

Draft for Pre-publication Check

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 Pre-publication Check

Commissioned by the National Institute for Health and Clinical Excellence

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Explaining the changes in the pre-publication version

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.

Recommendations are marked to indicate the year of the last evidence review: [2003] if the evidence has not been updated since the original guideline, [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, [2012] if the evidence has been reviewed but no change has been made to the recommendation and [new 2012] if the evidence has been reviewed and the recommendation has been added or updated.

New and updated evidence reviews and recommendations are shaded pink with 'Update 2012' in the right hand margin.

Appendix D.10 contains recommendations from the 2003 guideline that have been consulted on for deletion from this 2012 update. Details of any replacement recommendations are included. The original NICE guideline and supporting documents are available from www.nice.org.uk/guidance/CG2

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Infection prevention and control (partial update)

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Update 2012

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. In addition, we would like to thank Simon Harrison, Consultant urological surgeon, who helped with queries on care of patients with long-term urinary catheters.

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
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Stakeholder List (2012)

The full list of stakeholders is listed in Appendix C.

1 Introduction

1.1 Introduction (2012)

3 Clinical context

4 A wide variety of healthcare is delivered in primary and community care settings. Healthcare-
5 associated infections arise across a wide range of clinical conditions and can affect patients of all
6 ages. Healthcare workers, family members and carers are also at risk of acquiring infections when
7 caring for patients.

8 HCAI can occur in otherwise healthy individuals, especially if invasive procedures or devices are used.
9 For example: indwelling urinary catheters are the most common cause of urinary tract infections and
10 bloodstream infections are associated with vascular access devices.

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

15 Patient safety has become a cornerstone of care and preventing HCAI remains a priority. It is
16 estimated that 300,000 patients a year in England acquire a HCAI as a result of care within the
17 NHS¹⁸⁰. In 2007, meticillin resistant *Staphylococcus aureus* (MRSA) bloodstream infections and
18 *Clostridium difficile* infections were recorded as the underlying cause of, or a contributory factor in,
19 approximately 9000 deaths in hospital and primary care in England.

20 HCAI are estimated to cost the NHS approximately £1 billion a year, and; £56 million of this is
21 estimated to be incurred after patients are discharged from hospital¹⁸⁰. In addition to increased
22 costs, each one of these infections means additional use of NHS resources, greater patient
23 discomfort and a decrease in patient safety. A 'no tolerance' attitude is now prevalent in relation to
24 avoidable HCAI.

25 Rationale for the update

26 Since the publication of the NICE clinical guideline on the prevention of HCAI in primary and
27 community care in 2003, many changes have occurred within the NHS that place the patient firmly at
28 the centre of all activities. First, the NHS Constitution for England⁶⁹ defines the rights and pledges
29 that every patient can expect regarding their care. To support this, the Care Quality Commission
30 (CQC), the independent regulator of all health and adult social care in England, ensures that health
31 and social care is safe, and monitors how providers comply with established standards. In addition,
32 the legal framework that underpins the guidance has changed since 2003.

33 New guidance is needed to reflect the fact that, as a result of the rapid turnover of patients in acute
34 care settings, complex care is increasingly being delivered in the community. New standards for the
35 care of patients and the management of devices to prevent related healthcare-associated infections
36 are needed that will also reinforce the principles of asepsis.

37 This clinical guideline is a partial update of 'Infection control: prevention of healthcare-associated
38 infection in primary and community care' (NICE clinical guideline 2; 2003), and addresses areas in
39 which clinical practice for preventing HCAI in primary and community care has changed, where the
40 risk of HCAI is greatest or where the evidence has changed. The Guideline Development Group (GDG)
41 recognise the important contribution that surveillance makes to monitoring infection, but it is not
42 within the scope of this guideline to make specific recommendations about this subject. Where high-
43 quality evidence is lacking, the GDG has highlighted areas for further research.

1 **Audience**

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

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

10 Healthcare settings covered by this guideline are:

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

15 **Style**

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

19 The GDG was also aware that the consequences of not implementing some other recommendations
20 on patient safety would be very serious – that is, there would be a greatly increased risk of adverse
21 events, including death. The GDG therefore concluded that the use of the word 'must' in these
22 recommendations is justified, in line with the guidance in chapter 9 of 'The guidelines manual
23 (2009)'. For ease, the GDG have added details of the applicable legislation as footnotes to the
24 relevant recommendations. All other instances of 'must' in a recommendation should be considered
25 related to patient safety and the high risk of adverse events to patients if they are not implemented.

26 This update is integrated with the original recommendations and evidence from the 2003 guideline.
27 Changes in methodology and processes since 2003 have resulted in a different presentation of the
28 evidence that has informed the Guideline Development Group discussions in 2012. The
29 recommendations made in this update are clearly marked as New 2012 or Amended 2012. The
30 original recommendations for which the evidence has not been reviewed or updated are marked
31 2003. The 2003 recommendations that have not been deleted or replaced as part of this update
32 remain current and applicable to the NHS and are enhanced by the revisions made in this update.

33

34

1.2 Introduction (2003)

- 2 These guidelines were directly funded by the Department of Health (England) with additional funding
3 from The National Institute for Clinical Excellence (NICE).
- 4 NICE commissioned the development of these guidelines from Thames Valley University under the
5 auspices of the National Collaborating Centre for Nursing and Supportive Care. The full guidelines for
6 preventing healthcare-associated infections in community and primary care are published by Thames
7 Valley University and are available on its website <www.richardwellsresearch.com>, the NICE
8 website <www.nice.org.uk> and on the website of the National Electronic Library for Health
9 <www.nelh.nhs.uk>.
- 10 These guidelines were developed by a multidisciplinary Guideline Development Group (GDG) that
11 represented all key stakeholders and included a patient representative.
- 12 Due to the breadth of the guideline, several members were appointed for their specialist knowledge
13 of a particular medical device.
- 14 Conflicts of interest were formally monitored throughout the guideline development period and
15 none was noted.
- 16 The aim of the group was to develop recommendations for practice based on the available evidence
17 and knowledge of the practicalities of clinical practice.
- 18 The group met at approximately monthly intervals and followed the working procedures outlined by
19 NICE.
- 20 During the scoping exercise, patient groups were contacted for their advice and visits made to
21 specialist centres to discuss issues with patients and staff. Arrangements were made with a patients'
22 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?

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

8 NICE clinical guidelines can:

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

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

16 We produce our guidelines using the following steps:

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

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

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

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

2.2 Remit

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

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

- 1 We would like NICE to produce a guideline on infection control in primary and community care. This
2 guideline will be expected to address a standard approach to preventing and controlling healthcare-
3 associated infections in primary and community care and additional guidance for selected healthcare
4 interventions with a potential risk for infection.
- 5 NICE has commissioned the National Clinical Guidelines Centre for Acute and Chronic Conditions to
6 partially update 'Infection control: prevention of healthcare-associated infection in primary and
7 community care', NICE clinical guideline 2.

2.3 Who developed this guideline?

- 9 A multidisciplinary Guideline Development Group (GDG) comprising professional group members and
10 consumer representatives of the main stakeholders developed this guideline (see section on
11 Guideline Development Group Membership and acknowledgements).
- 12 The National Institute for Health and Clinical Excellence funds the National Clinical Guideline Centre
13 (NCGC) and thus supported the development of this guideline. The GDG was convened by the NCGC
14 and chaired by Carol Pellowe in accordance with guidance from the National Institute for Health and
15 Clinical Excellence (NICE).
- 16 The group met every 4 to 6 weeks during the development of the guideline. At the start of the
17 guideline development process all GDG members declared interests including consultancies, fee-paid
18 work, share-holdings, fellowships and support from the healthcare industry. At all subsequent GDG
19 meetings, members declared arising conflicts of interest, which were also recorded. Members were
20 either required to withdraw completely or for part of the discussion if their declared interest made it
21 appropriate. The details of declared interests and the actions taken are shown in Appendix B.
- 22 Staff from the NCGC provided methodological support and guidance for the development process.
23 The team working on the guideline included a project manager, systematic reviewers, health
24 economists and information scientists. They undertook systematic searches of the literature,
25 appraised the evidence, conducted meta analysis and cost effectiveness analysis where appropriate
26 and drafted the guideline in collaboration with the GDG.

2.4 What this guideline update covers

- 28 This guideline covers the following populations:
- 29 All adults and children receiving healthcare where standard infection control precautions apply in
30 primary and community care. Healthcare workers, family members and carers who provide
31 healthcare in primary and community settings. Guideline developers will pay particular attention to
32 the needs of different age groups, different genders, people with disabilities and minority ethnic
33 groups.
- 34 This guideline covers the following healthcare settings:
- 35 Primary care settings, such as general practices, dental clinics, health centres and polyclinics. This
36 also includes care delivered by the ambulance service. Community care settings (such as care homes,
37 patient's own home, schools and prisons) where NHS healthcare is provided or commissioned. This
38 guideline is commissioned for the NHS, but people providing healthcare in other settings, such as
39 private settings, may find the guidance relevant.
- 40 This guideline covers the following clinical issues:
- 41 Hand decontamination including when to decontaminate hands, the choice of hand cleaning
42 preparation and the most effective hand decontamination technique.

- 1 Personal protective equipment (PPE) including the safe disposal of personal protective equipment in
2 line with European Union (EU) legislation, the appropriate use of plastic aprons and fluid-repellent
3 gowns and which gloves provide the best protection against infections.
- 4 The safe use and disposal of sharps including the choice of sharps equipment and safe disposal of
5 sharp instruments and needles in line with current EU legislation.
- 6 Long-term urinary catheters (more than 28 days) including the use of antibiotics when changing
7 indwelling urinary catheters, the use of bladder irrigation, instillations and washouts, types of
8 catheters to use and aseptic technique.
- 9 Percutaneous gastrostomy feeding including the use of syringes in enteral feeding systems.
- 10 Vascular access devices (VADs), including types of dressings, decontamination of ports, hubs and skin
11 and aseptic technique.
- 12 Information and support for healthcare workers, patients and carers:
- 13 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

- 15 This guideline covers does not cover:
- 16 • people receiving healthcare in secondary care settings,
17 • advice on the diagnosis, treatment or management of specific infections,
18 • advice on the procedures of insertion of urinary catheters, percutaneous gastrostomies or
19 vascular access devices,
20 • infection prevention measures for invasive procedures carried out by paramedic services, such as
21 at a major trauma, other than in the clinical areas listed section 2.4,
22 • decontamination or cleaning of the healthcare environment and equipment, other than the
23 clinical devices listed in 2.4.

2.6 Structure of the updated guideline

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

2.6.1 Chapters

- 28 The structure of the updated guideline has been kept as close to the original guideline as possible:
- 29 • Standard principles general recommendations (including education of patients, carers and their
30 healthcare workers)
31 • Standard principles for hand decontamination
32 • Standard principles for the use of personal protective equipment
33 • Standard principles for the safe use and disposal of sharps
34 • Waste disposal (including general recommendation about disposal of healthcare waste)
35 • Long-term urinary catheterisation
36 • Enteral feeding
37 • Vascular access devices (VADs).

2.6.2 Methodology

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

2.6.3 Recommendations

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

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

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

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

2.6.4 Appendices

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

2.7 Relationships between the guideline and other NICE guidance

31 Related NICE Clinical Guidelines:

- 32 • Tuberculosis. NICE clinical guideline 117 (2011). Available from www.nice.org.uk/guidance/CG117
- 33 • Lower urinary tract symptoms. NICE clinical guideline 97 (2010). Available from
34 www.nice.org.uk/guidance/CG97
- 35 • Needle and syringe programmes. NICE public health guidance 18 (2009). Available from
36 www.nice.org.uk/guidance/PH18
- 37 • Surgical site infection. NICE clinical guideline 74 (2008). Available from
38 www.nice.org.uk/guidance/CG74
- 39 • Prophylaxis against infective endocarditis. NICE clinical guideline 64 (2008). Available from
40 <http://www.nice.org.uk/guidance/CG64>
- 41 • Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from
42 www.nice.org.uk/guidance/CG54

- 1 • Urinary incontinence. NICE clinical guideline 40 (2006). Available from
- 2 www.nice.org.uk/guidance/CG40
- 3 • Nutrition support in adults. NICE clinical guideline 32 (2006). Available from
- 4 www.nice.org.uk/guidance/CG32
- 5 **NICE Related Guidance currently in development:**
- 6 • Intravenous fluid therapy in adults in hospital. NICE clinical guideline. Publication expected June
- 7 2013.
- 8 • Urinary incontinence in neurological disease. NICE clinical guideline. Publication expected:
- 9 October 2012.
- 10 • Stroke rehabilitation. NICE clinical guideline. Publication expected: April 2012.
- 11 • Healthcare-associated infections in secondary care settings. NICE advice. Publication expected:
- 12 November 2011.

