbency, which is required when the site is oozing or bleeding. The trade offs are that it is more complex to apply (requires tape over the top), provides less secure fixation of the VAD and requires more frequent dressing changes than TSM dressings alone. It also allows less visibility, meaning that a Visual Infusion Phlebitis (VIP) score can only be undertaken during a gauze dressing change.
Economic considerations	In patients with bleeding or oozing insertion sites, the GDG agreed that sterile gauze dressings represent the only appropriate type of dressing. Under these circumstances the GDG thought that the use of any other type of dressing would represent an inefficient use of resources.
Quality of evidence	No clinical evidence was identified for dressings on bleeding or oozing VAD insertion sites or for frequency of gauze dressing changes. No relevant cost-effectiveness studies were identified.
Other considerations	The GDG were aware that skin damage from tape used to hold gauze in place may be caused, particularly in patients with sensitive or fragile skin. They felt gauze dressings should be changed to TSM dressings as soon as possible when there was no bleeding or oozing from the site. Where gauze dressings continued to be necessary the GDG considered by consensus that they should be changed at least every 24 hours.

Update 2012

12.6 Vascular access device frequency of dressing change

The following question aims to determine the most appropriate frequency of dressing change for peripherally or centrally inserted vascular access device sites with the aim of preventing healthcare-associated infections.

12.6.1 Review question

What is the clinical and cost effectiveness of frequency of dressing change (from daily up to 7 days) on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and phlebitis?

12.6.1.1 Clinical evidence

One RCT was identified for frequency of dressing change that compared semipermeable transparent polyurethane dressing changed once weekly vs. twice weekly[264]. No studies from the previous 2003 guideline met the inclusion criteria for this review question.

See Evidence Table G.7.3, Appendix G, Forest Plots in Figure 75-76, Appendix I

Table 102: Once weekly vs. twice weekly dressing changes – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Positive blood culture[264]	1	RCT	Serious limitations[(a)]	No serious inconsistency	Serious indirectness[(b)]	Serious imprecision[(c)]
CVC insertion site inflammation[264]	1	RCT	Serious limitations [(a)]	No serious inconsistency	Serious indirectness [(b)]	Serious imprecision[(c)]
Catheter tip colonisation	0	RCT				
Mortality	0	RCT				
Phlebitis	0	RCT				

(a) Only 58% of the dressing changes were performed to protocol for the intervention (mean interval was 5.4 days, instead of 7 days) and 80% of the changes were performed to protocol for the control/twice weekly change (with a mean interval of 3.8 days
(b) The studies are all hospital based rather than community settings.
(c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it difficult to know the true effect size for this outcome.

Table 103: Once weekly vs. twice weekly dressing changes - Clinical summary of findings

Outcome	Once weekly	Twice weekly	Relative risk	Absolute effect	Quality
Positive blood culture	8/39 (20.5%)	9/42 (21.4%)	RR 0.96 (0.41 to 2.23)	9 fewer per 1000 (126 fewer to 264 more)	VERY LOW
CVC insertion site inflammation	10/39 (25.6%)	23/42 (54.8%)	RR 0.47 (0.26 to 0.85)	290 fewer per 1000 (82 fewer to 405 fewer)	VERY LOW

Update 2012

12.5.1.2 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline. In the absence of any published cost-effectiveness analyses, current UK dressing costs, staff costs and infection-related cost estimates (Table 84 and Table 101) were presented to the GDG to inform decision making.

Table 104: Healthcare staff costs

Healthcare professional	Cost per home visit (£)
Community health visitor	35
GP practice nurse	13
Community clinical support nurse	9

Source/Note: PSSRU 2007 [56].

12.6.1.3 Evidence statements

Clinical

There is a statistically significant decrease of uncertain clinical importance in central venous catheter insertion site inflammation when changing transparent semipermeable membrane dressings once weekly compared to twice weekly. (VERY LOW QUALITY)

It is uncertain whether there is any difference in positive blood cultures when changing transparent semipermeable membrane dressings once weekly compared to twice weekly. (VERY LOW QUALITY)

No studies were identified that reported catheter tip colonisation, phlebitis or VAD related mortality.

Economic — No economic studies were identified.

12.6.1.4 Recommendations and link to evidence

Recommendations	83. Change the transparent semipermeable membrane dressing covering a central venous access device insertion site every 7 days or sooner if the dressing is no longer intact or moisture collects under it. [2012]
Relative values of different outcomes	Catheter tip colonisation, infection-related mortality, septicaemia, VAD related bacteraemia, phlebitis and skin infections were considered to be the most important outcomes.
Trade off between clinical benefits and harms	Transparent dressings provide a more secure fix allowing them to be kept in place for longer, whilst also allowing staff to inspect the VAD insertion site for signs of infection without removing the dressing. Transparent dressings are well tolerated in clinical care, including paediatrics and elderly care. One study[264] met the inclusion criteria and identified that longer periods between dressing changes (a mean interval of 5.4 days vs. 3.8 days) showed a significant reduction in central venous catheter insertion site inflammation and no difference in positive blood cultures.
Economic considerations	The GDG agreed that less frequent dressing changes would be cost saving in terms of staff time, resource use, and infection prevention than more frequent dressing changes.
Quality of evidence	Evidence from one RCT was considered, which was of very low quality. This was downgraded due to: limitations in study design; indirectness as no community data was identified; and imprecision due to wide confidence intervals and low event numbers. No clinical evidence was identified for frequency of dressing changes at bleeding or oozing VAD insertion sites. No relevant cost-effectiveness studies were identified. This recommendation was by GDG consensus.
Other considerations	Dressing adherence and water resistance were considered important issues in the community to enable patients to conduct their daily tasks, such as showering and washing. Therefore, it is important to consider the balance between maintaining an intact dressing and independence for patients to perform daily tasks and any impact of frequent nursing care on restriction of freedom.

Update 2012

Recommendations	84. Leave the transparent semipermeable membrane dressing applied to a peripheral cannula insertion site in situ for the life of the cannula, provided that the integrity of the dressing is retained. [new 2012]
Relative values of different outcomes	The GDG considered VAD related phlebitis as the most important outcome. They also considered dressing change or frequency of dressing change, infection-related mortality, septicaemia, VAD related bacteraemia, phlebitis and skin infections as important outcomes.
Trade off between clinical benefits and harms	The advantage of leaving insertion sites intact is that the risk of infection is reduced. No harms were identified, but dressings that are no longer intact should be replaced as soon as possible to reduce the risk of infection.

Recommendations	84. Leave the transparent semipermeable membrane dressing applied to a peripheral cannula insertion site in situ for the life of the cannula, provided that the integrity of the dressing is retained. [new 2012]
Economic considerations	It was the opinion of the GDG that less frequent dressing changes would be cost saving in terms of staff time, resource use, and infection prevention compared to more frequent dressing changes.
Quality of evidence	No clinical evidence was found for frequency of dressing changes for peripheral catheters. No relevant cost-effectiveness studies were identified.
Other considerations	The GDG discussed that appropriate patient education is needed to ensure that dressings are not tampered with or picked at in order to minimise the risk of infection. The GDG made this recommendation based on consensus opinion as no evidence was identified. In practice, transparent semipermeable membrane dressings applied to peripheral cannulae are left on for the life of the cannula; a 72 hour cut off time is common and extension beyond that requires a robust clinical rationale. In the absence of any contradictory evidence, the GDG agreed that this time-limit was appropriate. The GDG noted that the Department of Health Saving lives: reducing infection, delivering clean and safe care, peripheral intravenous cannula care bundle [66] also recommends that cannulae should be replaced in a new site after 72-96 hours or earlier if indicated clinically.

Update 2012

85. Dressings used on tunnelled or implanted central venous catheter sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner. [2003]

12.7 Decontaminating skin when changing dressings

The following review question was prioritised for update to determine the most effective decontamination solution for skin when changing dressings, as it was felt there are more types of decontamination products available since 2003. In particular, stakeholders highlighted uncertainty regarding what is the most appropriate concentration for chlorhexidine gluconate (CHG).

12.7.1 Review question

What is the most clinical and cost effective product or solution for skin decontamination when changing VAD dressings on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?

What is the most clinical and cost effective duration of application of decontamination product/solution to the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia, local or soft tissue infection and phlebitis?

12.7.1.1 Clinical evidence

Five RCTs which compared the effectiveness of different antiseptic solutions for the decontamination of skin during dressing changes were found. This included studies conducted in patients receiving central venous catheters. See Evidence Table G.7.4, Appendix G, Forest Plots in Figure 77-95, Appendix. The comparisons identified are shown below.

These studies provide different levels of details about the type of antiseptic used, and the descriptions used in this section reflect the information provided in the papers. For examples, in some comparisons, the type and concentration of alcohol used is specified whereas others just noted "alcohol".

Table 105: Number of RCTs comparing different types of antiseptic solutions

	2% CHG in aqueous	0.5% CHG in alcohol	0.25% CHG aqueous*	10% PVP-I in aqueous	5% PVP-I in 70% alcohol
0.5% CHG in alcohol	1 [261]				
0.25% CHG in aqueous*	None	None			
10% PVP-I in aqueous	2 [155,261]	2 [127,261]			
5% PVP-I in 70% alcohol	None	None	1 [169]	1 [192]	
70% isopropyl alcohol (IPA)	1 [155]	None	None	1 [155]	None

*** This aqueous solution contains 0.25% chlorhexidine gluconate, 0.025 benzalkanium chloride, and 4% benzylic alcohol (Biseptine TM, Bayer)*

Update 2012

2% Chlorhexidine gluconate (CHG) in aqueous vs. 10% Povidone Iodine (PVP-I) in aqueous

Table 106: 2 % Chlorhexidine gluconate (CHG) in aq vs 10% Povidone Iodine (PVP-I) in aq – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia[155,261]	2	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related septicaemia[261]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation[155,261]	2	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related local infection	0	RCT				
VAD related phlebitis	0	RCT				
Infection related mortality	0	RCT				
VAD line removal	0	RCT				

(a) Block randomisation followed by physically different interventions (not blinded) – unclear whether there were adequate allocation concealment methods[261], randomisation (done per catheter instead of patients) sequence generation and allocation concealment unclear[155].