2.8 Background and context to the Guidelines (2003)

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

19 Incorporating evidence-based infection prevention and control advice into routine clinical care
20 activities is believed to be important in reducing the incidence of preventable healthcare-associated
21 infections¹¹¹. Consequently, guidelines for preventing healthcare-associated infections in caring for
22 patients in primary and community care settings were commissioned.

2.9 Scope and Purpose of the Guidelines (2003)

24 The scope of these guidelines was established at the start of the guideline process, following a period
25 of consultation, including a survey and focus group discussions with community and primary care
26 practitioners. This consultation process has been previously described¹⁹⁹ and the full scoping exercise
27 is available from the NICE website <www.nice.org.uk> (Appendix D.2).

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

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

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

3 Methods

3.1 Methods (2012)

- 3 This guidance was developed in accordance with the methods outlined in the NICE Guidelines
4 Manual 2009.¹⁸²

3.1.1 Amendments to 2003 text

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

- 9 Exceptions include:

Text in previous guideline	Change made and reason for change
Must	Should or ensure. Must is only used 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 <i>Staphylococcus aureus</i>	Changed to Methicillin resistant <i>Staphylococcus aureus</i> to be consistent with current Department of Health terminology and the British National Formulary.

Update 2012

3.1.2 Developing the review questions and outcomes

- 11 Review questions were developed in a PICO framework (patient, intervention, comparison and
12 outcome) for intervention reviews. For qualitative reviews the SPICE framework (setting, population,
13 intervention, comparison and evaluation methods) was used. This was to guide the literature
14 searching process and to facilitate the development of recommendations by the guideline
15 development group (GDG). They were drafted by the NCGC technical team and refined and validated
16 by the GDG. The questions were based on the key clinical areas identified in the scope (Appendix A).
17 Further information on the outcome measures is shown below and detailed in the review protocols
18 (Appendix E).
19

1

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 decontamination to prevent healthcare-associated infections.
Hand decontamination	What is the clinical and cost effectiveness of when to decontaminate hands, including after the removal of gloves, on hand decontamination compliance, MRSA and <i>C. diff</i> reduction or cross infection, colony forming units and removal of physical contamination?	Colony forming units, hand decontamination compliance, MRSA and <i>C. diff</i> reduction and cross infection and removal of physical contamination.
Hand decontamination	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 decontamination compliance, MRSA and <i>C. diff</i> reduction or cross infection, colony forming units and removal of physical contamination?	Colony forming units, hand decontamination compliance, MRSA and <i>C. diff</i> reduction and cross infection and removal of physical contamination.
Hand decontamination	What is the clinical and cost effectiveness of healthcare workers decontaminating wrists vs. not decontaminating wrists or usual practice on MRSA and <i>C. diff</i> reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?	Colony forming units, hand decontamination compliance, MRSA and <i>C. diff</i> reduction and cross infection and removal of physical contamination and transient organisms.
Hand decontamination	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 <i>C. diff</i> reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?	Colony forming units, hand decontamination compliance, MRSA and <i>C. diff</i> 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	Blood borne infection, compliance, infection related mortality and morbidity, sharps injuries and user preference.

Chapter	Review questions	Outcomes
	mortality and morbidity and sharps injuries?	
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	Catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, VAD related

Chapter	Review questions	Outcomes
	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?	bacteraemia and VAD related 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 administering 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 <i>C. diff</i> reduction and mortality?	UTIs, infection related mortality, septicaemia, bacteraemia, phlebitis, compliance and MRSA or <i>C. diff</i> 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 and MRSA or <i>C. diff</i> 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 <i>C. diff</i> reduction and mortality?	Catheter tip colonisation, Infection related mortality, septicaemia, VAD related bacteraemia, VAD related phlebitis, compliance and MRSA or <i>C. diff</i> reduction.

3.1.3 Searching for evidence

3.1.321 Clinical literature search

3 Systematic literature searches were undertaken to identify evidence within published literature in
4 order to answer the review questions as per The Guidelines Manual [2009]¹⁸². Clinical databases
5 were searched using relevant medical subject headings, free-text terms and study type filters where
6 appropriate. Studies published in languages other than English were not reviewed. Where possible,
7 searches were restricted to articles published in English language. All searches were conducted on
8 core databases, MEDLINE, Embase, CINAHL and The Cochrane Library. The additional subject specific
9 database PsychInfo was used for the patient information questions. All searches were updated on
10 18th April 2011. No papers after this date were considered.

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

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

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

3.1.322 Health economic literature search

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

36 The search strategies for health economics are included in Appendix F. All searches were updated on
37 18th April 2011. No papers published after this date were considered.

3.1.323 Evidence synthesis

39 The Research Fellow:

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

- 1 • Reviewed full papers against pre-specified inclusion / exclusion criteria to identify studies that
2 addressed the review question in the appropriate population and reported on outcomes of
3 interest (review protocols are included in Appendix E).
- 4 • Critically appraised relevant studies using the appropriate checklist as specified in The Guidelines
5 Manual.¹⁸²
- 6 • Extracted key information about the study's methods and results into evidence tables (evidence
7 tables are included in Appendix G).
- 8 • Generated summaries of the evidence by outcome (included in the relevant chapter write-ups):
- 9 o Randomised studies: meta-analysed, where appropriate and reported in GRADE (Grading of
10 Recommendations Assessment, Development and Evaluation) profiles for clinical studies – see
11 section 3.1.3.6 for details.
- 12 o Observational studies: data presented as a range of values in GRADE profiles.
- 13 o Qualitative studies: each study summarised in a table (available in Appendix G) where possible,
14 and the quality of included studies assessed against the NICE quality checklists for qualitative
15 studies¹⁸². Key common themes between studies which were relevant to the review question
16 were summarised and presented with a comment of the quality of studies contributing to the
17 themes in the main guideline document. GRADE does not have a system for rating the quality
18 of evidence for qualitative studies or surveys, and therefore there are no GRADE quality ratings
19 for the themes identified.

3.1.304 Inclusion/exclusion

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

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

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

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

3.1.335 Methods of combining clinical studies

34 Data synthesis for intervention reviews

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

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

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

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

3.1.366 Appraising the quality of evidence by outcomes

17 After appropriate pooling of the results for each outcome across all studies, the quality of the
18 evidence for each outcome was evaluated and presented using the GRADE toolbox¹⁰⁷. The software
19 (GRADEpro) developed by the international GRADE working group was used to record the
20 assessment of the evidence quality for each outcome.

21 In this guideline, findings were summarised using two separate tables. The “Clinical Study
22 Characteristics” table includes details of the quality assessment. Reporting or publication bias was
23 only taken into consideration in the quality assessment and included in the Clinical Study
24 Characteristics table if it is clear there was a risk of bias. Each outcome was examined separately for
25 the quality elements listed and defined in Table 1 and each graded using the quality levels listed in
26 Table 2. The main criteria considered in the rating of these elements are discussed below (see section
27 3.1.3.7 Grading of Evidence). Footnotes were used to describe reasons for grading a quality element
28 as having serious or very serious problems. The ratings for each component were summed to obtain
29 an overall quality assessment for each outcome listed in Table 3.

30 The “Clinical Summary of Findings” table includes meta-analysed outcome data (where appropriate),
31 an absolute measure of intervention effect (calculated from the summary statistics for the meta-
32 analysed relative measure and the mean control event rate) and the summary of quality of evidence
33 for that outcome. In the Clinical Summary of Findings table, the columns for intervention and control
34 indicate the total of the sample size for continuous outcomes. For binary outcomes such as number
35 of patients with an adverse event, the event rates (n/N: total number of patients with events divided
36 by total number of patients across studies) are shown with percentages (note: this percentage is an
37 output of GRADEpro software. It is not the results of the meta-analysis and is not used in decision
38 making).
39

1 **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.

2 **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.

3 **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.

Update 2012

3.1.347 Grading the quality of clinical evidence

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

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

3.1.338 Study limitations

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

5 **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: <ul style="list-style-type: none"> • 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.

3.1.369 Inconsistency

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

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

3.1.3210 Indirectness

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

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

3.1.3.11 Imprecision

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

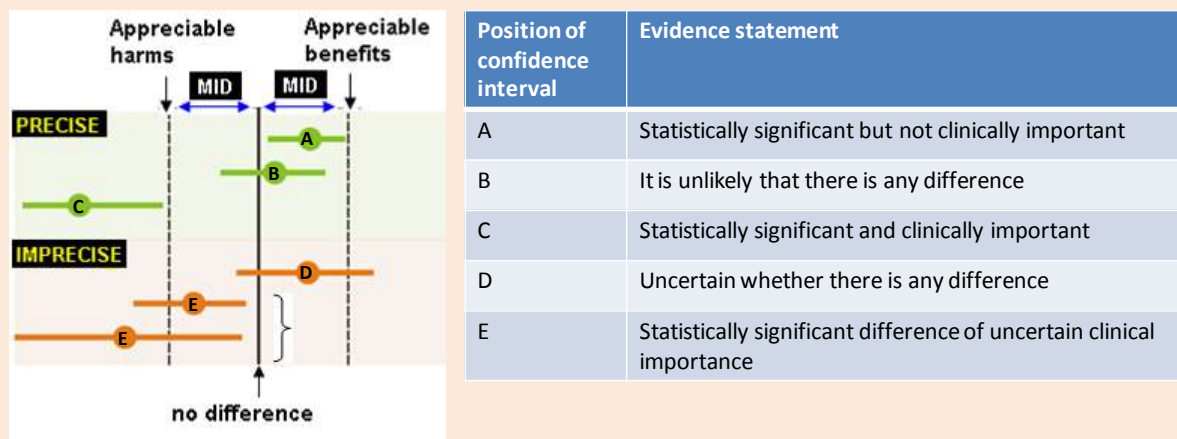
10 The thresholds of important benefits or harms, or the MID (minimal important difference) for an
11 outcome are important considerations for determining whether there is a “clinically important”
12 difference between interventions, and in assessing imprecision. For continuous outcomes, the MID is
13 defined as “the smallest difference in score in the outcome of interest that informed patients or
14 informed proxies perceive as important, either beneficial or harmful, and that would lead the patient
15 or clinician to consider a change in the management”.^{107,129,233,234} An effect estimate larger than the
16 MID is considered to be “clinically important”. For dichotomous outcomes, the MID is considered in
17 terms of changes in absolute risk.

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

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

27 For the purposes of this guideline, an intervention is considered to have a clinically important effect
28 with certainty if the whole of the 95% confidence interval describes an effect of greater magnitude
29 than the MID. Figure 1 illustrates how the clinical importance of effect estimates were considered
30 along with imprecision, and the usual way of documenting this is in the evidence statements
31 throughout this guideline. Results are imprecise when studies include relatively few patients and few
32 events and thus have wide confidence intervals around the estimate of the effect relative to the
33 clinically important threshold.
34

1 **Figure 1: Imprecision and evidence statements**



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.

2 For this guideline, there was no information in the literature on what was the most appropriate MID,
 3 and the GDG adopted the default threshold suggested by GRADE. This was a relative risk reduction of
 4 25% (relative risk of 0.75 for negative outcomes) or a relative risk increase of 25% (risk ratio 1.25 for
 5 positive outcomes) for binary outcomes. The GDG interpreted the risk ratio and 95% confidence
 6 interval relative to the threshold, also taking into account the 95% confidence intervals of the
 7 absolute effect estimates. For continuous outcomes, a standardised mean difference (SMD) of 0.5
 8 was considered the minimal important difference for most outcomes.

3.1.4 Evidence of cost-effectiveness

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

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

3.1.4.1 Literature review

15 The Health Economist:

- 16 • Identified potentially relevant studies for each review question from the economic search results
 17 by reviewing titles and abstracts – full papers were then obtained.
- 18 • Reviewed full papers against pre-specified inclusion / exclusion criteria to identify relevant studies
 19 (see below for details).
- 20 • Critically appraised relevant studies using the economic evaluations checklist as specified in The
 21 Guidelines Manual¹⁸².
- 22 • Extracted key information about the study's methods and results into evidence tables (evidence
 23 tables are included in Appendix H).
- 24 • Generated summaries of the evidence in NICE economic evidence profiles (included in the
 25 relevant chapter write-ups) – see below for details.

26 Inclusion/exclusion

27 Full economic evaluations (studies comparing costs and health consequences of alternative courses
 28 of action: cost-utility, cost-effectiveness, cost-benefit and cost-consequence analyses) and

1 comparative costing studies that addressed the review question in the relevant population were
2 considered as potentially applicable economic evidence.