(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 107: 2 % Chlorhexidine gluconate (CHG) in aqueous vs. 10% Povidone Iodine (PVP-I) in aqueous-clinical summary of findings

Outcome	2% CHG in aqueous	10% PVP-I in aqueous	Relative risk	Absolute effect	Quality
VAD related bacteraemia[(a)]	10/425 (2.4%)	15/421 (3.6%)	RR 0.63 (0.29 to 1.41)	13 fewer per 1000 (25 fewer to 15 more)	LOW
VAD related septicaemia[(a)]	17/211 (8.1%)	19/194 (9.8%)	RR 0.82 (0.44 to 1.54)	18 fewer per 1000 (55 fewer to 53 more)	LOW
Catheter tip colonisation[(a)]	135/543 (24.9%)	179/556 (32.2%)	RR 0.76 (0.64 to 0.90)	77 fewer per 1000 (32 fewer to 116 fewer)	LOW

(a) Studies reported outcomes per catheter, instead of per patient.

Update 2012

2% Chlorhexidine gluconate (CHG) in aqueous vs. 70% Isopropyl alcohol (IPA)

Table 108: 2% chlorhexidine gluconate (CHG) in aqueous vs 70% isopropyl alcohol (IPA) – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [155]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [155]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related phlebitis	0	RCT				
VAD related local infection	0	RCT				
Infection	0	RCT				

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
related mortality						
Septicaemia	0	RCT				
VAD line removal	0	RCT				

(a) Randomisation sequence generation and allocation concealment methods unclear, randomised per catheter instead or per patient.
(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 109: 2% chlorhexidine gluconate (CHG) in aqueous vs. 70% Isopropyl alcohol (IPA)

Outcome	2% CHG in aqueous	70% IPA	Relative risk	Absolute effect	Quality
VAD related bacteraemia [(a)]	1/214 (0.5%)	3/227 (1.3%)	RR 0.35 (0.04 to 3.37)	9 fewer per 1000 (13 fewer to 31 more)	LOW
Catheter tip colonisation [(a)]	5/214 (2.3%)	11/227 (4.8%)	RR 0.48 (0.17 to 1.36)	25 fewer per 1000 (40 fewer to 17 more)	LOW

(a) Studies reported outcomes per catheter, instead of per patient

2 % Chlorhexidine gluconate (CHG) in aqueous vs. 0.5% Chlorhexidine gluconate (CHG) in alcohol

Table 110: 2 % Chlorhexidine gluconate (CHG) in aq vs 0.5% CHG in alcohol – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [261]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related septicaemia [261]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [261]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related local infection	0	RCT				
VAD related phlebitis	0	RCT				
Infection related mortality	0	RCT				
VAD line removal	0	RCT				

(a) Block randomisation followed by physically different interventions (not blinded) – unclear whether there were adequate allocation concealment methods
(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 111: 2 % Chlorhexidine gluconate (CHG) in aqueous vs. 0.5% Chlorhexidine gluconate (CHG) in alcohol– Clinical summary of findings

Outcome	2% CHG in aqueous	0.5% CHG in alcohol	Relative risk	Absolute effect	Quality
Catheter tip colonisation [(a)]	130/329 (39.5%)	119/339 (35.1%)	RR 1.13 (0.92 to 1.37)	46 more per 1000 (28 fewer to 130 more)	LOW
VAD related septicaemia [(a)]	17/211 (8.1%)	15/226 (6.6%)	RR 1.21 (0.62 to 2.37)	14 more per 1000 (25 fewer to 91 more)	LOW
VAD related bacteraemia [(a)]	9/211 (4.3%)	9/226 (4%)	RR 1.07 (0.43 to 2.65)	3 more per 1000 (23 fewer to 66 more)	LOW

Update 2012

(a) Studies reported outcomes per catheter, instead of per patient

0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in aqueous

Table 112: 0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in aqueous – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [127,261]	2	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related local infection [127]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [127,261]	2	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related phlebitis	0	RCT				
Infection related mortality	0	RCT				
Septicaemia	0	RCT				
VAD line removal	0	RCT				

(a) Randomisation sequence generation and allocation concealment methods unclear
(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 113: 0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in aqueous – Clinical summary of findings

Outcome	2% CHG in IPA	10% PVP-I in aqueous	Relative risk	Absolute effect	Quality
Catheter tip colonisation [(a)]	155/455 (34.1%)	185/445 (41.6%)	RR 0.82 (0.69 to 0.97)	75 fewer per 1000 (12 fewer to 129 fewer)	LOW
VAD related bacteraemia [(a)]	13/419 (3.1%)	14/375 (3.7%)	RR 0.82 (0.39 to 1.72)	7 fewer per 1000 (23 fewer to 27 more)	LOW
VAD related local infection [(a)]	0/193 (0%)	4/181 (2.2%)	RR 0.1 (0.01 to 1.92)	20 fewer per 1000 (22 fewer to 20 more)	LOW

(a) Studies reported outcomes per catheter, instead of per patient

10% Povidone iodine (PVP-I) in aqueous vs. 5% Povidone iodine (PVP-I) in 70% ethanol

Table 114: 10% Povidone iodine (PVP-I) in aqueous vs. 5% Povidone iodine (PVP-I) in 70% ethanol – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [192]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [192]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related local infection [192]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related phlebitis	0	RCT				
Infection related mortality	0	RCT				
Septicaemia	0	RCT				

Update 2012

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD line removal	0	RCT				

(a) Number of patients randomised into each arm unclear (only reported a total of 125 patients). The denominators reported in this study are number of catheters, instead of number of patients.
(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 115: 10% Povidone iodine (PVP-I) in aqueous vs. 5% Povidone iodine (PVP-I) in 70% ethanol – clinical summary of findings

Outcome	10% PVP-I in aqueous	5% PVP-I alcohol	Relative risk	Absolute effect	Quality
Catheter tip colonisation [(a)]	41/117 (35%)	14/106 (13.2%)	RR 2.65 (1.54 to 4.58)	218 more per 1000 (71 more to 473 more)	LOW
VAD related bacteraemia [(a)]	4/117 (3.4%)	1/106 (0.9%)	RR 3.62 (0.41 to 31.91)	25 more per 1000 (6 fewer to 292 more)	LOW
VAD related local infection [(a)]	0	0	not pooled	not pooled	LOW

(a)The denominators reported in this study are number of catheters, instead of number of patients.

<u>10% Povidone Iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA)</u>

Table 116: 10% Povidone Iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA) – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [155]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [155]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related phlebitis	0	RCT				
VAD related local infection	0	RCT				
Infection related mortality	0	RCT				
Septicaemia	0	RCT				
VAD line removal	0	RCT				

(a) Randomisation sequence generation and allocation concealment methods unclear
(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 117: 10% Povidone Iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA) – Clinical summary of findings

Outcome	10% PVP-I in aqueous	70% IPA	Relative risk	Absolute effect	Quality
Catheter tip colonisation	21/227 (9.3%)	11/227 (4.8%)	RR 1.91 (0.94 to 3.87)	44 more per 1000 (3 fewer to 139 more)	LOW
VAD related bacteraemia	6/227 (2.6%)	3/227 (1.3%)	RR 2 (0.51 to 7.9)	13 more per 1000 (6 fewer to 91 more)	LOW

(a) Studies reported outcomes per catheter, instead of per patient

Update 2012

0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkanium chloride, and 4% benzylic alcohol in vs. 5% PVP in 70% alcohol

Table 118: 0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkanium chloride, and 4% benzylic alcohol in aq vs 5% PVP-I in 70% alc – Clinical study characteristics

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia [169]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
Catheter tip colonisation [169]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related phlebitis [169]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD line removal[169]	1	RCT	Serious limitations [(a)]	No serious inconsistency	No serious indirectness	Serious imprecision [(b)]
VAD related septicaemia	0	RCT				
VAD related local infection	0	RCT				
Infection related mortality	0	RCT				

(a) Unit of randomisation is catheter, instead of patent. The study randomised consecutively inserted central venous catheters, stratified by insertion site in blocks of 8. Allocation concealment potentially compromised

(b) Confidence intervals wide- crossed threshold of clinically important harms and benefits

Table 119: 0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkanium chloride, and 4% benzylic alcohol in aqueous vs. 5% PVP in 70% alcohol– Clinical summary of findings

Outcome	0.25% CHG mixture in aqueous	5% PVP-I in 70% alcohol	Relative risk	Absolute effect	Quality
Catheter tip colonisation[(a)]	28/242 (11.6%)	53/239 (22.2%)	RR 0.52 (0.34 to 0.8)	106 fewer per 1000 (from 44 fewer to 146 fewer)	LOW
VAD related bacteraemia[(a)]	4/242 (1.7%)	10/239 (4.2%)	RR 0.4 (0.13 to 1.24)	25 fewer per 1000 (from 36 fewer to 10 more)	LOW
VAD related phlebitis[(a)]	64/242 (26.4%)	64/239 (26.8%)	0.99 [0.73, 1.33]	268 fewer per 1000 (from 268 fewer to 268 fewer)	LOW
VAD line removal - mean duration of catheter placement [(a)]	242 catheters	239 catheters	-	MD 0.1 lower (1.74 lower to 1.54 higher)	LOW

The study randomised and reported outcomes per catheter, instead of per patient.

Update 2012

12.7.1.2 Evidence statements

Clinical

2% chlorhexidine gluconate (CHG) in aqueous vs. 10% povidone iodine (PVP-I) in aqueous

There is a statistically significant reduction of uncertain clinically importance in the number of catheter tip colonisation for 2% CHG in aqueous compared to 10% PVP-I in aqueous (LOW QUALITY).

It is uncertain whether there is any difference in number of VAD related bacteraemia and VAD related septicaemia for 2% CHG in aqueous compared to 10% PVP-I in aqueous(LOW QUALITY).

None of the studies identified reported VAD related phlebitis, VAD related local infection, VAD line removal frequency, and infection related mortality for2% CHG aqueous compared to 10% PVP-I in aqueous.

2% chlorhexidine gluconate (CHG) in isopropyl aqueous vs. 70% isopropyl alcohol

It was uncertain whether there is any difference in the number VAD related bacteraemia and catheter tip colonisation for 2% CHG in aqueous compared to 70% isopropyl alcohol (LOW QUALITY).

None of the studies identified reported VAD related phlebitis, VAD related local infection, septicaemia, VAD line removal frequency, and infection related mortality for 2% CHG in aqueous compared to 70% isopropyl alcohol.

2% chlorhexidine gluconate (CHG) in aqueous vs. 0.5% chlorhexidine gluconate (CHG) in alcohol

It was uncertain whether there is any difference in the number VAD related bacteraemia, VAD related septicaemia and catheter tip colonisation for 2% CHG in aqueous compared to 0.5% CHG in alcohol (LOW QUALITY).

None of the studies identified reported VAD related phlebitis, VAD related local infection, VAD line removal frequency, and infection related mortality for 2% CHG in aqueous compared to 0.5% CHG in alcohol.