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

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

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

13 For more details about the assessment of applicability and methodological quality see the economic
14 evaluation checklist (The Guidelines Manual).¹⁸²

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

17 **NICE economic evidence profiles**

18 The NICE economic evidence profile has been used to summarise cost and cost-effectiveness
19 estimates. The economic evidence profile shows, for each economic study, an assessment of
20 applicability and methodological quality, with footnotes indicating the reasons for the assessment.
21 These assessments were made by the health economist using the economic evaluation checklist from
22 The Guidelines Manual¹⁸². It also shows incremental costs, incremental outcomes (for example,
23 QALYs) and the incremental cost-effectiveness ratio from the primary analysis, as well as information
24 about the assessment of uncertainty in the analysis. See Table 5 for more details.

25 If a non-UK study was included in the profile, the results were converted into pounds sterling using
26 the appropriate purchasing power parity¹⁹² and Hospital and Community Health Services Pay and
27 Prices Inflation Index.⁵³

28 **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 ^(a) : <ul style="list-style-type: none"> • 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) : <ul style="list-style-type: none"> • 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

Item	Description
	<p>might possibly change the conclusions about cost effectiveness.</p> <ul style="list-style-type: none"> • 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.

1 (a) *Limitations and applicability were assessed using the economic evaluation checklist from The Guidelines Manual.*¹⁸²

3.1.422 Undertaking new health economic analysis

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

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

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

3.1.423 Cost-effectiveness criteria

13 NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the
 14 principles that GDGs should consider when judging whether an intervention offers good value for
 15 money.^{182,183}

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

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

23.1.5 Developing recommendations

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

- 25 • Evidence tables of the clinical and economic evidence reviewed from the literature. All evidence
 26 tables are in Appendix G and H.
- 27 • Summary of clinical and economic evidence and quality (as presented in chapters 5 to 12).
- 28 • Forest plots (Appendix I).

- 1 • A description of the methods and results of the cost-effectiveness analysis undertaken for the
2 guideline (Appendix J).

3 Recommendations were drafted on the basis of the GDG interpretation of the available evidence,
4 taking into account the balance of benefits and harms, quality of evidence, and costs. When clinical
5 and economic evidence was of poor quality, conflicting or absent, the GDG drafted recommendations
6 based on consensus. Expert advisors were invited to provide advice on how to interpret the
7 identified evidence. The considerations for making consensus based recommendations include the
8 balance between potential harms and benefits, economic or implications compared to the benefits,
9 current practices, recommendations made in other relevant guidelines, patient preferences and
10 equality issues. The consensus recommendations were made through discussions in the GDG, or
11 methods of formal consensus were applied. Formal consensus methods used in this guideline
12 included voting at the GDG or anonymous voting via email. The GDG Chair ensured sufficient time for
13 responding and encouraged all members to express their views. The GDG also considered whether
14 the uncertainty is sufficient to justify delaying making a recommendation to await further research,
15 taking into account the potential harm of failing to make a clear recommendation (See 3.1.5.1).

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

3.1.5.1 Research recommendations

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

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

3.1.5.2 Validation process

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

3.1.5.3 Updating the guideline

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

3.1.5.4 Disclaimer

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

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

3.1.535 Funding

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

3.2 Methods (2003)

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

- 9 For each set of guidelines, an electronic search was conducted for current national and international
10 guidelines. They were retrieved and subjected to critical appraisal using the AGREE Instrument²⁵⁹,
11 which provides “a framework for assessing the quality of clinical practice guidelines.”

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

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

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

- 21 • Medline
- 22 • Cumulated Index of Nursing and Allied Health Literature (CINAHL)
- 23 • Embase
- 24 • The Cochrane Library:
- 25 • The National Electronic Library for Health
- 26 • The NHS Centre for Reviews and Dissemination (CRD)
- 27 • CRD includes 3 databases: Database of Abstracts of Reviews of Effectiveness (DARE), NHS
- 28 Economic Evaluation Database (NHS EED), Health Technology Assessment (HTA) Database
- 29 • Health CD Database
- 30 • Health Management Information Consortium Database
- 31 • The National Research Register
- 32 • The Web of Science
- 33 • The Institute of Health Technology
- 34 • Health CD Database
- 35 • Health Management Information Consortium Database
- 36 • HMIC includes 3 databases: The Department of Health Library and Information Service (DHData),
- 37 Health Management Information Service (HELMIS) from the Nuffield Institute and the Kings Fund
- 38 Database.

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

- 41 • relevant to a review question;

- 1 • primary research/systematic review/meta-analysis;
- 2 • written in English.
- 3 Where there was no abstract, the full article was retrieved.
- 4 No research designs were specifically excluded but wherever possible, in use rather than in vitro
- 5 studies were retrieved.
- 6 The second sift involved a critical review of the full text, and articles relevant to a review question
- 7 were critically appraised. The SIGN data extraction form²³⁷ was used to document the results of
- 8 critical appraisal (Available from the SIGN website <http://www.sign.ac.uk>). A form for descriptive
- 9 studies was designed by us based on the SIGN methodology.
- 10 The evidence tables and reports were presented to the GDG for discussion. At this stage, expert
- 11 advice derived from seminal works and appraised national and international guidelines were
- 12 considered. Following extensive discussion the guidelines were drafted.
- 13 Although economic opinion was considered for each review question, the economic scope described
- 14 above did not identify any high quality cost-effectiveness evidence, e.g., economic evaluations
- 15 alongside randomised controlled trials. As a result, simple decision analytic modelling was employed
- 16 using estimates from published literature and expert opinion from the GDG. Results were estimated
- 17 initially for a “base case,” i.e., the most likely scenario. These results were then subjected to
- 18 sensitivity analysis where key parameter values were varied. Areas were targeted where the impact
- 19 on resource use was likely to be substantial. In addition, where there was no evidence of difference
- 20 in clinical outcomes between interventions, simple cost analyses were performed to identify the
- 21 potential resource consequences.
- 22 Factors influencing the guideline recommendations included:
- 23 • the nature of the evidence;
- 24 • the applicability of the evidence;
- 25 • costs and knowledge of healthcare systems.
- 26 Consensus within the GDG was mainly achieved though discussion facilitated by the group chair.
- 27 Where necessary, agreement was arrived at by open voting.

4 Guideline summary

4.1 Key priorities for implementation

3 From the full set of recommendations, the GDG selected 10 key priorities for implementation. The
4 criteria used for selecting these recommendations are listed in detail in The Guidelines Manual¹⁸².
5 For each key recommendation listed, the selection criteria and implementation support points are
6 indicated by the use of the letters shown in brackets below.

7 The GDG selected recommendations that would:

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

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

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

24.1.1 Standard principles – general advice

22 **1. Everyone involved in providing care should be:**

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

26 **2. Wherever care is delivered, healthcare workers must^a have available appropriate supplies**
27 **of:**

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

31

^a In accordance with current health and safety legislation (at the time of the pre-publication check of the guideline [December 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.

- 1 **3. Educate patients and carers about:**
2 • the benefits of effective hand decontamination
3 • the correct techniques and timing of hand decontamination
4 • when it is appropriate to use liquid soap and water or handrub
5 • the availability of hand decontamination facilities
6 • their role in maintaining standards of healthcare workers' hand decontamination. [A, B, C, E,
7 X, W, Y] [new 2012]

4.1.2 Standard principles for hand decontamination

- 9 **4. Hands must be decontaminated in all of the following circumstances:**
10 • immediately before every episode of direct patient contact or care, including aseptic
11 procedures
12 • immediately after every episode of direct patient contact or care
13 • immediately after any exposure to body fluids
14 • immediately after any other activity or contact with a patient's surroundings that could
15 potentially result in hands becoming contaminated
16 • immediately after removal of gloves. [A, W, X] [new 2012]

4.1.3 Long-term urinary catheters

- 18 **5. Select the type and gauge of an indwelling urinary catheter based on an assessment of the**
19 **patient's individual characteristics, including:**
20 • age
21 • any allergy or sensitivity to catheter materials
22 • gender
23 • history of symptomatic urinary tract infection
24 • patient preference and comfort
25 • previous catheter history
26 • reason for catheterisation. [A, B, C, D, F, W, Y, Z] [new 2012]
27 **6. All catheterisations carried out by healthcare workers should be aseptic procedures. After**
28 **training, healthcare workers should be assessed for their competence to carry out these**
29 **types of procedures. [A, B, C, X, Y] [2003]**

- 30 **7. When changing catheters in patients with a long-term indwelling urinary catheter:**
31 • do not offer antibiotic prophylaxis routinely
32 • consider antibiotic prophylaxis^b for patients who:
33 – have a history of symptomatic urinary tract infection after catheter change or
34 – experience trauma^c during catheterisation. [A, B, C, W, X, Y, Z] [new 2012]

^b At the time of the pre-publication check of the guideline (December 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented

^c The GDG defined trauma as frank haematuria following catheterisation or two or more attempts of catheterisation.

4.1.4 Vascular access devices

- 2 **8. Before discharge from hospital, patients and their carers should be taught any techniques**
3 **they may need to use to prevent infection and safely manage a vascular access device^d. [A,**
4 **F, Y] [2003, amended 2012]**
- 5 **9. Healthcare workers caring for a patient with a vascular access device^d should be trained, and**
6 **assessed as competent, in using and consistently adhering to the infection prevention**
7 **practices described in this guideline. [A, B, C, F, X, Y, Z] [2003, amended 2012]**
- 8 **10. Decontaminate the skin at the insertion site with chlorhexidine gluconate in 70% alcohol**
9 **before inserting a peripheral vascular access device or a peripherally inserted central**
10 **catheter. [A, B, F, W, X] [new 2012]**
11

Update
2012

^d 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.

4.2 Full list of recommendations

4.2.1 Standard Principles

4.2.1.1 General advice

- 4 **1. Everyone involved in providing care should be:**
- 5
 - 6 • **educated about the standard principles of infection prevention and control and**
 - 7 **trained in hand decontamination, the use of personal protective equipment, and the safe use and disposal of sharps. [2012]**
- 8 **2. Wherever care is delivered, healthcare workers must^e have available appropriate supplies**
- 9 **of:**
- 10
 - 11 • **materials for hand decontamination**
 - 12 • **sharps containers**
 - 13 • **personal protective equipment. [new 2012]**
- 14 **3. Educate patients and carers about:**
- 15
 - 16 • **the benefits of effective hand decontamination**
 - 17 • **the correct techniques and timing of hand decontamination**
 - 18 • **when it is appropriate to use liquid soap and water or handrub**
 - 19 • **the availability of hand decontamination facilities**
 - 20 • **their role in maintaining standards of healthcare workers' hand decontamination. [new 2012]**

4.2.1.2 Hand decontamination

- 21 **4. Hands must be decontaminated in all of the following circumstances:**
- 22
 - 23 • **immediately before every episode of direct patient contact or care, including aseptic procedures**
 - 24 • **immediately after every episode of direct patient contact or care**
 - 25 • **immediately after any exposure to body fluids**
 - 26 • **immediately after any other activity or contact with a patient's surroundings that could potentially result in hands becoming contaminated**
 - 27 • **immediately after removal of gloves. [new 2012]**
- 28 **5. Decontaminate hands preferably with a handrub (conforming to current British standards^f),**
- 29 **except in the following circumstances, when liquid soap and water must be used:**
- 30
 - 31 • **when hands are visibly soiled or potentially contaminated with body fluids or**

^e In accordance with current health and safety legislation (at the time of the pre-publication check of the guideline [December 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.

^f At the time of the pre-publication check of the guideline (December 2011): BS EN 1500:1997.

- 1 • in clinical situations where there is potential for the spread of alcohol-resistant organisms
2 (such as *Clostridium difficile* or other organisms that cause diarrhoeal illness). [new 2012]
- 3 **6. Healthcare workers should ensure that their hands can be decontaminated throughout the**
4 **duration of clinical work by:**
- 5 • being bare below the elbow^g
6 • removing wrist and hand jewellery
7 • making sure that fingernails are short, clean and free of nail polish
8 • covering cuts and abrasions with waterproof dressings. [new 2012]
- 9 **7. An effective handwashing technique involves three stages: preparation, washing and**
10 **rinsing, and drying. Preparation requires wetting hands under tepid running water before**
11 **applying liquid soap or an antimicrobial preparation. The handwash solution must come into**
12 **contact with all of the surfaces of the hand. The hands must be rubbed together vigorously**
13 **for a minimum of 10–15 seconds, paying particular attention to the tips of the fingers, the**
14 **thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying**
15 **with good quality paper towels. [2003]**
- 16 **8. When decontaminating hands using an alcohol handrub, hands should be free from dirt and**
17 **organic material. The handrub solution must come into contact with all surfaces of the hand.**
18 **The hands must be rubbed together vigorously, paying particular attention to the tips of the**
19 **fingers, the thumbs and the areas between the fingers, until the solution has evaporated**
20 **and the hands are dry. [2003]**
- 21 **9. An emollient hand cream should be applied regularly to protect skin from the drying effects**
22 **of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol**
23 **product causes skin irritation an occupational health team should be consulted. [2003]**

Update
2012

4.2.143 Use of personal protective equipment

- 25 **10. Selection of protective equipment must^h be based on an assessment of the risk of**
26 **transmission of microorganisms to the patient, and the risk of contamination of the**
27 **healthcare worker's clothing and skin by patients' blood, body fluids, secretions or**
28 **excretions. [2003]**
- 29 **11. Gloves used for direct patient care**
- 30 • must^h conform to current EU legislation (CE marked as medical gloves for single-use)ⁱ and
31 • should be appropriate for the task. [new 2012]

Update
2012

^g 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 decontamination.

^h In accordance with current health and safety legislation (at the time of the pre-publication check of the guideline [December 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.

ⁱ At the time of the pre-publication check of the guideline (December 2011): BS EN 455 Parts 1 - 4 Medical gloves for single-use.

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

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

9 **14. Ensure that gloves used for direct patient care that have been exposed to body fluids are**
10 **disposed of correctly, in accordance with current national legislation^k or local policies (see**
11 **section 4.2.1.5). [new 2012]**

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

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

15 **17. When delivering direct patient care:**

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

20 **18. When using disposable plastic aprons or gowns:**

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

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

25 **20. Respiratory protective equipment, for example a particulate filter mask, must^j be used**
26 **when clinically indicated. [2003]**

4.2.174 Safe use and disposal of sharps

28 **21. Sharps should^l not be passed directly from hand to hand, and handling should be kept to a**
29 **minimum [2003, amended 2012]**
30

^j In accordance with current health and safety legislation (at the time of the pre-publication check of the guideline [December 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 the pre-publication check of the guideline [December 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

^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).

1 **22. Used needles:**

- 2 • **must not be bent or broken before disposal**
3 • **must not be recapped.**

4 **In dentistry, if recapping or disassembly is unavoidable, a risk assessment must be**
5 **undertaken and appropriate safety devices should be used. [new 2012]**

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

8 **24. Sharps containers:**

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

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

19 **26. Train and assess all users in the correct use and disposal of sharps and sharps safety**
20 **devices. [new 2012]**

4.2.15 Waste disposal

22 **27. Healthcare waste must be segregated immediately by the person generating the waste into**
23 **appropriate colour-coded storage or waste disposal bags or containers defined as being**
24 **compliant with current national legislationⁿ and local policies. [new 2012]**

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

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

^m At the time of the pre-publication check of the guideline (December 2011): UN3291 and BS 7320

ⁿ For guidance see (at the time of the pre-publication check of the guideline [December 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

4.2.2 Long-term urinary catheters

4.2.221 Education of patients, their carers and healthcare workers

- 3 **30. Patients and carers should be educated about and trained in techniques of hand**
4 **decontamination, insertion of intermittent catheters where applicable, and catheter**
5 **management before discharge from hospital. [2003]**
- 6 **31. Community and primary healthcare workers must be trained in catheter insertion, including**
7 **suprapubic catheter replacement and catheter maintenance. [2003]**
- 8 **32. Follow-up training and ongoing support of patients and carers should be available for the**
9 **duration of long-term catheterisation. [2003]**

4.2.202 Assessing the need for catheterisation

- 11 **33. Indwelling urinary catheters should be used only after alternative methods of management**
12 **have been considered. [2003]**
- 13 **34. The patient's clinical need for catheterisation should be reviewed regularly and the urinary**
14 **catheter removed as soon as possible. [2003]**
- 15 **35. Catheter insertion, changes and care should be documented. [2003]**

4.2.263 Catheter drainage options

- 17 **36. Following assessment, the best approach to catheterisation that takes account of clinical**
18 **need, anticipated duration of catheterisation, patient preference and risk of infection should**
19 **be selected. [2003]**
- 20 **37. Intermittent catheterisation should be used in preference to an indwelling catheter if it is**
21 **clinically appropriate and a practical option for the patient. [2003]**
- 22 **38. Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent**
23 **self-catheterisation. [new 2012]**
- 24 **39. Select the type and gauge of an indwelling urinary catheter based on an assessment of the**
25 **patient's individual characteristics, including:**
- 26 • age
 - 27 • any allergy or sensitivity to catheter materials
 - 28 • gender
 - 29 • history of symptomatic urinary tract infection
 - 30 • patient preference and comfort
 - 31 • previous catheter history
 - 32 • reason for catheterisation. [new 2012]
- 33 **40. In general, the catheter balloon should be inflated with 10 ml of sterile water in adults and**
34 **3–5 ml in children. [2003]**

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

4.2.234 Catheter insertion

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

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

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

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

4.2.235 Catheter maintenance

14 **46. Indwelling catheters should be connected to a sterile closed urinary drainage system or**
15 **catheter valve. [2003]**

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

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

22 **49. Patients managing their own catheters, and their carers, must be educated about the need**
23 **for hand decontamination^o before and after manipulation of the catheter, in accordance**
24 **with the recommendations in the standard principles section (section 4.2.1.). [2003,**
25 **amended 2012]**

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

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

29 **52. A link system should be used to facilitate overnight drainage, to keep the original system**
30 **intact. [2003]**

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

^o The text 'Patients managing their own catheters, and their carers, must be educated about the need for hand decontamination...' has replaced 'Carers and patients managing their own catheters must wash their hands...' in the 2003 guideline.

1 **54. The meatus should be washed daily with soap and water. [2003]**

2

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

- 5 • **develop a patient-specific care regimen**
- 6 • **consider approaches such as reviewing the frequency of planned catheter changes and**
7 **increasing fluid intake**
- 8 • **document catheter blockages. [new 2012]**

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9 **56. Bladder instillations or washouts must not be used to prevent catheter-associated**
10 **infections. [2003]**

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

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

- 14 • **do not offer antibiotic prophylaxis routinely**
- 15 • **consider antibiotic prophylaxis^p for patients who:**
 - 16 – **have a history of symptomatic urinary tract infection after catheter change or**
 - 17 – **experience trauma^q during catheterisation. [new 2012]**

Update 2012

4.2.3 Enteral feeding

4.2.3.1 Education of patients, their carers and healthcare workers

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

23 **60. Healthcare workers should be trained in enteral feeding and management of the**
24 **administration system. [2003]**

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

4.2.3.2 Preparation and storage of feeds

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

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

32 **64. Effective hand decontamination must be carried out before starting feed preparation.**
33 **[2003]**

^p At the time of the pre-publication check of the guideline (December 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented.

^q The GDG defined trauma as frank haematuria following catheterisation or two or more attempts of catheterisation.

- 1 **65. When decanting, reconstituting or diluting feeds, a clean working area should be prepared**
2 **and equipment dedicated for enteral feed use only should be used. [2003]**
- 3 **66. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-**
4 **touch technique. [2003]**
- 5 **67. Feeds should be stored according to the manufacturer's instructions and, where applicable,**
6 **food hygiene legislation. [2003]**
- 7 **68. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a**
8 **refrigerator, and used within 24 hours. [2003]**

4.2.393 Administration of feeds

- 10 **69. Use minimal handling and an aseptic technique to connect the administration system to the**
11 **enteral feeding tube. [new 2012]**
- 12 **70. Ready-to-use feeds may be given for a whole administration session, up to a maximum of**
13 **24 hours. Reconstituted feeds should be administered over a maximum 4-hour period.**
14 **[2003]**
- 15 **71. Administration sets and feed containers are for single-use and must be discarded after each**
16 **feeding session. [2003]**

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4.2.374 Care of insertion site and enteral feeding tube

- 18 **72. The stoma should be washed daily with water and dried thoroughly. [2003]**
- 19 **73. To prevent blockages, flush the enteral feeding tube before and after feeding or**
20 **administering medications using single-use syringes or single-patient-use (reusable) syringes**
21 **according to the manufacturer's instructions. Use:**
- 22
 - freshly drawn tap water for patients who are not immunosuppressed
 - either cooled freshly boiled water or sterile water from a freshly opened container for

23
 - patients who are immunosuppressed. [new 2012]

24

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4.2.2.4 Vascular access devices

4.2.261 Education of patients, their carers and healthcare workers

- 27 **74. Before discharge from hospital, patients and their carers should be taught any techniques**
28 **they may need to use to prevent infection and safely manage a vascular access device^f**
29 **[2003, amended 2012]**
- 30 **75. Healthcare workers caring for a patient with a vascular access device^f should be trained,**
31 **and assessed as competent, in using and consistently adhering to the infection prevention**
32 **practices described in this guideline [2003, amended 2012]**

^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.

- 1 **76. Follow-up training and support should be available to patients with a vascular access**
2 **device^r and their carers [2003, amended 2012]**

4.2.432 General asepsis

- 4 **77. Hands must be decontaminated (see section 4.2.1.2) before accessing or dressing a vascular**
5 **access device. [new 2012]**

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

4.2.433 Vascular access device site care

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

- 12 **80. Use a sterile, transparent semipermeable membrane dressing to cover the vascular access**
13 **device insertion site. [new 2012]**

- 14 **81. Consider a sterile gauze dressing covered with a sterile transparent semipermeable**
15 **membrane dressing only if the patient has profuse perspiration, or if the vascular access**
16 **device insertion site is bleeding or oozing. If a gauze dressing is used:**
17
 - **change it every 24 hours, or sooner if it is soiled and**
 - **replace it with a sterile transparent semipermeable membrane dressing as soon as possible.**

18 **[new 2012]**

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

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

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

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

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

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

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4.2.414 General principles for management of vascular access devices

- 2 **88. Decontaminate the injection port or vascular access device catheter hub before and after**
3 **accessing the system using chlorhexidine gluconate in 70% alcohol. Consider using an**
4 **aqueous solution of chlorhexidine gluconate if the manufacturer's recommendations**
5 **prohibit the use of alcohol with their catheter. [new 2012]**
- 6 **89. In-line filters should not be used routinely for infection prevention. [2003]**
- 7 **90. Antibiotic lock solutions should not be used routinely to prevent catheter-related**
8 **bloodstream infections (CRBSI). [2003]**
- 9 **91. Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter**
10 **colonisation or CRBSI, either before insertion or during the use of a central venous catheter.**
11 **[2003]**
- 12 **92. Preferably, a single lumen catheter should be used to administer parenteral nutrition. If a**
13 **multilumen catheter is used, one port must be exclusively dedicated for total parenteral**
14 **nutrition, and all lumens must be handled with the same meticulous attention to aseptic**
15 **technique. [2003]**
- 16 **93. Preferably, a sterile 0.9 percent sodium chloride injection should be used to flush and lock**
17 **catheter lumens. [2003]**
- 18 **94. When recommended by the manufacturer, implanted ports or opened-ended catheter**
19 **lumens should be flushed and locked with heparin sodium flush solutions. [2003]**
- 20 **95. Systemic anticoagulants should not be used routinely to prevent CRBSI. [2003]**
- 21 **96. If needleless devices are used, the manufacturer's recommendations for changing the**
22 **needleless components should be followed. [2003]**
- 23 **97. When needleless devices are used, healthcare workers should ensure that all components**
24 **of the system are compatible and secured, to minimise leaks and breaks in the system.**
25 **[2003]**
- 26 **98. When needleless devices are used, the risk of contamination should be minimised by**
27 **decontaminating the access port with either alcohol or an alcoholic solution of chlorhexidine**
28 **gluconate before and after using it to access the system. [2003]**
- 29 **99. In general, administration sets in continuous use need not be replaced more frequently**
30 **than at 72-hour intervals unless they become disconnected or a catheter-related infection is**
31 **suspected or documented. [2003]**
- 32 **100. Administration sets for blood and blood components should be changed every 12 hours,**
33 **or according to the manufacturer's recommendations. [2003]**
- 34 **101. Administration sets used for total parenteral nutrition infusions should generally be**
35 **changed every 24 hours. If the solution contains only glucose and amino acids,**
36 **administration sets in continuous use do not need to be replaced more frequently than**
37 **every 72 hours. [2003]**

- 1 **102. Avoid the use of multidose vials, in order to prevent the contamination of infusates. [new**
2 **2012]**

4.3 Key research recommendations

- 4 The following research recommendations are those prioritised by the GDG. Additional
5 recommendations have been made and are detailed within the chapters.

4.3.1 Standard principles of infection prevention and control

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

4.3.2 Hand decontamination

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

4.3.3 Intermittent urinary catheters: catheter selection

- 13 **3. For patients performing intermittent self-catheterisation over the long term, what is the clinical**
14 **and cost effectiveness of single-use non-coated versus single-use hydrophilic versus single-use**
15 **gel reservoir versus reusable non-coated catheters with regard to the following outcomes:**
16 **symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality,**
17 **patient comfort and preference, quality of life, and clinical symptoms of urethral damage?**

4.3.4 Indwelling urinary catheters: catheter selection

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

4.3.5 Indwelling urinary catheters: antibiotic prophylaxis

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

4.3.6 Vascular access devices: skin decontamination

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

5 Standard Principles

5.1 Introduction

3 The updated review question in this chapter is:

- 4 • Education of patients, carers and healthcare workers.