0.5% chlorhexidine gluconate (CHG) in alcohol vs. 10% povidone iodine (PVP-I) in aqueous

It was uncertain whether there is any difference in number of VAD related bacteraemia and VAD related local infection for 0.5% CHG in alcohol compared to 10% PVP-I in aqueous (LOW QUALITY).

There is a statistically significant decrease of uncertain clinical importance in the number of patient with catheter tip colonisation for 0.5% CHG in alcohol compared to 10% PVP-I in aqueous (LOW QUALITY).

None of the studies identified reported VAD related phlebitis, septicaemia, VAD line removal frequency, and infection related mortality for 0.5% CHG in alcohol compared to 10% PVP-I in aqueous.

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	10% povidone iodine (PVP-I) in aqueous vs. 5% povidone iodine(PVP-I) in 70% ethanol It was uncertain whether there is any difference in number of VAD related bacteraemia for 10% (PVP-I) in aqueous compared to 5% PVP-I in 70% ethanol (LOW QUALITY). There is a statistically significant and clinically important increase in number of patient with catheter tip colonisation for 10% PVP-I in aqueous compared to 5% PVP-I in 70% ethanol (LOW QUALITY). None of the studies identified reported VAD related phlebitis, septicaemia, VAD line removal frequency, and infection related mortality for 10% PVP-I in aqueous compared to 5% PVP-I in 70% ethanol. **10% povidone iodine (PVP-I) vs. 70% isopropyl alcohol (IPA)** It was uncertain whether there is any difference in number of VAD related bacteraemia and catheter tip colonisation for 10% PVP-I in aqueous compared to 70% isopropyl alcohol (LOW QUALITY). None of the studies identified reported VAD related phlebitis, VAD related local infection, septicaemia, VAD line removal frequency, and infection related mortality for 10% PVP-I in aqueous compared to 70% isopropyl alcohol. **0.25% chlorhexidine gluconate (CHG), 0.025% benzalkanium chloride and 4% benzylic alcohol in aqueous vs. 5% povidone iodine (PVP-I) in 70% alcohol** It is uncertain whether there is any difference in number of VAD related bacteraemia or VAD related phlebitis, and in the VAD line removal (measured as duration of catheter placement) for a proprietary solution containing a combination of 0.25% CHG and other disinfectants compared to 5% PVP-I in alcohol (LOW QUALITY). There is a statistically significant decrease of uncertain clinical importance in the number of patient with catheter tip colonisation for a proprietary solution containing a combination of 0.25% CHG and other disinfectants compared to 5% PVP-I in alcohol (LOW QUALITY). None of the studies identified reported VAD related local infection, VAD related phlebitis, VAD line removal frequency, and infection related mortality for 0.25% CHG and other disinfectants compared to 5% PVP-I in alcohol.
Economic	No economic evidence was identified.

Update 2012

12.7.1.3 Recommendations and link to evidence

86. Healthcare workers should ensure that catheter-site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations. [2003]

Recommendations	**87. Decontaminate the catheter insertion site and surrounding skin during dressing changes using chlorhexidine gluconate in 70% alcohol, and allow to air dry. Consider using an aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations prohibit the use of alcohol with their catheter. [2012]**
Relative values of different outcomes	The GDG considered the prevention of infection-related mortality, septicaemia and VAD related infections such as septicaemia, bacteraemia and phlebitis as the most important and relevant outcomes to patients. The frequency of VAD line removal and clinician time involved are also important outcomes.
Trade off between clinical benefits and harms	Reduction of infections was considered against the potential for developing resistance against decontamination solutions and costs.
Economic considerations	The GDG considered the incremental cost of different decontamination solutions as well as the cost and quality of life associated with VAD-related infections. The group agreed by consensus that the greater incremental cost of alcoholic chlorhexidine solution would be justified by a decrease in vascular catheter related infections.
Quality of evidence	There were serious methodological limitations. Only one or two small studies were found for some comparisons and there is no RCT comparing different concentrations of chlorhexidine gluconate in alcohol for skin decontamination during dressing change. These studies were conducted in hospitalised patients, and may not be applicable to the community setting. The GDG reached the recommendation through analysis of the limited and low quality evidence and consensus. Although the level of uncertainty in the evidence found was high and it is difficult to conclude that one particular antiseptic solution is better than another, the trend in the evidence suggests that chlorhexidine gluconate in alcohol may be more effective than alcoholic povidone iodine solutions. There is no RCT evidence comparing different concentrations of chlorhexidine gluconate in alcohol. Among the non-alcoholic solutions reviewed, there was low quality evidence suggesting that the risk of catheter tip infections for patients using 2% chlorhexidine gluconate in aqueous was lower than those using 10% PVP-I. It is uncertain whether there are any differences between 2% CHG aqueous compared to 10% PVP-I aqueous for VAD related bacteraemia or septicaemia because of the wide confidence intervals observed. There was no direct comparison between different concentrations of chlorhexidine when dissolved in the same solutions. One study comparing 2% chlorhexidine gluconate in aqueous vs. 0.5% chlorhexidine gluconate in alcohol did not provide any conclusive evidence related to whether there were any difference in catheter tip colonisation, septicaemia and bacteraemia cases. There were slightly more cases for patients using 2% chlorhexidine gluconate in aqueous compared to 0.5% chlorhexidine gluconate in alcohol but this was not statistically significant and there was uncertainty as to whether the effect size was potentially clinically significant. The confidence intervals were very wide.

Update 2012

	In addition, the clinical importance of the results observed was difficult to interpret because most of the studies had been randomised by catheters, and reported the outcomes per catheter, rather than per patient.
Other considerations	The GDG noted that the discussions that they had related to the evidence surrounding the most appropriate solution to use to decontaminate the skin at the insertion site prior to the insertion of a peripheral vascular access device or peripherally inserted central catheter (see recommendation 80) were broadly applicable to the evidence reviewed as part of this recommendation. In particular considering the evidence behind this recommendation, regarding the choice of disinfectant when changing dressings, the GDG noted that in practice, it is important to recommend the same type of disinfectant solutions for both decontaminating the skin and also the ports and hubs of the device that is already in situ. They noted that ensuring this could reduce the chance of confusion of which to solution to use. Evidence for decontamination prior to insertion suggested that chlorhexidine gluconate in alcohol is the best option, and there is no specific evidence for decontamination prior access to ports and hubs. The GDG were aware, however, that some catheters and hubs are not compatible with the use of alcohol and that some manufacturers prohibit the use of alcohol with their catheter and therefore this should be taken into account when decontaminating the skin during dressing changes. For these patients, it remains important that the decontamination is carried out but that a suitable non-alcoholic alternative is available. Based on the on the evidence reviewed which showed there were fewer catheter tips with colonisation when using 2% chlorhexidine gluconate in aqueous solution rather than 10% povidone iodine in aqueous and also considering the potential disadvantages of staining from iodine solutions, the GDG considered chlorhexidine gluconate remains the best option when only aqueous disinfectants could be used. The GDG used consensus to agree the choice of solution given the limited directly applicable evidence behind the use of non-alcohol based decontamination where manufacturers prohibit the use of alcohol with their catheter.

Update 2012

88. Individual sachets of antiseptic solution or individual packages of antiseptic-impregnated swabs or wipes should be used to disinfect the dressing site. [2003]

12.8 General Principles for Catheter Management

12.8.1 Decontaminating peripheral and centrally inserted catheter ports and hubs before access

The following review question was prioritised for update to determine the most effective decontamination solution for decontaminating peripheral and centrally inserted catheter ports and hubs before access, as it was felt there are more types of decontamination products are available since 2003. In particular, stakeholders highlighted uncertainty regarding what is the most appropriate concentration to use for chlorhexidine gluconate.

12.8.2 Review question

What is the most clinical and cost effective product or solution for decontaminating VAD ports and hubs prior to access on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and frequency of line removal?

12.8.3 Clinical evidence

No clinical studies were identified. No clinical evidence was identified in the previous 2003 guideline.

12.8.4 Cost-effectiveness evidence

No cost-effectiveness evidence was identified. No cost-effectiveness evidence was identified in the previous 2003 guideline.

In the absence of any published cost-effectiveness analyses, current UK decontamination product costs, estimated infection-related costs (Table 84 and Table 101) and quality of life data (Table 85) were presented to the GDG to inform decision making.

Table 120: Ports and hubs decontamination product costs

Decontamination product	Average cost (£)
70% Isopropyl alcohol swabs	2.35 (per 100 individual sachets)
2% Chlorhexidine in 70% isopropyl alcohol	4.35 (per 200 individual sachets)
Alcohol free	3.03 (per 200 wipes)

Source/Note: *NHS Supply Catalogue 2010* [185]

12.8.5 Evidence statements

Clinical — No clinical evidence was identified.

Economic — No economic studies were identified.

Update 2012

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12.8.6 Recommendations and link to evidence

Recommendations	89. Decontaminate the injection port or vascular access device catheter hub before and after accessing the system using chlorhexidine gluconate in 70% alcohol. Consider using an aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations prohibit the use of alcohol with their catheter. [new 2012]
Relative values of different outcomes	The GDG considered preventing infection-related mortality, and VAD related infections such as septicaemia, bacteraemia and phlebitis as most important and relevant outcomes to patients. The frequency of VAD line removal and clinician time involved is also important. There is a potential delay to treatment following line removal or reduced venous access and these are important for patient outcomes.
Trade off between clinical benefits and harms	Reduction of infections was considered against the potential for developing resistance against decontamination solutions and costs.
Economic considerations	The GDG considered the incremental cost of different decontamination solutions as well as the cost and quality of life associated with VAD-related infections. The group agreed by consensus that the greater incremental cost of alcoholic chlorhexidine gluconate solution would be justified by a decrease in vascular catheter related infections.
Quality of evidence	There was no direct evidence from RCTs specifically comparing different methods of decontaminating ports and hubs prior to access found. No relevant cost-effectiveness studies were identified. The recommendation was developed based on consensus, and information obtained from studies of decontamination of skin prior to insertion and during dressing changes reviewed.
Other considerations	The GDG took into account the evidence reviewed for skin decontamination prior to insertion of vascular access devices, and skin decontamination during dressing changes. Although these studies had important methodological limitations, there was a trend that chlorhexidine gluconate in alcohol solution was more effective in skin decontamination prior to insertion and during dressing changes than other alcoholic or aqueous based disinfectants. The evidence in these sections was considered relevant by the GDG when drafting this recommendation. The GDG noted that in practice, it is important to recommend the same type of disinfectant solutions for both decontaminating the skin and also the ports and hubs. They noted that this could reduce the chance of confusion of which to solution to use. Using chlorhexidine gluconate in alcohol was considered important to minimize the number of alternative preparations that may be used with VAD lines. The residual antimicrobial effect of chlorhexidine gluconate was also discussed, and had been documented in the recommendations about decontamination prior to insertion and during dressing changes (see recommendation 80). The GDG decided that only chlorhexidine gluconate in alcohol should be recommended for decontamination of hubs and ports for vascular access devices. Cleaning with only alcohol was not considered an effective option. Where the use of alcohol is prohibited in the manufacturer's instruction, decontamination of the port or hub using chlorhexidine gluconate in aqueous was recommended in line with the recommendation about skin decontamination during dressing changes (recommendation number 87). Based on the evidence reviewed for that recommendation which showed there were fewer catheter tips with colonisation when using 2% chlorhexidine

Update 2012

Recommendations	89. **Decontaminate the injection port or vascular access device catheter hub before and after accessing the system using chlorhexidine gluconate in 70% alcohol. Consider using an aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations prohibit the use of alcohol with their catheter. [new 2012]**
	gluconate in aqueous solution rather than 10% povidone iodine in aqueous and in also considering the potential disadvantages of staining from iodine solutions, the GDG considered chlorhexidine gluconate remains the best option when only aqueous disinfectants could be used. Considerations about the use of alcohol in infection control was also taken into account, and discussed at length in the recommendation about hand hygiene. Please see section 6.4 for more details.

Update 2012

12.8.7 Inline filters do not help prevent infections

Although in-line filters reduce the incidence of infusion-related phlebitis, HICPAC could find no reliable evidence to support their efficacy in preventing infections associated with intravascular catheters and infusion systems. Infusate-related BSI is rare and HICPAC concluded that filtration of medications or infusates in the pharmacy is a more practical and less costly way to remove the majority of particulates. Furthermore, in-line filters might become blocked, especially with certain solutions, e.g., dextran, lipids, mannitol, thereby increasing the number of line manipulations and decreasing the availability of administered drugs.[188] In our systematic review we found no additional good quality evidence to support their use for preventing infusate-related BSI. However, there may be a role for the use of in-line filtration of parenteral nutrition solutions for reasons other than the prevention of infection but these are beyond the scope of these guidelines.

12.8.7.1 Recommendation

90. In-line filters should not be used routinely for infection prevention. [2003]

12.8.8 Antibiotic lock solutions have limited uses in preventing infection

Antibiotic lock prophylaxis, i.e., flushing and then filling the lumen of the CVC with an antibiotic solution and leaving it to dwell in the lumen of the catheter, is sometimes used in special circumstances to prevent CRBSI, e.g., in treating a patient with a long-term cuffed or tunnelled catheter or port who has a history of multiple CRBSI despite optimal maximal adherence to aseptic technique. Evidence reviewed by HICPAC[188] demonstrated the effectiveness of this type of prophylaxis in neutropenic patients with long-term CVCs. However, they found no evidence that routinely using this procedure in all patients with CVCs reduced the risk of CRBSI and may lead to increasing numbers of antimicrobial resistant microorganisms.

12.8.8.1 Recommendation

91. Antibiotic lock solutions should not be used routinely to prevent catheter-related bloodstream infections (CRBSI). [2003]

12.8.9 Systemic antibiotic prophylaxis does not reliably prevent CRBSI

No studies appraised by HICPAC demonstrated that oral or parenteral antibacterial or antifungal drugs might reduce the incidence of CRBSI among adults. However, among low birth weight infants, two studies reviewed by HICPAC had assessed vancomycin prophylaxis; both demonstrated a

reduction in CRBSI but no reduction in mortality. They noted that because the prophylactic use of vancomycin is an independent risk factor for the acquisition of vancomycin-resistant enterococcus (VRE), the risk for acquiring VRE probably outweighs the benefit of using prophylactic vancomycin.[188]

12.8.9.1 Recommendation

92. Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter. [2003]

12.8.10 A dedicated catheter lumen is needed for parenteral nutrition

HICPAC reviewed evidence from a prospective epidemiologic study examining the risk for CRBSI in patients receiving Total Parenteral Nutrition (TPN). They concluded that either using a single lumen CVC or a dedicated port in a multilumen catheter for TPN would reduce the risk for infection.[188]

12.8.10.1 Recommendation

93. Preferably, a single-lumen catheter should be used to administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for total parenteral nutrition, and all lumens must be handled with the same meticulous attention to aseptic technique. [2003]

12.8.11 Maintaining catheter patency and preventing catheter thrombosis may help prevent infections

Indwelling central venous and pulmonary artery catheters are thrombogenic. Thrombus forms on these catheters in the first few hours following placement[122] and may serve as a nidus for microbial colonization of intravascular catheters.[215] Thrombosis of large vessels occurs after long-term catheterisation in 35 to 65% of patients.[14,44,138,252,260] Prophylactic heparin and warfarin have been widely used to prevent catheter thrombus formation and catheter related complications, such as deep venous thrombosis (DVT).[188,216]

Two types of heparin can be used: unfractionated (standard) heparin and low molecular weight heparins. Although more expensive, low molecular weight heparins have a longer duration of action than unfractionated heparin and are generally administered by subcutaneous injection once daily. The standard prophylactic regimen of low molecular weight heparins are at least as effective and as safe as unfractionated heparin in preventing venous thrombo-embolism and does not require laboratory monitoring.[167]

12.8.12 Systemic Anticoagulation

A meta-analysis of randomised controlled trials[216] evaluating the benefit of infused prophylactic heparin through the catheter, given subcutaneously or bonded to the catheter in patients with CVCs found that prophylactic heparin:

- was associated with a strong trend for reducing catheter thrombus (RR, 0.66; 95% confidence interval [CI], 0.42,1.05). The test for heterogeneity of variance was not significant (p=0.681);
- significantly decreased central venous catheter-related venous thrombosis by 57% (RR, 0.43; 95% CI, 0.23,0.78). The test for heterogeneity of variance was not significant (p=0.526). Significant reduction of deep venous thrombosis was still present after excluding one trial of heparin-bonded catheters (RR, 0.44; 95% CI, 0.22,0.87);

- significantly decreased bacterial colonisation of the catheter (RR, 0.18; 95% CI, 0.06, 0.60). The test for heterogeneity of variance was not significant (p=0.719). The significant benefit for heparin remained after excluding one trial of heparin-bonded catheters (RR, 0.19; 95% CI, 0.04, 0.86).
- showed a strong trend for a reduction in CRBSI (RR, 0.26; 95% CI, 0.07,1.03). The test for heterogeneity of variance was not significant (p=0.859); This trend decreased when one trial of heparin-bonded catheters was excluded (RR,0.33; 95% CI, 0.07,1.56

The authors of this meta-analysis concluded that heparin administration effectively reduces thrombus formation and may reduce catheter-related infections in patients who have central venous and pulmonary artery catheters in place. They suggest that various doses of subcutaneous and intravenous unfractionated and low molecular weight heparins and new methods of heparin bonding need further comparison to determine the most cost-effective strategy for reducing catheter-related thrombus and thrombosis.

There are many different preparations and routes of administration of heparin, and as yet there is no definite evidence that heparin reduces the incidence of CRBSI, but this may reflect the heterogeneity of heparin and its administration.

Warfarin has also been evaluated as a means for reducing catheter-related thrombosis. A controlled trial of 82 patients with solid tumours randomised to receive or not to receive low-dose warfarin (1 mg a day) beginning 3 days prior to catheter insertion and continuing for 90 days, warfarin was shown to be effective in reducing catheter-related thrombosis.[21] The rates of venogram-proved thrombosis 4 of 42 in the treatment group versus 15 of 40 in the control group with 15 having symptomatic thromboses. In this study, warfarin was discontinued in 10% of patients due to prolongation of the prothrombin time.

12.8.13 Heparin versus Normal Saline Intermittent Flushes

Although many clinicians use low dose intermittent heparin flushes to fill the lumens of CVCs locked between use in an attempt to prevent thrombus formation and to prolong the duration of catheter patency, the efficacy of this practice is unproven. Despite its beneficial antithrombotic effects, decreasing unnecessary exposure to heparin is important to minimise adverse effects associated with heparin use, e.g., autoimmune-mediated heparin-induced thrombocytopenia, allergic reactions and the potential for bleeding complications following multiple, unmonitored heparin flushes.[194] The risks of these adverse effects can be avoided by using 0.9 percent sodium chloride injection instead of heparin flushes. A systematic review and meta-analysis of randomised controlled trials evaluating the effect of heparin on duration of catheter patency and on prevention of complications associated with the use of peripheral venous and arterial catheters concluded that heparin at doses of 10 U/ml for intermittent flushing is no more beneficial than flushing with normal saline alone.[217] This finding was in agreement with two other meta-analyses.[106,199] Manufacturers of implanted ports or opened-ended catheter lumens may recommend heparin flushes for maintaining catheter patency and many clinicians feel that heparin flushes are appropriate for flushing CVCs that are infrequently accessed.

HICPAC reviewed all of the evidence[14,21,44,106,122,138,194,199,215-217,252,260] for intermittent heparin flushes and systemic heparin and warfarin prophylaxis and concluded that no data demonstrated that their use reduces the incidence of CRBSI and did not recommend them.[188] Although their use for preventing CRBSI remains controversial, patients who have CVCs may also have risk factors for DVT and systemic anticoagulants may be prescribed for DVT prophylaxis.

12.8213.1 Recommendations

94. Preferably, a sterile 0.9 percent sodium chloride injection should be used to flush and lock catheter lumens. [2003]

95. When recommended by the manufacturer, implanted ports or opened-ended catheter lumens should be flushed and locked with heparin sodium flush solutions. [2003]

96. Systemic anticoagulants should not be used routinely to prevent CRBSI. [2003]

12.8.14 Needleless devices require vigilance

Needleless infusion systems have been widely introduced into clinical practice to reduce the incidence of sharp injuries and the potential for the transmission of blood borne pathogens to healthcare workers. HICPAC examined evidence that these devices may increase the risk for CRBSI and concluded that when they are used according to the manufacturers' recommendations, they do not substantially affect the incidence of CRBSI.[188]

12.8.14.1 Recommendations

97. If needleless devices are used, the manufacturer's recommendations for changing the needleless components should be followed. [2003]

98. When needleless devices are used, healthcare workers should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system. [2003]

99. When needleless devices are used, the risk of contamination should be minimised by decontaminating the access port with either alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system. [2003]

See also recommendation 90. (Decontaminate the injection port or catheter hub using chlorhexidine gluconate in 70% alcohol before and after it has been used to access the system unless contraindicated by manufacturer).