5 The new review question in this chapter is:

- 6 • Patient information about hand decontamination.

7 This chapter introduces hand decontamination, personal protective equipment (PPE) and sharps.
8 Several new questions and updates are included in the hand decontamination, PPE and sharps
9 chapters. Key health and safety legislation^{1,3,4,68,115} has also been considered when drafting these
10 recommendations.

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

14 The GDG has prioritised three recommendations in this chapter as a key priority for implementation,
15 see sections 5.2.1.1 and 5.2.2.4.

16

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

5.2 Education of patients, carers and their healthcare workers

22 To improve patient outcomes and reduce healthcare costs, it is essential that everyone providing
23 care in the community is educated about hand decontamination, the appropriate use of gloves and
24 protective clothing, and the safe disposal of sharps. Adequate supplies of soap, alcohol rub, towels
25 and sharps bins must be made available wherever care is delivered and this may include providing
26 healthcare workers undertaking home visits, with their personal supply. Patients and carers should
27 request that healthcare workers follow these principles²⁴.
28

- 1 The following recommendations have been updated based on the evidence reviewed in the standard
- 2 principles chapters for hand hygiene, personal protective equipment and the safe use and disposal of
- 3 sharps in chapters 6, 7 and 8, respectively.

5.2.141 Recommendations

Recommendations	1. Everyone involved in providing care should be: <ul style="list-style-type: none"> • 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	<p>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.</p> <p>The GDG wish to emphasise the safe use of sharps, and want to increase the awareness of safe sharps use and reduce injuries.</p>
Trade off between clinical benefits and harms	<p>The clinical benefit from education about standard principles (hand decontamination, personal protective equipment and sharps) would lead to decreased healthcare-associated infections, sharps injuries and a better understanding of why standard principles are important.</p> <p>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</p> <p>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 this was linked to a lack of, or ineffective, training. GDG consensus was that without adequate education sharps injuries will continue to be a problem.</p>
Economic considerations	<p>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.</p>
Quality of evidence	<p>See also the review questions in chapter 8 regarding safe use of sharps.</p> <p>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.</p>
Other considerations	<p>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.</p> <p>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 for further details.</p>

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1

Recommendations	<p>2. Wherever care is delivered, healthcare workers must⁵ have available appropriate supplies of:</p> <ul style="list-style-type: none"> • materials for hand decontamination • sharps containers • personal protective equipment. [new 2012]
Relative values of different outcomes	<p>The GDG have added “personal protective equipment” to the list of supplies that must be provided.</p> <p>The most important outcome is to protect healthcare workers from health care associated infections and prevent cross contamination of infections from patient to patient.</p>
Trade off between clinical benefits and harms	<p>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 1974¹, Health and Safety Regulations 2002⁴, Control of Substances Harmful to Health Regulations 2002¹¹⁵, Management of Health and Safety at Work Regulations 1999³, Health and Social Care Act 2008⁶⁸).</p> <p>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</p>
Economic considerations	<p>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.</p>
Quality of evidence	<p>See sharps waste disposal chapter, which refers to Safe Management of Healthcare Waste.⁷²</p> <p>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.</p>
Other considerations	<p>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 2002,¹¹⁵ Management of Health and Safety at Work Regulations 1999,³ Health and Social Care Act 2008⁶⁸) in line with the guidance from the NICE Guidelines Manual (2009).¹⁸²</p> <p>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 equality. See section 4.1 for further details.</p>

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2

⁵ In accordance with current health and safety legislation (at the time of the pre-publication check of the guideline [December 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.

5.2.2 Review question

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

5.2.241 Focus of the review:

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

11 See Evidence table G.1.1, Appendix G.

5.2.222 Evidence reviewed

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

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

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

32 Details about the quality and applicability that are specific to the themes found are documented
33 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.	
<p>4 x Survey 80,163,195,204</p> <p>1 x Cohort study¹⁵⁹</p> <p>1 x [Survey +Interviews]³³</p> <p>1 x [FGD +Interviews]¹⁷⁵</p> <p>1 x Telephone survey²²⁶</p>	<p>1.1 Hand washing is widely believed to be effective in preventing infection (including MRSA, healthcare-associated infections, flu outbreaks and wound care):</p> <ul style="list-style-type: none"> • 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].²⁰⁴ • Flu prevention: More than 80% members of the public thought hand washing was an effective prevention measure for flu [UK]¹⁷⁵, and swine flu²²⁶, although only 28.1% reported washing their hands more than usual because of swine flu [UK].²²⁶ • More than 90% of participants perceived hand-washing as an effective measure to prevent H1N1 (avian flu) infection [Korea].¹⁹⁵ 	<p>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.^{80,163,195,204}</p> <p>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^{175,195,226} and 3 among inpatients.^{33,80,204}</p> <p>Consistent themes emerged across different settings and populations.</p>
<p>1x survey¹⁹⁵</p> <p>1 x Telephone survey²²⁶</p>	<p>1.2 Perceived efficacy of washing hands is associated with hand washing:</p> <ul style="list-style-type: none"> • Perceived effectiveness of hand-washing was positively correlated (p=0.002) with hand-washing frequency [Korea]¹⁹⁵, and actually washing hands more regularly (odds ratio 1.8. 95% CI 1.5 to 2.2) [UK].²²⁶ 	<p>Indirectness: Both surveys were conducted to investigate perceptions during flu outbreaks.^{195,226}</p> <p>Consistency: Both UK and Korean studies showed the correlation.</p>
<p>3 x [Survey +Interviews]^{33,207,256}</p> <p>1 x Survey²⁵²</p> <p>1 x [Structured observations +Interview + FGD]²³¹</p>	<p>1.3 Variation in preference for alcohol gels and hand rubs:</p> <ul style="list-style-type: none"> • Hand wipes (82% of inpatients,[UK])³³, soap and water (54.3% of parents in A&E, US)²⁵² were the preferred options . • Rinse free alcohol gel was well received (children and teachers, UK)²³¹, 85% of inpatients would use it for themselves [UK].²⁰⁷ .= • 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].²⁵⁶ 	<p>Limitations: Small sample size and poor sampling strategy in one study (non random sampling³³).</p> <p>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.²⁵⁶</p> <p>Indirectness: Studies were indirect in terms of</p>

		population and setting (conducted among inpatients in hospitals).
1 x [Survey +Interviews] ³³	<p>1.4 Lack of accessibility of hand washing facilities, alcohol gels and hand rubs:</p> <ul style="list-style-type: none"> 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] ^{54,56,130,231}	<p>Among studies done mostly in mothers, disgust was associated with:</p> <ul style="list-style-type: none"> bodily fluids or excrement: such as “after you’ve been to the loo” (UK),⁵⁴ “women have-periods” (mothers, India.⁵⁶ visible dirt on hands: “bits on our hands” (children, UK),²³¹ dirt [Botswana].¹³⁰ unpleasant smell: “I don’t want the scent of that thing [faeces] to remain on my hands.”[Ghana]⁵⁶, “whenever I’ve had a cigarette .. I wash my hands” [UK].⁵⁴ unpleasant feeling on hands: “... I don’t particularly like the feel on my hands ...sticky”[UK 2003]⁵⁴ “stickiness”,[Botswana].¹³⁰ 	<p>Limitations: Poor sampling strategies (convenience based sampling/ non-random sampling);^{54,56} No details of verification of results or triangulation reported in any of the studies.</p> <p>Indirectness: Two studies were conducted in developing countries.^{56,130} 2 studies were conducted in the UK and were also indirect in terms of population (school children²³¹, mothers⁵⁴).</p> <p>Consistency: Disgust as a motivator of hand washing was consistent across different settings (countries), and populations (children, adults).</p>
2 x [Structured observations +Interview + FGD] ^{54,56} 1 x [FGD +Interviews] ¹⁷⁵ 1 x Survey ¹⁶³	<p>2.2 Responsibility: not wanting to pass on to others, and a responsibility of protecting others:</p> <ul style="list-style-type: none"> 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,^{54,56} and also the wider, members of the general public expressed a wider sense of responsibility to protect the health of ‘others’ in society [UK].¹⁷⁵ 	<p>Limitations: Poor sampling strategies (convenience based sampling/non random sampling).^{54,56} No details of verification of results or triangulation reported in any of the studies.</p> <p>Indirectness: 1 review included studies from developing countries.⁵⁶</p> <p>Consistency: Consistent themes emerged across different settings and populations</p>
1 x Survey ¹⁹⁵ , 1 x [Structured observations +Interview +	<p>2.3 Perceived themselves (or others) to be susceptible to infections:</p> <ul style="list-style-type: none"> Hand-washing was associated with perceived susceptibility of flu infection(p=0.001).[university students, Korea]¹⁹⁵, (Adjusted OR 1.5, 95% CI 1.3 to 1.8)[general public, UK 2009].²²⁶ Frightened of more germs going about ... they have got no immune system really”[mothers, UK 	<p>Limitations: The frequency of hand washing was self reported, which may be different from actual practice.^{195,226}</p> <p>Indirectness: Studies in conducted among</p>

<p>FGD⁵⁴] 1 x Telephone survey²²⁶</p>	<p>2003].⁵⁴</p>	<p>mothers and child carers;⁵⁴ in flu outbreak situations,^{226,195} and in Korea.¹⁹⁵ Consistency: Consistent themes emerge in spite of differences.</p>
<p>3 x [Structured observations +Interview + FGD]^{54,56,231} 2 x Survey^{204,236}</p>	<p>2.4 Believed or understood that it is important in prevention of Infection:</p> <ul style="list-style-type: none"> 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].⁵⁴ ‘So I don’t get ill’ (Year 2 child).²³¹ Not washing hands was associated with spreading diseases (e.g. cholera and diarrhoea) to children [mothers, Uganda, Ghana 2009].⁵⁶ Hands should be washed before dressing is changed (98.7% of public) [USA 2007].²⁰⁴ hand washing was considered very important after touching infected skin (87%), after coughing/sneezing (79%).²³⁶ 	<p>Limitations: Poor sampling strategies(use of convenience based sampling or non-random sampling strategies);^{54,56} Small sample size²⁰⁴ Indirectness: Studies were conducted among mothers and child carers;⁵⁴ and in developing countries .⁵⁶ Consistency: Consistent themes emerge in spite of differences in population and settings.</p>
	<p>3. Patient perceptions and experience of participation in healthcare worker hand decontamination.</p>	
	<p>3.1 Perceptions and experience of patients regarding their own participation in improving HCW compliance with hand decontamination:</p>	
<p>4 x Survey^{81,151,153,273} 1 x Cohort study¹⁵⁹ 1 x [Survey +Interviews]²⁰⁷</p>	<p>There were variations in studies about whether patients were comfortable or likely to ask doctors or nurses to clean their hands:</p> <ul style="list-style-type: none"> 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]²⁷³, 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].²⁷³ 94% of inpatient had not asked their nurse or doctor; 53% trusted that the HCWs would have already cleaned their hands [UK].²⁰⁷ 	<p>Limitations: Validation of questionnaire and verification of findings not reported in any of the surveys.^{81,151,153,273} Indirectness: All studies were conducted in acute care settings among inpatients.^{81,153,207,273}</p>
	<p>3.2 Factors affecting patient participation in implementation of hand decontamination among healthcare workers:</p>	
<p>4 x</p>	<p>Believing that it is alright to ask based on encouragement from HCW, presence of reminders, or</p>	<p>Limitations: Validation of questionnaire and</p>

<p>Survey^{58,81,151,153} 1 x [Survey +Interviews]²⁰⁷</p>	<p>observing similar behaviour in other patients encourages participants, for example:</p> <ul style="list-style-type: none"> • An explicit invitation from a HCW increased the intention to ask a physician from 29.9% to 77.8% 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].⁵⁸ • 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].²⁰⁷ • Intention to ask healthcare workers about handwashing is an important factor in actually asking about hand washing (covariance 0.36, p<0.001).¹⁵³ 	<p>verification of findings not reported in any of the surveys;^{58,81,151,153} one study at risk of responder bias as interviews were conducted by HCW.¹⁵¹</p> <p>Indirectness: Indirect in terms of population and settings (conducted in acute care settings among inpatients).^{58,81,151,153,207}</p>
<p>3 x Survey^{58,81,151} 1 x Cohort study¹⁵⁹ 1 x [Survey +Interviews]²⁰⁷</p>	<p>Profession or seniority of healthcare workers (HCW)</p> <p>There are variations whether one group of HCW are more likely to be asked than others:</p> <ul style="list-style-type: none"> • 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^{58,207}], 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 	<p>Validation of questionnaire and verification of findings not reported in the surveys.^{58,81,151}</p> <p>Indirectness: All studies were indirect to the target population and settings (conducted in acute care settings among inpatients).</p>
<p>2 x Survey^{80,153} 1 x Cohort study¹⁵⁹</p>	<p>Knowledge about infections, previous hospital admissions, history of infections</p> <ul style="list-style-type: none"> • Patients would be more willing to ask healthcare workers whether they have washed their hands if they were less anxious about asking hospital staff and had prior hospital admissions[UK]⁸⁰ or 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 	<p>Validation of questionnaire and verification of findings not reported in the surveys.^{80,153}</p> <p>Indirectness: All studies were indirect to target population and settings (conducted in acute care settings among inpatients).</p>

5.2.213 Economic evidence:

2 No economic evidence was identified.

5.2.234 Recommendations:

Recommendations	<p>3. Educate patients and carers about:</p> <ul style="list-style-type: none"> • the benefits of effective hand decontamination • 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 decontamination. [new 2012]
Relative values of different outcomes	<p>The reduction of healthcare-associated infections through increased awareness and practice of hand decontamination is important. The involvement of patients in their own and healthcare workers' hand decontamination in healthcare settings will be likely to contribute to better practice of hand decontamination.</p>
Trade off between clinical benefits and harms	<p>Patient education has the potential to improve awareness and encourage hand decontamination 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.</p>
Economic considerations	<p>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.</p>
Quality of evidence	<p>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.</p> <p>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 decontamination in affecting behaviours.</p> <p>However, the themes which emerged about the perception and factors which encourage or discourage hand decontamination are consistent across settings and populations, increasing the confidence that these findings are applicable to patients in the community.</p>
Other considerations	<p>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.</p> <p>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 <i>“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, i.e., not derived from fermented fruit. Alcohol gel is widely used throughout Islamic countries in health care setting”</i>¹⁷⁸.</p> <p>When information is available, the GDG felt it would be useful to direct the</p>

patients to these information sources to clarify the positions. The GDG were aware that not all patients may be comfortable in asking health care workers to wash their hands and that they will need encouragement to do so along with education. The review looked at factors which encouraged patients to do so and be more involved in hand decontamination of healthcare workers. The GDG 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.

5.3 Research recommendation

2 1. What are the barriers to compliance with standard precautions of infection prevention and 3 control that patients and carers experience in their own homes?

4 Why this is important

5 Recent changes to the delivery of healthcare mean that care is increasingly delivered within a
6 patient's home environment. Infection prevention in this setting is just as important as in hospital.
7 There are currently approximately six million unpaid carers in the UK, a number that is likely to
8 increase with an aging population. The association between carer training and infection rates is
9 unknown. No evidence of surveillance of healthcare-associated infections in the community is
10 currently available in the UK.

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

6 Standard principles for hand decontamination

6.1 Introduction

3 The updated review questions in this chapter are:

- 4 • When to decontaminate hands?
5 • Which hand cleaning preparation to use?

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

8 New review questions included in this chapter are:

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

11 These two new review questions are important and have been prioritised for inclusion in this update
12 as they continue to be contentious and healthcare workers need to be able to identify best practice
13 based on the evidence. Although current practice is that wrists should be washed as part of hand
14 decontamination, there is uncertainty as to whether there is evidence to support this. In addition,
15 there is a need to identify an end point to the areas of the hand to be included. It is recognised that
16 workwear should not impede effective hand decontamination, as detailed and reviewed in section
17 4.2.1.3, and should not come into contact with patients when delivering direct patient care or
18 environmental surfaces when cleaning.

19 Sections not updated in this chapter are:

- 20 • Hand washing techniques
21 • Skin damage due to hand decontamination.

22 The GDG were made aware that current guidance on hand decontamination for the dental
23 profession is detailed in the Department of Health's 'Health Technical Memorandum 01-05:
24 Decontamination in primary care dental practices'.⁶⁷

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

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

38 The areas discussed include:

- 39 • assessment of the need to decontaminate hands
40 • the efficacy of hand decontamination agents and preparations;
41 • the rationale for choice of hand decontamination practice;

- 1 • technique for hand decontamination
- 2 • 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?

4
5 Overviews of epidemiological evidence conclude that hand-mediated transmission is a major
6 contributing factor in the current infection threats to hospital in-patients. These include both
7 meticillin-sensitive and meticillin-resistant *Staphylococcus aureus* (MRSA), and multi-resistant Gram-
8 negative aerobes and enterococci. The transmission of microorganisms from one patient to another
9 via the hands, or from hands that have become contaminated from the environment, can result in
10 adverse outcomes. Primary exogenous infection is a direct clinical threat where microorganisms are
11 introduced into susceptible sites, such as surgical wounds, intravascular cannulation sites, enteral
12 feeding systems or catheter drainage systems. Secondary endogenous infection creates an indirect
13 clinical threat where potential pathogens transmitted by the hands establish themselves as
14 temporary or permanent colonisers of the patient and subsequently causes infection at susceptible
15 sites. Evidence from two previous reviews²¹⁰ conclude that in outbreak situations contaminated
16 hands are responsible for transmitting infections and our previous systematic review indicates that
17 effective hand decontamination can significantly reduce infection rates in gastro-intestinal infections
18 and in high-risk areas, such as intensive care units.²¹⁰

19 Our systematic review identified two clinically-based trials^{88,228} and two descriptive studies that
20 confirmed the association between hand decontamination and reductions in infection^{106,206}. In a non-
21 randomised controlled trial (NRCT) a hand washing programme was introduced and in the post
22 intervention period respiratory illness fell by 45%²²⁸. A further NRCT, introducing the use of alcohol
23 hand gel to a long-term elderly care facility, demonstrated a reduction of 30% in HCAI over a period
24 of 34 months when compared to the control unit.⁸⁸ One descriptive study demonstrated the risk of
25 cross infection resulting from inadequate hand decontamination in patient's homes.¹⁰⁶

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

29

6.3 When to decontaminate hands

6.3.1 Review question

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

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

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

6.3.1.1 Clinical evidence

13 Four cohort studies were identified, where the intervention was the introduction of a hand
14 decontamination guideline (before and after implementation studies). All studies aimed to increase
15 hand decontamination compliance through a multi-modal hand decontamination intervention.
16 Allegranzi et al., 2010⁷ implemented the World Health Organisation (WHO) hand hygiene
17 improvement strategy (including the 5 moments of hand hygiene) in a hospital in Mali, Africa. The
18 WHO 5 moments of hand hygiene encourages health-care workers to clean their hands (1) before
19 touching a patient, (2) before clean/aseptic procedures, (3) after body fluid exposure/risk, (4) after
20 touching a patient and (5) after touching patient surroundings. Other elements of implementation
21 strategy include improving access to handrub, training and education, evaluation and feedback and
22 reminders in the workplace. Aragon et al., 2005¹⁵ implemented the Centres for Disease Control (CDC)
23 2002 guideline in one US hospital and Larson et al., 2007¹⁴⁵ implemented the same guideline in 40 US
24 hospitals. This intervention encourages healthcare workers to use handrub or wash their hands
25 before and after every contact. Aragon et al., 2005¹⁵ also used reminders in the workplace. Rosenthal
26 et al., 2005²²² implemented the Association for Professionals in Infection Control (APIC) hand hygiene
27 guideline in a hospital in Buenos Aires, Argentina. This intervention used education and reminders in
28 the workplace.

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

30 See Evidence Table G.2.1, Appendix G, Forest Plots in Figure 1-5, Appendix I.
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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 decontamination compliance - overall ²²²	1	Observational studies	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Nosocomial infections – per 1000 bed days ²²²	1	Observational studies	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Implementation of WHO 5 moments of hand hygiene						
Hand decontamination compliance - overall ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Hand decontamination compliance – before patient contact ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Hand decontamination compliance – before aseptic task ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Hand decontamination compliance – After body fluid exposure risk ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Hand decontamination compliance – After patient contact ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Hand decontamination 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	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness	Serious imprecision

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Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
infections – Urinary tract infections ⁷					(b)	(c)
Healthcare-associated infections – Primary blood stream infections ⁷	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness (b)	Serious imprecision (c)
Implementation of CDC 2002 guideline						
Hand decontamination compliance – Before patient care ¹⁵	1	Observational studies	Serious limitations ^(d)	No serious inconsistency	Serious indirectness (b)	No serious imprecision
Hand decontamination 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				
<i>C. diff</i> reduction or cross infection	0	RCT or observational studies				
Removal of physical contamination	0	RCT or observational studies				

- 1 (a) Authors note that in addition to the implementation of a hand hygiene guideline other CVC and urinary catheter specific
- 2 infection control interventions were also being conducted simultaneously.
- 3 (b) Hospital intervention rather than community.
- 4 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
- 5 difficult to know the true effect size for this outcome.
- 6 (d) Unclear as to the exact population of patients and HCW involved in the study. Limited baseline data given.
- 7 (e) Baseline hand decontamination compliance not stated.
- 8

1
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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
<u>Implementation of APIC guideline</u>					
Hand decontamination 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
<u>Implementation of WHO 5 moments of hand hygiene</u>					
Hand decontamination 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 decontamination 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 decontamination 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 decontamination 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 decontamination 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 decontamination 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
<u>Implementation of CDC 2002 guideline</u>					
Hand decontamination 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 decontamination 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	524/17315 4 (0.3%)	498/17162 5 (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	771/16195 4 (0.5%)	848/15300 3 (0.6%)	RR 0.86 (0.78 to 0.95)	1 fewer per 1000 (0 fewer to 1 fewer)	VERY LOW

Update 2012

3

6.3.112 Cost-effectiveness evidence

Two studies were identified which evaluated the costs and consequences associated with relevant hand hygiene guidance. Cummings et al 2010^{52,52} developed a mathematical model to estimate the cost of noncompliance between patient contacts and potential contamination of surfaces after exposure; Stone et al., 2007^{250,251} evaluated the relationship between adherence to CDC guidelines and the cost of hand decontamination 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 decontamination products in the 2003 guideline but seems better placed here, since it was not a comparative analysis of different hand decontamination 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 suggests¹¹⁸ 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 ⁵²	Minor limitations ^(a)	Partially applicable ^(c)	Outcomes: MRSA colonisation and MRSA infection after noncompliant patient contact episodes; cost per noncompliant episode.
Stone 2007 ²⁵¹	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.

1 **Table 10: Hand hygiene guidance – Economic summary of findings**

Study	Incremental cost	Incremental effects	ICER	Uncertainty
Cummings 2010 ⁵²	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 ²⁵¹	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

6.3.123 **Evidence statements**

- 3 Clinical There is a statistically significant and clinically important increase in hand
4 decontamination compliance (before patient contact, before aseptic task, after body
5 fluid exposure and after patient contact) with the implementation of the WHO 5
6 moments (VERY LOW QUALITY).
- 7 It is uncertain whether there is any difference in hand decontamination compliance
8 after contact with patient surroundings, or healthcare-associated infections with the
9 implementation of the WHO 5 moments (VERY LOW QUALITY).
- 10 There is a statistically significant and clinically important increase in hand
11 decontamination compliance before patient care with the implementation of the
12 CDC 2002 hand hygiene guideline (VERY LOW QUALITY).
- 13 It is unlikely that there is any difference in hand decontamination compliance after
14 patient care, or in catheter associated UTIs with the implementation of the CDC 2002
15 hand hygiene guideline (VERY LOW QUALITY).
- 16 There is a statistically significant decrease of uncertain clinical importance in central
17 line associated blood stream infections with the implementation of the CDC 2002
18 hand hygiene guideline (VERY LOW QUALITY).
- 19 There is a statistically significant and clinically important increase in hand
20 decontamination compliance and a statistically significant decrease in nosocomial
21 infections per 1000 bed days with the implementation of the APIC hand hygiene
22 guideline (VERY LOW QUALITY).
- 23 No studies were identified that reported colony forming units, MRSA reduction or
24 cross infection, *C. diff* reduction or cross infection or removal of physical
25 contamination.
- 26 Economic Noncompliance with hand hygiene guidance is associated with infection-related costs
27 (MINOR LIMITATIONS AND PARTIALLY APPLICABLE). Although compliance with hand
28 hygiene guidelines is associated with an increase in the use of hand decontamination
29 products (POTENTIALLY SERIOUS LIMITATIONS AND PARTIALLY APPLICABLE), it is

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

6.3.134 Recommendations and link to evidence

<p>Recommendations</p>	<p>4. Hands must be decontaminated in all of the following circumstances:</p> <ul style="list-style-type: none"> • immediately before every episode of direct patient contact or care, including aseptic procedures • 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]
<p>Relative values of different outcomes</p>	<p>The GDG felt that reducing colony forming units (CFUs), and improving hand decontamination 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.</p> <p>Reduction of MRSA and <i>C. diff</i> infections, prevention of MRSA and <i>C. diff</i> 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.</p>
<p>Trade off between clinical benefits and harms</p>	<p>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:</p> <ul style="list-style-type: none"> • protection of patients • protection of healthcare workers • protection of healthcare environment • prevention of cross infection of pathogenic organisms. <p>The evidence shows that there is an increase in hand decontamination 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 decontamination compliance before patient care, but no statistically significant difference in hand decontamination 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.</p> <p>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.</p> <p>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</p>

	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	<p>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 country⁷. 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 decontamination 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.</p> <p>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.</p>
Other considerations	<p>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)¹⁸². The recommendation is consistent with the WHO 5 moments of hand hygiene. Whilst the GDG felt that ‘direct patient contact or care’ should cover aseptic procedures within the first bullet point, they felt that adding in ‘including aseptic procedures’ clarified this.</p> <p>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 5.2.1.1 in the standard precautions chapter detailing the importance of access to hand decontamination supplies.</p> <p>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.</p>

6.4 Choice of hand cleaning preparation

6.4.1 Review question

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

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

6.4.1.1 Clinical evidence

13 Five trials were identified (three RCTs and two randomised crossover trials) comparing alcohol
14 handrub with antiseptic handwash^{102,144,152} or non-antiseptic handwash.^{152,282,287} Alcohol handrub
15 containing 45% 2-propanol and 30% 1-propanol was used in Girou et al., 2002¹⁰², Lucet et al., 2002¹⁵²,
16 Winnefeld et al., 2000²⁸² and Zaragoza et al., 1999²⁸⁷ and the handrub in Larson et al., 2001¹⁴⁴
17 contained 61% ethanol. All of these studies were included in the previous 2003 guideline, no
18 additional studies were found from the update search.