12.8.15 Change intravenous administration sets appropriately

The optimal interval for the routine replacement of intravenous (IV) administration sets has been examined in three well-controlled studies reviewed by HICPAC. Data from each of these studies reveal that replacing administration sets no more frequently than 72 hours after initiation of use is safe and cost-effective. When a fluid that enhances microbial growth is infused, e.g., lipid emulsions, blood products, more frequent changes of administration sets are indicated as these products have been identified as independent risk factors for CRBSI.[188]

12.8215.1 Recommendations

100. In general, administration sets in continuous use need not be replaced more frequently than at 72 hour intervals unless they become disconnected or if a catheter-related infection is suspected or documented. [2003]

101. Administration sets for blood and blood components should be changed every 12 hours, or according to the manufacturer's recommendations. [2003]

102. Administration sets used for total parenteral nutrition infusions should generally be changed every 24 hours. If the solution contains only glucose and amino acids, administration sets in continuous use do not need to be replaced more frequently than every 72 hours. [2003]

12.9 Administering infusions or drugs

12.9.1 Review question

What is the clinical and cost effectiveness of multi dose vials vs. single use vials for administrating infusions or drugs on preventing contamination of the infusate and healthcare-associated infection?

12.9.2 Clinical evidence

No clinical evidence was identified.

This review question was not covered in the previous 2003 guideline.

12.9.3 Cost-effectiveness evidence

No cost-effectiveness evidence was identified.

This review question was not covered in the previous 2003 guideline.

The co-opted expert advisors were approached about the likely costs of single- compared to multiple- use vials. They indicated that single use vials were generally more expensive than multiple use, but did not think it would represent a good use of time to evaluate the costs of individual infusion medications. Similarly, the infections which may arise as a consequence of infusate contamination are many and varied. It was not considered an effective use of time to calculate the costs and quality of life associated with all possible infections. Instead, the GDG was encouraged to use their clinical experience to consider the most likely costs of single versus multiple use vials and the likely consequences arising from their contamination.

Update 2012

12.9.4 Evidence statements

Clinical	No clinical studies were identified
Economic	No economic studies were identified

12.9.5 Recommendations and link to evidence

Recommendations	**103. Avoid the use of multidose vials, in order to prevent the contamination of infusates. [new 2012]**
Relative values of different outcomes	The GDG considered that as multi dose vials are accessed more than once the most important outcomes as VAD related bacteraemia, septicaemia and infection related mortality.
Trade off between clinical benefits and harms	There is a risk of contamination of the infusate if vials are not used correctly and incorrect storage may lead to pharmacological instability.
Economic considerations	The GDG discussed the trade-off between the (assumed) increased cost and potential infusate wastage associated with single-use vials compared to the

Recommendations	103. Avoid the use of multidose vials, in order to prevent the contamination of infusates. [new 2012]
	cost and quality of life implications of the potentially severe infections associated with infusate contamination. The GDG considered the marginally increased cost of single-use vials to be justified in order to prevent these infections.
Quality of evidence	No clinical evidence was identified. The recommendation was formulated using the expert opinion of the GDG. Further details about the GDG discussion and considerations are details in "Other considerations" below.
Other considerations	The GDG agreed that the correct dose of infusate in a single container should be used and the vial should then be discarded in order to reduce the risk of contamination during preparation and administration. Re-accessing multi-dose vials can lead to loss of integrity of the vial through puncturing the bung multiple times.

12.10 Areas for Further Research

This is a well researched area and few realistic research needs were identified in developing these guidelines. The following investigations, along with a health economic assessment, may inform future clinical practice.

12.10.1 Current issues

The effectiveness of subcutaneous low molecular weight heparins or low dose warfarin to prevent catheter thrombus, colonisation and CRBSI.

12.10.2 Emerging Technologies

The efficacy of antimicrobial impregnated CVCs and catheters with new forms of heparin bonding to provide sustained protection against CRBSI in patients with long-term CVCs in the community.

12.11 Research recommendations

5. What is the clinical and cost effectiveness of chlorhexidine 2% in alcohol versus chlorhexidine 0.5% in alcohol versus chlorhexidine 2% aqueous solution versus chlorhexidine 0.5% aqueous solution for cleansing skin (before insertion of peripheral vascular access devices [VADs] and during dressing changes of all VADs) on reducing VAD-related bacteraemia and VAD site infections?

Why is this important?

The effective management of vascular access devices (VADs) is important for reducing phlebitis and bacteraemia. In the community, compliance is improved when a single solution is used for all aspects of VAD-related skin care. There is no direct evidence comparing different percentages of chlorhexidine in aqueous and alcohol solutions, and little evidence on the use of such solutions in the community. A randomised controlled trial is required to compare the clinical and cost effectiveness of the different solutions available. The trial should enrol patients in the community with a VAD. The protocol would need to use the same skin preparation technique regardless of solution, and could also investigate decontamination technique and drying time. The primary outcome measures should be rate of VAD-related bacteraemia, rate of VAD site infections, mortality, cost and quality of life. Secondary outcomes measures should include Visual Infusion Phlebitis (VIP) score, insertion times and skin irritation.

Update 2012

13 Glossary

Term	Definition
Abstract	Summary of a study, which may be published alone or as an introduction to a full scientific paper.
Alcohol-based/Alcoholic handrub	An alcohol-containing preparation designed for application to the hands for reducing the number of viable microorganisms on the hands. In the UK, such preparations usually contain 60-90% ethanol and isopropanol.
Algorithm (in guidelines)	A flow chart of the clinical decision pathway described in the guideline, where decision points are represented with boxes, linked with arrows.
Allocation concealment	The process used to prevent advance knowledge of group assignment in a RCT. The allocation process should be impervious to any influence by the individual making the allocation, by being administered by someone who is not responsible for recruiting participants.
Antiseptic handwash or soap	An antiseptic containing preparation designed for frequent use; it reduces the number of microorganisms on intact skin to an initial baseline level after adequate washing, rinsing, and drying; it is broad-spectrum and fast-acting,
Applicability	The degree to which the results of an observation, study or review are likely to hold true in a particular clinical practice setting.
Arm (of a clinical study)	Sub-section of individuals within a study who receive one particular intervention, for example placebo arm
Asepsis	A condition in which living pathogenic organisms are absent; a state of sterility.
Aseptic non touch technique	A specific type of aseptic technique with a unique theory and practice framework (www.antt.co.uk).
Aseptic techniques	Healthcare procedures designed to prevent the risk of transmission of pathogenic microorganisms to patients by ensuring that only sterile fluids and equipment are used and that the risks of airborne contamination are minimised.
Autonomic dysreflexia	Autonomic dysreflexia, also known as hyperreflexia, is where a stimulus, such as overstretching or irritation of the bladder wall, causes an over-activity of the sympathetic part of the autonomic nervous system resulting in remarkably high blood pressure (often ≥200mm/Hg systolic).
Bacteraemia	The presence of bacteria in the bloodstream.
Bacteriuria	The presence of bacteria in the urine with, or without associated symptoms of infection. In the absence of symptoms this is referred to as asymptomatic bacteriuria or, in the case of a patient with an indwelling catheter, catheter colonisation.
Bare below the elbows	The GDG defined this as not wearing false nails or nail polish when delivering direct patient care. Not wearing wrist-watch or stoned rings. Healthcare workers garments should be short sleeved or be able to roll or push up sleeves when delivering direct patient care and performing hand hygiene.
Baseline	The initial set of measurements at the beginning of a study (after run-in period where applicable), with which subsequent results are compared.
Bias	Systematic (as opposed to random) deviation of the results of a study from the 'true' results that is caused by the way the study is designed or conducted.
Bladder instillation	Introducing a sterile therapeutic liquid into the bladder and leaving it there for a variable 'holding' time to dissolve particulates/encrustation, altering pH, or suppressing bacterial growth.
Bladder irrigation	The continuous introduction of a sterile fluid into the bladder via a three way catheter to allow for the drainage of blood and debris from the bladder.

Term	Definition
Bladder washout	The introduction into the bladder of a sterile fluid which is allowed to drain more or less immediately, for the purpose of diluting the bladder contents/unblocking an obstruction to restore free catheter drainage.
Blinding	Keeping the study participants, caregivers, researchers and outcome assessors unaware about the interventions to which the participants have been allocated in a study.
Blood borne viruses	A virus that is carried in the bloodstream, and transmitted via contact with infected blood e.g. HBV, HCV and HIV.
Septicaemia	A systemic disease caused by the spreading of micro-organisms and their toxins in the circulating blood.
Bodily fluid contamination	Contamination with any bodily fluid which would include urine, faeces, saliva or vomit and could result in transmission of infection.
Buried bumper syndrome	A complication of PEG tubes where the internal disc becomes buried in the stomach lining.
C.diff cross infection	The transmission of the disease from one person to another because of a breach in a barrier.
C.diff reduction	A reduction in the incidence (number of new cases) of *Clostridium difficile*.
Cannula	A peripheral device consisting of a hollow tube made of plastic or metal, used for accessing the body.
Carer (caregiver)	Someone other than a health professional who is involved in caring for a person with a medical condition.
Catheter blockage	Blockage either by deposits and encrustations or by mechanical means, such as occlusion of catheter due to kinking of the tube, that prevents urine from draining out of the bladder.
Catheter encrustation	Deposits of gritty urine crystals on the catheter tube which can increase the risk of blockage and infection.
Catheter thrombus	Clot adherent to or occluding the catheter or a fibrin sleeve in the vessel around the catheter.
Catheter tip colonisation	In clinical studies on the prevention of vascular catheter-related infections, catheter-tip colonization (CTC) is frequently used as a surrogate end point for the most severe form of vascular catheter-related infection, catheter-related BSI. Use of this end point is based on observations that, in bacteraemic patients who have an intravascular catheter in place, the catheter is more likely to be the source of bacteraemia if culture of the catheter tip yields the same bacteria as blood culture. The higher the load of bacteria found on the catheter, the better the positive predictive value for catheter-related bacteraemia. More recently—and for practical reasons—in most studies of catheter-related infection, an absolute cutoff value for catheter culture positivity has been used.
Catheter valve	A valve connected to the catheter outlet allowing the bladder to be used to store urine. Urine is drained by opening the valve at regular intervals.
Catheter-associated Urinary Tract Infection	The occurrence of local, or distant, clinical symptoms or signs attributable to bacteria present either within the urinary tract, or in the bloodstream (with the urinary tract as the source). Infection may arise: either at the time of, or immediately following catheter insertion; or subsequently, because the colonising flora within the catheterised urinary tract becomes invasive (this may occur spontaneously, or follow catheter manipulation).
Cellulitis	An infection of the skin and tissues beneath the skin, symptoms include tenderness, swelling, erythema and may cause pyrexia.