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

20 **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	1	Crossover	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Mean CFU (Hand printing on blood agar plates) ²⁸⁷	1	Crossover	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
CFU (Mean log change) ²⁸²	1	RCT	Serious limitations ^(c)	No serious inconsistency	Serious indirectness ^(b)	N/A ^(d)
Hand decontamination compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
<i>C. diff</i> reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

21 (a) Crossover study, healthcare workers used both intervention and control.

- 1 (b) Hospitals setting rather than community.
2 (c) Unclear allocation concealment.
3 (d) No standard deviation reported so confidence intervals are unknown, therefore unknown whether effect is precise or
4 not.

5 **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)	43	43	-	MD 0.76 lower (0.93 to 0.59 lower)	LOW
Mean CFU (Hand printing on blood agar plates)	43	43	-	MD 7 lower (32.27 lower to 18.27 higher)	LOW
CFU (Mean log change)	26	25	-	Intervention: -0.342 Control: +0.122 P = 0.004 ^(a)	LOW

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

7 **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) ¹⁰²	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 decontamination compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
<i>C. diff</i> reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

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

13

1 **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

2 **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 decontamination compliance	0	RCT				
MRSA reduction or cross infection	0	RCT				
<i>C. diff</i> reduction or cross infection	0	RCT				
Removal of physical contamination	0	RCT				

3 (a) Crossover study, healthcare workers used both intervention and control.

4 (b) Hospitals setting rather than community.

5 **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

6 (a) Number of healthcare workers in each study arm.

7 (b) Mean log change in CFUs given for intervention and control.

6.4.182 Cost-effectiveness evidence

9 Two trial-based cost-analyses^{44,144} and one cost-consequence analysis²⁵¹ comparing the use of alcohol
10 handrub to non-antiseptic soap were included. For a list of excluded studies and reasons for
11 exclusion, please refer to Appendix L.

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

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

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

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

Study	Limitations	Applicability	Other Comments
Cimiotti 2004 ⁴⁴	Potentially serious limitations ^(a)	Partially applicable ^(b)	Outcomes: observed hand decontamination 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 ²⁵¹	Potentially serious limitations ^(e)	Partially applicable ^(f)	Outcomes: Difference in hand decontamination product costs between hospitals with high and low rates of compliance to CDC guidelines.

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

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

Study	Incremental cost	Incremental effects	ICER	Uncertainty
Cimiotti 2004 ⁴⁴	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 ²⁵¹	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

12 **Table 19: Hand decontamination 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)

13 *Source: Based on average 2010 Supply Chain¹⁸⁷ prices.*

6.4.113 Evidence statements

2	Clinical	There is a statistically significant reduction of uncertain clinical 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).
3		
4		
5		
6		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).
7		
8		
9		It is uncertain whether there is any difference in CFUs (glove juice technique) with alcohol handrubs compared to antiseptic soap and water (LOW QUALITY).
10		
11		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).
12		
13		
14		No studies were identified that reported hand decontamination compliance, MRSA reduction or cross infection, <i>C. diff</i> reduction or cross infection or removal of physical contamination.
15		
16		
17	Economic	On a per-hand decontamination episode basis, alcohol-based handrub appears to be less costly and lead to better hand decontamination practice than non-antiseptic soap. (POTENTIALLY SERIOUS LIMITATIONS AND PARTIALLY APPLICABLE EVIDENCE)
18		
19		

6.4.104 Recommendations and link to evidence

Recommendations	<p>5. Decontaminate hands preferably with a handrub (conforming to current British Standards[†]), except in the following circumstances, when liquid soap and water must be used:</p> <ul style="list-style-type: none"> • 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 <i>Clostridium difficile</i> or other 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 decontamination compliance, removal of physical contamination and general reduction of cross infection of all infections. However the only outcome reported in the included studies were CFUs.
Trade off between clinical benefits and harms	<p>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.</p> <p>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 decontamination compliance, which is also found in the multi model hand decontamination interventions included in the ‘when to wash your hands’ review question, see section 6.3.1.4.</p> <p>The exceptions in the bullet points for when to perform hand washing are</p>

[†] At the time of consultation on the guideline (December 2011): BS EN 1500: 1997.

	<p>based on GDG informal consensus, based on discussions at the GDG meeting, as no RCT evidence was identified, but are also consistent with WHO guidance. The GDG considered that during outbreaks such as diarrhoeal illness (which is outside the scope of this guideline), alcohol is ineffective at killing spores such as <i>C. diff</i>. Mechanical friction from washing hands with soap and water was considered more appropriate for physically removing spores from the surface of contaminated hands. The GDG also sought advice from the microbiologist co-optee.</p> <p>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.</p>
Economic considerations	<p>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.</p>
Quality of evidence	<p>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.</p> <p>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.</p>
Other considerations	<p>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).¹⁸²</p> <p>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.</p> <p>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 <i>Escherichia coli</i> 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).</p> <p>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</p>

and/or wipes. Please see recommendation 5.2.1.1 in the standard precaution general recommendation detailing importance of access to hand decontamination supplies. Also see the recommendation on hand decontamination 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 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”*.¹⁷⁸

6.5 Decontaminating wrists and bare below the elbow policy

6.5.1 Review question

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

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

- 10 The GDG considered cross infections as the most important outcome.

6.5.1.1 Clinical evidence

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

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

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

- 24 See Evidence Table G.2.3, Appendix G, Forest Plots in Figure 13, Appendix I.
- 25

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

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Compliance: Percentage of the areas of the hands (wrist & palm) missed ⁸⁷	1	RCT	Serious limitation ^(a)	No serious inconsistency	No serious indirectness ^(b)	Serious imprecision ^(c)
Compliance: Percentage of the areas of the wrists missed ⁸⁷	1	RCT	Serious limitation ^(a)	No serious inconsistency	No serious indirectness ^(b)	Serious imprecision ^(c)
Compliance: Percentage of the areas of the palms missed ⁸⁷	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 <i>C. diff</i>	0	RCT				
Removal of physical contamination and transient organisms	0	RCT				

- 3 (a) Randomisation allocation and concealment method not reported. Participants were aware of the observation and
4 evaluation of their hand washing - there is a risk of performing better (i.e. wash hands more thoroughly) than usual.
5 (b) Indirect population. The study only recruited medical students and doctors working in a teaching hospital. Other
6 healthcare professionals were not recruited and there were no further information about the population. Outcomes
7 were indirect – measured % of areas of missed by the alcohol gel. However, the GDG believe this is not serious
8 indirectness and did not lower their confidence of the results.
9 (c) Actual values were not reported, and number of participants in each arm not reported. Number of participants were
10 obtained from authors.
11

12 **Table 21: Bare below elbow policy vs. control (usual uniform) group - Clinical summary of**
13 **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	N/A	1.80 [-4.46, 0.86]	LOW
Compliance: Percentage of the areas of the wrists missed	38.9±38.7	52.8 ±27.9	N/A	-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	N/A	-1.00 [-3.17, 1,17]	LOW

- 14 (a) Calculated by NCGC based on the information from authors – BBE policy arm had 73 participants, control arm had 76
15 participants.
16

6.5.112 Cost-effectiveness evidence

- 2 No cost-effectiveness evidence was identified in the update search and none was included in the
3 previous 2003 guideline.
- 4 This question was not thought relevant for economic consideration.

6.5.153 Evidence statements

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

6.5.164 Recommendations and link to evidence

Recommendations	<p>6. Healthcare workers should ensure that their hands can be decontaminated throughout the duration of clinical work by:</p> <ul style="list-style-type: none"> • being bare below the elbow^u • 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 decontamination 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 and more effective hand decontamination. There is some evidence that healthcare professionals following BBE 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 decontaminating the wrist in hand decontamination were found. There were

^u 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 decontamination.

	<p>also no relevant laboratory studies comparing bacterial counts on the wrists. Only one RCT was found comparing the impact of BBE 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.</p> <p>There is no evidence that washing the wrist helps to reduce infections.</p> <p>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.</p>
<p>Other considerations</p>	<p>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 Health⁷⁰, WHO²⁸⁵ and professional bodies such as the Royal College of Nursing²²⁵. The recommendation is congruent with the uniform or hand decontamination policies of these bodies.</p> <p>The GDG considered that ‘duration of clinical work’ covered any instance when clinical work was being delivered for example, a shift.</p> <p>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.</p> <p>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 BBE 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 decontamination.</p> <p>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 BBE, as they thought that BBE may be interpreted only as rolling sleeves up.</p> <p>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 can be worn.</p> <p>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 employers⁷⁰ to ensure that local dress code policies are sensitive to the obligations of faith groups whilst maintaining equivalent standards of decontamination. 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.</p> <p>Because the advice for different cultural groups regarding hand decontamination remains the same despite sensitivities to cultural or faith dress requirements, the GDG did not feel that a separate recommendation was</p>

necessary to address the issues outlined above.

6.6 Is hand decontamination technique important?

2 Investigations into the technique of hand decontamination are limited. Our systematic review
3 identified one RCT comparing different durations of handwashing and handrubbing on bacterial
4 reduction that found no significant differences between the two study groups¹⁵². One laboratory
5 study investigating methods of hand drying found no statistically significant differences between the
6 four methods studied.¹¹⁰

7 Recommendations are therefore based on existing expert opinion that the duration of hand
8 decontamination, the exposure of all aspects of the hands and wrists to the preparation being used,
9 the use of vigorous rubbing to create friction, thorough rinsing in the case of handwashing, and
10 ensuring that hands are completely dry are key factors in effective hand hygiene and the
11 maintenance of skin integrity.^{24,211}

6.6.121 Recommendations

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

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

6.7 Does hand decontamination damage skin?

26 Expert opinion concludes that skin damage is generally associated with the detergent base of the
27 preparation and/or poor handwashing technique.^{24,211} However, the frequent use of hand
28 preparation agents may cause damage to the skin and normal hand flora is altered which may result
29 in increase carriage of pathogens responsible for healthcare-associated infection.^{24,211} In addition, the
30 irritant and drying effects of hand preparations have been identified as one of the reasons why
31 healthcare practitioners fail to adhere to hand hygiene guidelines.^{24,211} A previous systematic review
32 found no consistent evidence to suggest that any product currently in use caused more skin irritation
33 and damage than another.²¹⁰

34 Our systematic review identified six studies of which three were RCT conducted in clinical
35 settings.^{23,144,282} They compared the use of alcohol-based preparations with soap and the self
36 assessment of skin condition by nurse. In these studies a greater level of irritation was associated
37 with the use of soap. Two further studies, one clinically based quasi experimental study and one
38 descriptive clinical study concluded that alcohol-based handrubs caused less skin irritation.^{90,144,205} A
39 laboratory study demonstrated a strong relationship between the frequency of handwashing with a
40 chlorhexidine preparation and dermatitis.²⁰⁵

41 Expert opinion suggests that hand care is an important factor in maintaining regular hand
42 decontamination practices and assuring the health and safety of healthcare practitioners.^{24,211}

6.7.111 Recommendation

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

6.8 Research recommendations

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

8 Why is this important?

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

7 Standard principles for the use of personal protective equipment

7.1 Introduction

4 The updated review questions in this chapter are:

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

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

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

12 Sections not updated in this chapter are:

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

16 The primary role of personal protective equipment (PPE) is to reduce the risk of transmission of
17 microorganisms between patients, healthcare workers and the environment. The recommendations
18 in this chapter are in line with Health and Safety requirements (Health and Safety Regulations 2002⁴,
19 Health and Safety at work Act 1974¹).