Term	Definition
Central venous catheter	Catheter inserted into a centrally located vein with the tip residing in the lower third of the superior vena cava: permits access to the venous system.
Clean procedure	Hands are decontaminated before and after the procedure and key parts are not touched.
Clean technique	A technique that is designed to prevent the introduction of microorganisms, but in recognition that the site is already colonised with bacteria it is not aseptic. Non sterile gloves may be used.
Clinical effectiveness	The extent to which an intervention produces an overall health benefit in routine clinical practice.
Clinical efficacy	The extent to which an intervention is active when studied under controlled research conditions.
Clinical importance:	This refers to whether the size of the effect observed between groups are If the MID is less than the lower limit of the 95% confidence interval, results are likely to be statistically significant and clinically important. If the MID is greater than the upper limit of the 95% confidence interval, results are likely to be clinically unimportant. If the MID lies within the limits of the 95% confidence interval, it is unclear if the effect is clinically important or not [42]
Clinical waste	Clinical waste is defined as: 1. ". . . any waste which consists wholly or partly of human or animal tissue, blood or other body fluids, excretions, drugs or other pharmaceutical products, swabs or dressings, syringes, needles or other sharp instruments, being waste which unless rendered safe may prove hazardous to any person coming into contact with it; and 2. any other waste arising from medical, nursing, dental, veterinary, pharmaceutical or similar practice, investigation, treatment, care, teaching or research, or the collection of blood for transfusion, being waste which may cause infection to any person coming into contact with it." Clinical waste can be divided into three broad groups of materials: 1. any healthcare waste which poses a risk of infection (and therefore by definition possesses the hazardous property H9 Infectious); 2. certain healthcare wastes which pose a chemical hazard (for example one of H1 to H8, H10 to H15); 3. medicines and medicinally-contaminated waste containing a pharmaceutically-active agent.
Clinician	A healthcare professional providing direct patient care, for example doctor, nurse or physiotherapist.
Closed System (enteral feeding)	Sterile, pre-filled ready-to-use feeds that do not expose the feed to the air during assembly.
Cohort study	A retrospective or prospective follow-up study. Groups of individuals to be followed up are defined on the basis of presence or absence of exposure to a suspected risk factor or intervention. A cohort study can be comparative, in which case two or more groups are selected on the basis of differences in their exposure to the agent of interest.
Colony forming units	A measure of viable bacteria or fungi numbers per millilitre
Comparability	Similarity of the groups in characteristics likely to affect the study results (such as health status or age).
Concordance	This is a recent term whose meaning has changed. It was initially applied to the consultation process in which doctor and patient agree therapeutic decisions that incorporate their respective views, but now includes patient support in medicine

Term	Definition
	taking as well as prescribing communication. Concordance reflects social values but does not address medicine-taking and may not lead to improved adherence.
Confidence interval (CI)	A range of values for an unknown population parameter with a stated 'confidence' (conventionally 95%) that it contains the true value. The interval is calculated from sample data, and generally straddles the sample estimate. The 'confidence' value means that if the method used to calculate the interval is repeated many times, then that proportion of intervals will actually contain the true value.
Confounding	In a study, confounding occurs when the effect of an intervention on an outcome is distorted as a result of an association between the population or intervention or outcome and another factor (the 'confounding variable') that can influence the outcome independently of the intervention under study.
Consensus methods	Techniques that aim to reach an agreement on a particular issue. Consensus methods may used when there is a lack of strong evidence on a particular topic.
Control group	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment) - in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Cost benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-consequence analysis (CCA)	A type of economic evaluation where various health outcomes are reported in addition to cost for each intervention, but there is no overall measure of health gain.
Cost-effectiveness analysis (CEA)	An economic study design in which consequences of different interventions are measured using a single outcome, usually in 'natural' units (For example, life-years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions are then compared in terms of cost per unit of effectiveness.
Cost-effectiveness model	An explicit mathematical framework, which is used to represent clinical decision problems and incorporate evidence from a variety of sources in order to estimate the costs and health outcomes.
Cost-utility analysis (CUA)	A form of cost-effectiveness analysis in which the units of effectiveness are quality-adjusted life-years (QALYs).
CRBSI (Catheter-related Bloodstream Infection)	Patient has one or more recognized pathogens cultured from a single blood culture OR If the microorganism is a common skin organism then... • It must have been cultured from 2 or more blood cultures drawn on separate occasions, or from one blood culture in a patient in whom antimicrobial therapy has been started, and • Patient has one of the following: fewer of >38°C, chills, or hypotension AND • The presence of one or more central venous catheters at the time of the blood culture, or up to 48 hrs following removal of the CVC AND one of the following: i. a positive semiquantitative (>15 CFU/catheter segment) or quantitative (>10^3 CFU /ml or >10^3 CFU/catheter segment) culture whereby the same organism (species and antibiogram) is isolated from blood sampled from the CVC or from the catheter tip, and peripheral blood; ii. simultaneous quantitative blood cultures with a >5:1 ratio CVC versus peripheral.
Credible Interval	The Bayesian equivalent of a confidence interval.
Decision analysis	An explicit quantitative approach to decision making under uncertainty, based on

Term	Definition
	evidence from research. This evidence is translated into probabilities, and then into diagrams or decision trees which direct the clinician through a succession of possible scenarios, actions and outcomes.
Dermatitis (Standard infection control)	Inflammation of the skin either due to direct contact with an irritant or due to an allergic reaction. It maybe eczematous or non eczematous. Non eczematous is usually due to direct contact with an irritant.
Direct patient care	Hands-on or face-to-face contact with patients. Any physical aspect of the healthcare of a patient, including treatments, self-care, and administration of medication.
Discounting	Discounting makes current costs and benefits worth more than those that occur in the future. This is common practice in health economic evaluation due to the 'time preference' expressed by most people, in which there is a desire to enjoy benefits in the present while deferring the negative.
Disposable gloves	Gloves that are used for single use only. May be latex, latex free or vinyl.
Disposable plastic aprons	An apron which is for single use and normally made from a plastic material.
Dominance	An intervention is said to be dominated if there is an alternative intervention that is both less costly and more effective.
Drop-out	A participant who withdraws from a trial before the end.
Economic evaluation	Comparative analysis of alternative health strategies (interventions or programmes) in terms of both their costs and consequences.
Effect (as in effect measure, treatment effect, estimate of effect, effect size)	The observed association between interventions and outcomes or a statistic to summarise the strength of the observed association.
Effectiveness	See 'Clinical effectiveness'.
Efficacy	See 'Clinical efficacy'.
Enteral feeding	Feeding via a tube that can include any method of providing nutrition via the gastrointestinal tract.
Epidemiological study	The study of a disease within a population, defining its incidence and prevalence and examining the roles of external influences (For example, infection, diet) and interventions.
EQ-5D (EuroQol-5D)	A standardised instrument used to measure health-related quality of life. It provides a single utility value for a health state.
Evidence	Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients).
Exclusion criteria (clinical study)	Criteria that define who is not eligible to participate in a clinical study.
Exclusion criteria (literature review)	Explicit standards used to decide which studies should be excluded from consideration as potential sources of evidence.
Expert opinion	Opinion derived from seminal works and appraised national and international guidelines. This also includes invited clinical experts.
Extended dominance	If Option A is both more clinically effective than Option B and has a lower cost per unit of effect, when both are compared with a do-nothing alternative then Option A is said to have extended dominance over Option B. Option A is therefore more efficient and should be preferred, other things remaining equal.
Extrapolation	In data analysis, predicting the value of a parameter outside the range of observed values.

Term	Definition
Fill line	The manufacturer's mark on the sharps bin that relates to the bin being ¾ full.
Follow up	Observation over a period of time of an individual, group or initially defined population whose appropriate characteristics have been assessed in order to observe changes in health status or health related variables.
Full body fluid repellent gowns	Full gown that includes full length sleeves that is fluid repellent and should be used when there is excessive risk of splashing of bodily fluids and secretions.
Fungal Colonisation	The presence of fungi on the skin that does not cause disease.
Gastrostomy site infection	An infection of the gastrostomy site often caused by skin flora which includes inflammation around the insertion site. There may be associated pus formation.
Gauze dressings	Woven or nonwoven fabric swab.
GDG Consensus	GDG Consensus may be used when there is a lack of strong evidence on a particular topic to reach an agreement for a recommendation.
Gel reservoir catheter	A type of intermittent catheter that is lubricated by passing it through a pre-packaged sterile integral reservoir of lubricating gel.
Generalisability	The extent to which the results of a study based on measurement in a particular patient population and/or a specific context hold true for another population and/or in a different context. In this instance, this is the degree to which the guideline recommendation is applicable across both geographical and contextual settings. For instance, guidelines that suggest substituting one form of labour for another should acknowledge that these costs might vary across the country.
Gloves porosity	The risk of micropuncture within the gloves structure that allows fluids to breach the glove surface. Defined by the amount of spaces/voids within a solid material which can absorb fluids.
Gold standard	See 'Reference standard'.
GRADE / GRADE profile	A system developed by the GRADE Working Group to address the shortcomings of present grading systems in healthcare. The GRADE system uses a common, sensible and transparent approach to grading the quality of evidence. The results of applying the GRADE system to clinical trial data are displayed in a table known as a GRADE profile.
HACCP (Hazard analysis and critical control point)	Hazard analysis and critical control point. A system to identify potential hazards in food preparation.
Hand decontamination	The physical removal of blood, body fluids, and transient microorganisms from the hands, for example handwashing,.
Hand hygiene	A general term that applies to either handwashing, antiseptic handwash, antiseptic hand rub, or surgical hand antisepsis.
Hand hygiene compliance	A measure of compliance to best practice ideals or policy related to hand decontamination.
Handrub (compliant with EN 1500)	A preparation designed for application to the hands for reducing the number of viable microorganisms. EN 1500 is the European Standard for efficacy of hygienic handrubs defined by having log bacterial load reductions statistically similar or superior to reductions using a reference (60% isopropyl alcohol)
Hand washing	Washing hands with plain (ie, nonantimicrobial) soap and water
Hand /skin wipes	Moist towelettes impregnated with various products used for cleansing of skin, or inactivating pathogenic microorganisms on the skin.
Hang time	The total time during which the feed is held in the nutrient container at room temperature while being administered. This includes periods of time when administration of the feed is interrupted temporarily.
Harms	Adverse effects of an intervention.

Term	Definition
Health economics	The study of the allocation of scarce resources among alternative healthcare treatments. Health economists are concerned with both increasing the average level of health in the population and improving the distribution of health.
Healthcare-associated infection	Infections that occur as a result of contact with the healthcare system in its widest sense – in community and hospital settings. Previously, when most complex healthcare was hospital based, the term 'hospital acquired (or nosocomial) infection' was used. (See Nosocomial infection)
Healthcare waste	Waste from natal care, diagnosis, treatment or prevention of disease in humans/animals. Examples of healthcare waste include: • infectious waste; • laboratory cultures; • anatomical waste; • sharps waste; • medicinal waste; • offensive/hygiene waste from wards or other healthcare areas.
Healthcare worker	Any person employed by the health service, social service, local authority or agency to provide care for sick, disabled or elderly people.
Health-related quality of life (HRQoL)	A combination of an individual's physical, mental and social well-being; not merely the absence of disease.
Heterogeneity Or lack of homogeneity.	The term is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different – in terms of the size of treatment effects or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of variables or duration of follow-up.
Hydrophilic catheter	Hydrophilic urinary catheters are coated with a water absorbent polymer. When exposed to water the coating becomes wet and slippery, reducing friction between the catheter surface and the urethral mucosa during insertion. Hydrophilic catheters are sterile and have either packaged with an activated coating (i.e. ready to use) or a dry coating which requires immersion in water for 30 seconds in order to activate the coating.
Hypersensitivity	A state of altered reactivity in which the body reacts with an exaggerated immune response to what is perceived as a foreign substance.
Implanted port	A VAD catheter surgically placed into a vein and attached to a reservoir located under the skin (usually in the chest region). The catheter is tunnelled under the skin and the tip lies in the lower third of the superior vena cava
Imprecision	Results are imprecise when studies include relatively few patients and few events and thus have wide confidence intervals around the estimate of effect.
Impregnated dressings	Dressing permeated with a chemical, usually with antimicrobial properties, to reduce the level of bacteria at the wound surface. Examples of active ingredients include: medical grade honey, iodine, silver and chlorhexidine.
Inclusion criteria	Explicit criteria used to decide which studies should be considered as potential sources of evidence.
Incremental analysis	The analysis of additional costs and additional clinical outcomes with different interventions.
Incremental cost	The mean cost per patient associated with an intervention minus the mean cost per patient associated with a comparator intervention.
Incremental cost	The difference in the mean costs in the population of interest divided by the

Term	Definition
effectiveness ratio (ICER)	differences in the mean outcomes in the population of interest for one treatment compared with another.
Incremental net benefit (INB)	The value (usually in monetary terms) of an intervention net of its cost compared with a comparator intervention. The INB can be calculated for a given cost-effectiveness (willingness to pay) threshold. If the threshold is £20,000 per QALY gained then the INB is calculated as: (£20,000 x QALYs gained) – Incremental cost.
Indirectness	The available evidence is different to the review question being addressed, in terms of PICO (population, intervention, comparison and outcome).
Indwelling (urethral) catheter	A catheter that is inserted into the bladder via the urethra and remains in place for a period of time.
Infusate-related BSI (Bloodstream Infection)	Concordant growth of the same organism from the infusate and blood cultures (preferably percutaneously drawn) with no other identifiable source of infection.
Injection access site, such as caps/ ports	Resealable cap or other configuration designed to accommodate needles or needleless devices for administration of solutions into the vascular system. Also includes injection caps, needle free caps, catheter hubs or administration ports integral to an administration set.
Intention to treat analysis (ITT)	A strategy for analysing data from a randomised controlled trial. All participants are included in the arm to which they were allocated, whether or not they received (or completed) the intervention given to that arm. Intention-to-treat analysis prevents bias caused by the loss of participants, which may disrupt the baseline equivalence established by randomisation and which may reflect non-adherence to the protocol.
Intervention	Healthcare action intended to benefit the patient, for example, drug treatment, surgical procedure, psychological therapy.
Kappa statistic	A statistical measure of inter-rater agreement that takes into account the agreement occurring by chance.
Length of stay	The total number of days a participant stays in hospital.
Licence	See 'Product licence'.
Life-years gained	Mean average years of life gained per person as a result of the intervention compared with an alternative intervention.
Likelihood ratio	The likelihood ratio combines information about the sensitivity and specificity. It tells you how much a positive or negative result changes the likelihood that a patient would have the disease. The likelihood ratio of a positive test result (LR+) is sensitivity divided by 1- specificity.
Link system	An extension attached to the drainage outlet of the day urine collection bag and connected to a larger capacity night drainage bag.
Localised Catheter Colonisation	Significant growth of a microorganism (> 15 CFU) from the catheter tip, subcutaneous segment of the catheter, or catheter hub in the absence of a positive blood culture.
Long-term care	Residential care in a home that may include skilled nursing care and help with everyday activities. This includes nursing homes and residential homes.
Long-term catheter/catheterisation	Long-term catheter: a catheter that is designed to stay in place for a period greater than 28 days. Long- term catheterisation: The use of a catheter (indwelling or intermittent) for a period greater than 28days.
Loss to follow-up	Also known as attrition. The loss of participants during the course of a study. Participants that are lost during the study are often call dropouts.
Markov model	A method for estimating long-term costs and effects for recurrent or chronic conditions, based on health states and the probability of transition between them

Term	Definition
	within a given time period (cycle).
Meta-analysis	A statistical technique for combining (pooling) the results of a number of studies that address the same question and report on the same outcomes to produce a summary result. The aim is to derive more precise and clear information from a large data pool. It is generally more reliably likely to confirm or refute a hypothesis than the individual trials.
Midline catheter	A peripheral device that permits venous access. The catheter is inserted via the antecubital veins and advanced into the veins of the upper arm but not extending past the axilla (usually about 20cm in length). It is used for short-term (up to four weeks) intravenous access.
MCID (minimal clinical important difference)	Minimal clinical important difference (MCID) was defined as smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management [129]. This is also sometimes referred as "minimal important change" in clinical papers. See MID, clinical importance, statistical significance.
MID (minimal important difference)	The MID is the smallest difference in score in the outcome of interest that informed patients or informed proxies perceive as important, either beneficial or harmful, and that would lead the patient or clinician to consider a change in the management [129,231,232]. This term was adapted from the earlier definition used for MCID (minimal clinically important difference) with the term "clinical" removed to emphasise on the importance of patient perspective. The term "MID" has been adopted by GRADE. In this guideline, we also use the term to refer to the clinically important thresholds or harms when considering imprecision. See MCID, clinical importance, statistical significance.
MRSA cross infection	The transmission of the disease from one person to another because of a breach in a barrier.
MRSA reduction	A reduction in the incidence (number of new cases) of MRSA.
Multivariate model	A statistical model for analysis of the relationship between two or more predictor (independent) variables and the outcome (dependent) variable.
Needle safety devices	Any device that aims to reduce the incidence of sharps' injuries. This may include needleless syringes, needle protection devices and needle free devices.(see safety needle devices)
Night drainage bag	Bags used for overnight urine collection.
No touch technique	Avoiding direct contact of the hand with feed ingredients.
Non-alcohol based decontamination products	Hand washing products that do not contain alcohol, such as plain soap and water, or antimicrobial/antiseptic washes.
Nosocomial	Related to hospital or care, e.g., nosocomial. infection is a hospital-acquired infection.
Number needed to treat (NNT)	The number of patients that who on average must be treated to prevent a single occurrence of the outcome of interest.
Observational study	Retrospective or prospective study in which the investigator observes the natural course of events with or without control groups; for example, cohort studies and case–control studies.
Open System	Feeds that need to be reconstituted, diluted and/or decanted into a feed container and/or where the feed is exposed to the atmosphere during assembly of feeding system.
Opportunity cost	The loss of other healthcare programmes displaced by investment in or introduction of another intervention. This may be best measured by the health benefits that

Term	Definition
	could have been achieved had the money been spent on the next best alternative healthcare intervention.
Outcome	Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints. See 'Intermediate outcome'.
Percutaneous endoscopic gastrstomy feeding tube	A polyurethane or silicone tube, which has been inserted directly through the abdominal wall into the stomach. An internal retention disc (flange) anchors the tube in place and prevents the leakage of gastric juices or food. An external fixation plate keeps the PEG in position next to the skin. They are suitable for long-term use.
Peristomal infection	Oropharyngeal bacteria can be brought through the abdominal wall during percutaneous endoscopic gastrostomy (PEG). Peristomal infection is one of the most frequent complications in patients who undergo the procedure.
Peritonitis	Inflammation of the peritoneum (the membrane lining the inner wall of the abdomen and pelvis). Peritonitis may be primary (ie spontaneous, usually associated with ascites) or secondary due to: infection by bacteria or parasites; bleeding; leakage of irritants (such as bile, stomach acid or pancreatic enzymes); or some systemic diseases (eg porphyria). It can result from bacteria tracking inwards/internally from the gastrostomy site.
Persistent activity or residual activity	Persistent activity is defined as the prolonged or extended antimicrobial activity that prevents or inhibits the proliferation or survival of microorganisms after application of the product. This activity may be demonstrated by sampling a site several minutes or hours after application and demonstrating bacterial antimicrobial effectiveness when compared with a baseline level. This property also has been referred to as "residual activity." Both substantive and nonsubstantive active ingredients can show a persistent effect if they substantially lower the number of bacteria during the wash period.
Personal Protective Equipment (PPE)	All equipment, which is intended to be worn or held by a person to protect them from risks to health and safety whilst at work. Examples of PPE include gloves, aprons and eye and face protection.
PICC: Peripherally inserted central catheter	Soft flexible central venous catheter inserted into an arm vein and advanced until the tip is positioned in the lower third of the superior vena cava. Permits access to the venous system.
Placebo	An inactive and physically identical medication or procedure used as a comparator in controlled clinical trials.
Plain soap	Detergents that do not contain antimicrobial agents or contain low concentrations of antimicrobial agents that are effective solely as preservatives
Power (statistical)	The ability to demonstrate an association when one exists. Power is related to sample size; the larger the sample size, the greater the power and the lower the risk that a possible association could be missed.
Primary care	Healthcare delivered to patients outside hospitals. Primary care covers a range of services provided by general practitioners, nurses, dentists, pharmacists, opticians and other healthcare professionals.
Primary outcome	The outcome of greatest importance, usually the one in a study that the power calculation is based on.
Product licence	An authorisation from the MHRA to market a medicinal product.
Prospective study	A study in which people are entered into the research and then followed up over a period of time with future events recorded as they happen. This contrasts with studies that are retrospective.
Publication bias	Also known as reporting bias. A bias caused by only a subset of all the relevant data being available. The publication of research can depend on the nature and direction

Term	Definition
	of the study results. Studies in which an intervention is not found to be effective are sometimes not published. Because of this, systematic reviews that fail to include unpublished studies may overestimate the true effect of an intervention. In addition, a published report might present a biased set of results (e.g. only outcomes or sub-groups where a statistically significant difference was found.
Pulmonary aspiration	Entry of secretions or foreign material, including gastrostomy feed, via the trachea into the lungs
P-value	The probability that an observed difference could have occurred by chance, assuming that there is in fact no underlying difference between the means of the observations. If the probability is less than 1 in 20, the P value is less than 0.05; a result with a P value of less than 0.05 is conventionally considered to be 'statistically significant'.
Quality of life	See 'Health-related quality of life'.
Quality-adjusted life year (QALY)	An index of survival that is adjusted to account for the patient's quality of life during this time. QALYs have the advantage of incorporating changes in both quantity (longevity/mortality) and quality (morbidity, psychological, functional, social and other factors) of life. Used to measure benefits in cost-utility analysis. The QALYs gained are the mean QALYs associated with one treatment minus the mean QALYs associated with an alternative treatment.
Randomisation	Allocation of participants in a research study to two or more alternative groups using a chance procedure, such as computer-generated random numbers. This approach is used in an attempt to ensure there is an even distribution of participants with different characteristics between groups and thus reduce sources of bias.
Randomised controlled trial (RCT)	A comparative study in which participants are randomly allocated to intervention and control groups and followed up to examine differences in outcomes between the groups.
Ready-to-use	Feeds prepared and supplied by the manufacturer, that only require attaching to the feeding tube.
Relative risk (RR)	The number of times more likely or less likely an event is to happen in one group compared with another (calculated as the risk of the event in group A/the risk of the event in group B).
Removal of physical contamination	The procedure which enables the user to clean all contamination from a specific surface.
Reporting bias	See publication bias.
Resident (hand) flora	Microorganisms that colonise the deeper crevices of the skin and hair follicles as they have adapted to the hostile environment. Not readily transferred to other people or objects. Not easily removed by the mechanical action of soap and water, but can be reduced in number with the use of an antiseptic solution.
Resource implication	The likely impact in terms of finance, workforce or other NHS resources.
Retractable needles	Built-in safety mechanism is activated by fully depressing plunger while needle is still in patient. Once activated, needle is automatically retracted from patient, virtually eliminating exposure.
Retrospective study	A retrospective study deals with the present/ past and does not involve studying future events. This contrasts with studies that are prospective.
Reusable syringe	See single patient use
Review question	In guideline development, this term refers to the questions about treatment and care that are formulated to guide the development of evidence-based recommendations.
Risk assessment	Making a suitable and sufficient assessment of risks – this will involve identifying the

Term	Definition
	hazards (something with the potential to do harm), and evaluating the extent of risks (the likelihood that the harm from a particular hazard is realised); and identifying measures needed to comply with legal requirements.
Safety cannula	A type of cannula that prevents sharps injuries. These can be active (requires pressing a button to trigger the withdrawal of the needle in to a plastic sleeve using a spring) or passive (with a protective shield that automatically covers the needlepoint during its withdrawal)
Safety needle devices	These include needle free devices, retractable needles and safety resheathing devices that prevents sharps injuries.
Secondary outcome	An outcome used to evaluate additional effects of the intervention deemed a priori as being less important than the primary outcomes.
Selection bias	A systematic bias in selecting participants for study groups, so that the groups have differences in prognosis and/or therapeutic sensitivities at baseline. Randomisation (with concealed allocation) of patients protects against this bias.
Self-catheterisation	Intermittent self catheterisation: urinary catheterisation is undertaken by the patient to drain the bladder with the immediate removal of the catheter. Intermittent catheterisation: urinary catheterisation is performed by a carer with the immediate removal of the catheter.
Sensitivity analysis	A means of representing uncertainty in the results of economic evaluations. Uncertainty may arise from missing data, imprecise estimates or methodological controversy. Sensitivity analysis also allows for exploring the generalisability of results to other settings. The analysis is repeated using different assumptions to examine the effect on the results. One-way simple sensitivity analysis (univariate analysis): each parameter is varied individually in order to isolate the consequences of each parameter on the results of the study. Multi-way simple sensitivity analysis (scenario analysis): two or more parameters are varied at the same time and the overall effect on the results is evaluated. Threshold sensitivity analysis: the critical value of parameters above or below which the conclusions of the study will change are identified. Probabilistic sensitivity analysis: probability distributions are assigned to the uncertain parameters and are incorporated into evaluation models based on decision analytical techniques (For example, Monte Carlo simulation).
Sepsis	A systemic response typically to a serious usually localized infection (as of the abdomen or lungs) especially of bacterial origin that is usually marked by abnormal body temperature and white blood cell count, tachycardia, and tachypnoea ; specifically : systemic inflammatory response syndrome induced by a documented infection.
Septicaemia	Invasion of the bloodstream by virulent microorganisms (including bacteria, viruses, or fungi) from a focus of infection that is accompanied by acute systemic illness. Also called blood poisoning.
Sharps	Sharps are any medical item or device that can cause laceration or puncture wounds: eg needles, cannulae, scalpels and lancets.
Significance (statistical)	A result is deemed statistically significant if the probability of the result occurring by chance is less than 1 in 20 ($p < 0.05$).
Single use	The medical device/item/equipment is intended to be used on an individual patient during a single procedure and then discarded. The device is not intended to be reprocessed.
Single-patient use	Items that can be used several times but are reserved for the use of one patient only.

Term	Definition
Skin tunnelled catheter	Vascular access device whose proximal end is tunnelled subcutaneously from the insertion site and brought out through the skin at an exit site. The tip of the catheter lies in the lower third of the superior vena cava.
Stakeholder	Those with an interest in the use of the guideline. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups.
Sterile	Free from any living microorganisms, eg, sterile gloves, sterile catheter.
Sterile technique	A technique that prevents any possibility for the transmission of microorganisms.
Substantivity	Substantivity is an attribute of certain active ingredients that adhere to the stratum corneum (ie, remain on the skin after rinsing or drying) to provide an inhibitory effect on the growth of bacteria remaining on the skin.
Suprapubic catheter/catheterisation	Suprapubic catheterisation creates a tunnel from the abdominal wall to the bladder. Urine can then be drained directly from the bladder into a bag through a catheter inserted into this tunnel.
Symptomatic UTI	An urinary tract infection causing symptoms which may include: dysuria, loin pain, supra pubic tenderness, fever, pyuria and confusion.
Systematic review	Research that summarises the evidence on a clearly formulated question according to a pre-defined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis.
Time horizon	The time span over which costs and health outcomes are considered in a decision analysis or economic evaluation.
Transient microorganisms	Micro-organisms acquired on the skin through contact with surfaces. The hostile environment of skin means that they can usually only survive for a short time, but they are readily transferred to other surfaces touched. Can be removed by washing with soap and water or inactivated by alcohol handrub and antiseptic agent.
Transparent semipermeable membrane (TSM) dressing	Adhesive sterile dressing that allows the passage of water vapour and oxygen but is impermeable to water and micro-organsims, usually transparent to allow visual inspection of the skin/site.
Treatment allocation	Assigning a participant to a particular arm of the trial.
Univariate	Analysis which separately explores each variable in a data set.
Urethral	Relating to the tube that conveys urine from the bladder to the external urethral orifice.
User preference	The preferred technique or product used by the clinician/patient/carer.
Utility	A measure of the strength of an individual's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.
VAD related blood stream infection	See CRBSI
VAD related local infection	See VAD related soft tissue infection.
VAD related phlebitis	Inflammation of the vein, may be accompanied by pain, erythema, oedema, streak formation and/or palpable cord associated with an indwelling VAD.
VAD related skin infection	See VAD related soft tissue infection.
VAD related soft	Presence and growth of a pathogenic micro-orgasnism in the soft tissue around the

Term	Definition
tissue infection	entry site of a VAD or along the length of a skin tunnelled catheter with signs of infection/inflammation indicated by pain, redness, Immobility (loss of function), swelling and heat.
VAD related thromobophlebitis	Inflammation of the vein in conjunction with the formation of a blood clot in associated with an indwelling VAD.
Visibly soiled hands	Hands showing visible dirt or visibly contaminated with proteinaceous material, blood, or other body fluids (eg, fecal material or urine).
Visual Infusion Phlebitis (VIP) score	A tool for monitoring intravenous infusion sites and determining when access should be removed.
Washout(s)	See 'Bladder washout'.

14 Abbreviations

AGREE	Appraisal of Guidelines Research and Evaluation
ANS	Artificial nutrition support
APIC	Association for Professionals in Infection Control
ANTT	Aseptic non touch technique
BANS	British Artificial Nutrition Survey
BBE	Bare below elbow
BSI	Bloodstream infection
CDC	Centers for Disease Control
C.diff	*Clostridium difficile*
CE	European Community
CFU	Colony forming unit
CI / 95% CI	Confidence interval / 95% confidence interval
CRBSI	Catheter-related Bloodstream Infection
CVC	Central venous catheter
DOH	Department of Health
EF	Enteral feeding
DVT	Deep venous thrombosis
GDG	Guideline Development Group
GP	General Practitioner
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HACCP	Hazard analysis and critical control point
HCAI	Healthcare-associated infection
HBV/Hep B	Hepatitis B Virus
HCV/Hep C	Hepatitis C Virus
HCW	Healthcare Worker
HETF	Home enteral tube feeding
HICPAC	Healthcare Infection Control Practices Advisory Committee
HIV	Human Immunodeficiency Virus
ICER	Incremental cost-effectiveness ratio
ICU	Intensive Care Unit
ISC	Intermittent self catheterisation
LTC	Long-term urinary catheterisation
MD	Mean Difference
MDA	Medical Device Agency
MCID	Minimal clinical important difference
MID	Minimal important difference
MRSA	Meticillin resistant Staphylococcus aureus
N/A	Not applicable
NCGC	National Clinical Guideline Centre
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence

NPSA	National Patient Safety Agency
N/R	Not reported
NRCT	Non-randomised control trial
NRL	Natural rubber latex
NST	Nutrition support team
PEG	Percutaneous endoscopic gastrostomy
PICC	Peripherally inserted central catheter
PICO	Framework incorporating patients, interventions, comparison and outcome
PPE	Personal protective equipment
PTFE	Polytetrafluoroethylene
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RR	Relative risk
TPN	Total parenteral nutrition
TSM dressing	Transparent semipermeable membrane dressing
UTI	Urinary tract infection
VAD	Vascular access devices
VIP Score	Visual Infusion Phlebitis Score
VRE	Vancomycin resistant enterococci
vs.	Versus
WHO	World Health Organisation

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