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

21

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

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

26 Expert opinion suggests that the primary uses of personal protective equipment are to protect staff
27 and patients, and reduce opportunities for the transmission of microorganisms in hospitals^{95,281}.
28 However, as more healthcare is undertaken in the community,^{156,188,245} the same principles apply. A
29 trend to eliminate the unnecessary wearing of aprons, gowns and masks in general care settings has
30 evolved over the past twenty years due to the absence of evidence that they are effective in
31 preventing HCAI.⁹⁵

32 The decision to use or wear personal protective equipment must be based upon an assessment of
33 the level of risk associated with a specific patient care activity or intervention and take account of
34 current health and safety legislation.^{62,86,113,114}

7.2.111 Recommendation

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

7.3 Gloves: their uses and abuses

- 7 Since the mid-1980s the use of gloves as an element of personal protective equipment has become
8 an everyday part of clinical practice for healthcare workers.^{37,45,86,95,104,132} Expert opinion agrees that
9 there are two main indications for the use of gloves in preventing HCAI^{37,45,86,95}:
- 10 • to protect hands from contamination with organic matter and microorganisms;
 - 11 • to reduce the risks of transmission of microorganisms to both patients and staff.

7.3.1 To glove or not to glove?

- 13 Gloves should not be worn unnecessarily as their prolonged and indiscriminate use may cause
14 adverse reactions and skin sensitivity.^{45,211} As with all items of personal protective equipment the
15 need for gloves and the selection of appropriate materials must be subject to careful assessment of
16 the task to be carried out and its related risks to patients and healthcare practitioners^{45,211}. Risk
17 assessment should include consideration of:
- 18 • who is at risk (whether it is the patient or the healthcare practitioner) and whether sterile or non-
19 sterile gloves are required;
 - 20 • the potential for exposure to blood, body fluids, secretions or excretions;
 - 21 • contact with non-intact skin or mucous membranes during general care and invasive procedures.
- 22 Gloves must be discarded after each care activity for which they were worn in order to prevent the
23 transmission of microorganisms to other sites in that individual or to other patients. Washing gloves
24 rather than changing them is not safe and therefore not recommended.^{45,211}

7.3.2 Do gloves leak?

- 26 A previous systematic review provided evidence that gloves used for clinical practice leak when
27 apparently undamaged.²¹⁰ In terms of leakage, gloves made from natural rubber latex (NRL)
28 performed better than vinyl gloves in laboratory test conditions. Revised standards (2000) relating to
29 the manufacture of medical gloves for single-use have been devised and implemented.²⁸⁻³⁰ These
30 require gloves regardless of material to perform to the same standard.
- 31 Expert opinion supports the view that the integrity of gloves cannot be taken for granted and
32 additionally, hands may become contaminated during the removal of gloves.^{37,45,86,95,211} Our
33 systematic review found evidence that vancomycin resistant enterococcus remained on the hands of
34 healthcare workers after the removal of gloves.²⁵⁷ Therefore, the use of gloves as a method of barrier
35 protection reduces the risk of contamination but does not eliminate it and hands are not necessarily
36 clean because gloves have been worn.

^v In accordance with current health and safety legislation (at the time of pre-publication of the guideline [December 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.

7.3.211 Recommendations

Recommendations	<p>11. Gloves used for direct patient care:</p> <ul style="list-style-type: none"> • must^w conform to current EU legislation (CE marked as medical gloves for single-use)^x 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 Medical gloves for single-use) 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 in section 7.4.
Other considerations	No evidence was identified for vinyl gloves, but the GDG considered that if they met the relevant CE standards they could be used. 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). ¹⁸² 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).

Update 2012

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

6 **13. Gloves must^w be worn as single-use items. They must be put on immediately before an**
7 **episode of patient contact or treatment and removed as soon as the activity is completed.**

^w In accordance with current health and safety legislation (at the time of pre-publication of the guideline [December 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.

^x At the time of pre-publication of the guideline [December 2011]: BS EN 455 Parts 1 - 4 Medical gloves for single-use.

1 **Gloves must be changed between caring for different patients, and between different care**
2 **or treatment activities for the same patient. [2003]**

3

Recommendations	14. Ensure that gloves used for direct patient care that have been exposed to body fluids are disposed of correctly, in accordance with current national legislation^y 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) ¹⁸² . The GDG considered it important to update the original recommendation as a result of legislative 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 decontamination chapter, see recommendation 6.3.1.4.

Update 2012

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

5

7.4.1 Review question

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

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

7.4.1.1 Clinical evidence

16 One crossover trial was identified, comparing non-powdered nitrile gloves with non-powdered latex
17 gloves.¹⁷⁷ This study was also included in the previous 2003 guideline for this review question. No
18 evidence was identified for vinyl gloves.

^y For guidance see (at the time of pre-publication of the guideline [December 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

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

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

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Glove punctures ¹⁷⁷	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				

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

4 **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

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

7.4.162 Cost-effectiveness evidence

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

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

13 **Table 24: Glove costs**

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

14 Source: Based on average NHS Supply Chain Catalogue¹⁸⁷ prices.

15

7.4.113 Evidence statements

2	Clinical	There is a statistically significant and clinically important decrease in glove punctures with latex gloves compared to nitrile gloves (LOW QUALITY).
3		
4		No studies were identified that reported blood borne infections, glove porosity,
5		hypersensitivity, user preference or ability to perform tasks.
6	Economic	No relevant cost-effectiveness data were identified.

7.4.174 Recommendations and link to evidence

Recommendations	15. Alternatives to natural rubber latex gloves must² 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	The GDG thought that the latex sensitivity of anyone living with the patient should be taken into consideration when deciding which glove type to use. The Health and Safety Executive also provide information on the use of latex gloves. ¹¹⁷ 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). ¹⁸² A minor change has been made to the order of wording of this recommendation following update to the previous guideline.

8

² In accordance with current health and safety legislation (at the time of pre-publication of the guideline [December 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.

1

Recommendations	16. Do not use polythene gloves for clinical interventions. [new 2012]
Relative values of different outcomes	The GDG stated that prevention of 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, because 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. 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.

Update 2012

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

7.5.1 Review question

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

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

7.5.1.2 Clinical evidence

13 Two observational studies investigating contamination of uniforms when disposable plastic aprons
14 were worn were included for this review question,^{34,96} one of which was included in the previous
15 2003 guideline.³⁴ Two intensive care based, observational, before and after studies were included,
16 comparing isolation procedures with gowns and gloves against isolation procedures with gloves
17 alone in preventing the acquisition of vancomycin resistant enterococci (VRE).^{216,246}

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

1 **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) ⁹⁶	1	Observational studies	Very serious ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
MRSA contamination of uniform (Care assistants; aprons worn when washing, changing and for meal assistance) ⁹⁶	1	Observational studies	Very serious ^(a)	No serious inconsistency	No serious indirectness	No serious imprecision
MRSA contamination of uniform (Nurses; aprons worn for dressing) ⁹⁶	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) ⁹⁶	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				

- 2 (a) Study poorly reported. Not clear how the indications to wear aprons were allocated. Results were excluded for HCW who
3 did not use aprons where indicated on more than 5 occasions per shift.
4 (b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
5 difficult to know the true effect size for this outcome.
6 (c) Study poorly reported. Study conducted in 2 wards but no baseline data reported regarding care activities for each ward,
7 patient characteristics (including numbers) or staffing in the 2 wards.
8 (d) Study conducted in hospital population not primary or community care.
9 (e) No standard deviation reported so confidence intervals are unknown, therefore unknown whether effect is precise or
10 not.
11

1 **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) ⁹⁶	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) ⁹⁶	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) ⁹⁶	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 uniform (Nurses; aprons worn for dressing and biological sampling) ⁹⁶	2/20 (10%)	7/16 (43.8%)	0.23 (0.05 to 0.95)	337 fewer per 1000 (from 22 fewer to 416 fewer)	VERY LOW
Bacterial Contamination of uniform ³⁴	Mean colony count in apron group: 59.40 ^(a)	Mean colony count in no apron group: 44.80 ^(a)	N/R	N/R	VERY LOW

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

4 **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) ²⁴⁶	1	Observational	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision ^(c)
VRE acquisition rate (cases per 1000 MICU days) ²¹⁶	1	Observational	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision ^(c)
Bodily fluid contamination	0	RCT or observational				

5 (a) Studies investigated impact of policy change over two consecutive periods of time. No blinding and so some bias due to
6 changes in behaviour could have occurred.

7 (b) Study conducted in hospital population not primary or community care.

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

10

1 **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

2 (a) Results expressed as cases per 100 days at risk.

3 (b) Results expressed as cases per 1000 MICU days.

7.5.10 Cost-effectiveness evidence

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

9 Results of a cost analysis by Puzniak et al., (2004)²¹⁵ were presented to the GDG. The GDG were also
10 presented with current UK gown and apron costs to inform decision making.

11 No economic studies were identified in the previous 2003 guideline.

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

Study	Limitations	Applicability	Other Comments
Puzniak 2004 ²¹⁵	Potentially serious limitations ^(a)	Partial applicability ^(b)	ICU setting

13 (a) Based on a before and after trial designed to assess the impact of a policy change, difficult to isolate the effect of gowns
14 as was part of an intervention package.

15 (b) USA hospital perspective; ICU isolation setting.

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

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Puzniak 2004 ²¹⁵	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

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

18 **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)

19 Source: Based on average NHS Supply Chain Catalogue¹⁸⁷ prices.

7.5.10 Evidence statements

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

- 1 There is a statistically significant and clinically important reduction in MRSA
 2 contamination of care assistant uniforms when aprons were used for washing, and
 3 meal assistance in a long-term care facility compared with when no aprons were
 4 used (VERY LOW QUALITY).
- 5 There is a statistically significant reduction of uncertain clinical importance in MRSA
 6 contamination of nurses uniforms when aprons were used for dressing changes and
 7 biological sampling compared with when no aprons were used (VERY LOW QUALITY).
- 8 There was a statistically significant reduction of uncertain clinical importance in VRE
 9 acquisition when gowns and gloves were worn in isolation procedures compared to
 10 when gloves alone were worn (VERY LOW QUALITY).
- 11 No studies were identified that reported bodily fluid contamination.
- 12 Economic Wearing a gown or apron is likely to be cost-effective where there is a risk of
 13 infection transmission to the healthcare worker or between patients (POTENTIALLY
 14 SERIOUS LIMITATIONS; PARTIALLY APPLICABLE).
- 15 No economic studies comparing gowns to aprons were identified.

7.5.164 Recommendations and link to evidence (2012)

Recommendations	<p>17. When delivering direct patient care:</p> <ul style="list-style-type: none"> • wear a disposable plastic apron if there is a risk that clothing may be exposed to blood, body fluids, secretions or excretions, or • wear a long-sleeved fluid-repellent gown if there is a risk of extensive splashing of blood, body fluids, secretions or excretions, 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	<p>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.^{1,3,4,115} In turn, this should help prevent the spread of microorganisms to other patients.</p> <p>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.</p>
Economic considerations	<p>The cost of disposable aprons, cost of uniforms, cost of laundering uniforms, and consequences of infection were taken into consideration.</p> <p>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).</p> <p>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.</p>
Quality of evidence	Four clinical studies were included. Two very low quality, poorly reported

	<p>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 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.</p> <p>The GDG agreed the changes to the recommendation by consensus.</p>
<p>Other considerations</p>	<p>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 5.2.1.1.</p> <p>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 potential contamination.</p> <p>The GDG acknowledged that ambulance staff wear aprons when required, but it is unusual to wear full gowns in the community. Full gowns are generally only available in exceptional circumstances, such as high risk transfers and/or previously known risks or scenarios, which are rare. The GDG considered that the recommendation is appropriate for the majority of healthcare workers in the community.</p> <p>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.</p> <p>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.</p>

1

1

Recommendations	<p>18. When using disposable plastic aprons or gowns:</p> <ul style="list-style-type: none"> • 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	<p>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.</p> <p>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).</p>

Update 2012

2

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

3 Our previous systematic review failed to reveal any robust experimental studies that suggested any
4 clinical benefit from wearing surgical masks to protect patients during routine ward procedures such
5 as wound dressing or invasive medical procedures.^{211,212}

6 Personal respiratory protection is required in certain respiratory diseases, e.g., HIV-related or
7 multiple drug-resistant tuberculosis²⁶⁰ and where patients who are severely immunocompromised
8 are at an increased risk of infection. In these instances, surgical masks are not effective protection
9 and specialised respiratory protective equipment should be worn, e.g., a particulate filter
10 mask.^{113,212,260}

11 Our previous systematic review indicated that different protective eyewear offered protection
12 against physical splashing of infected substances into the eyes (although not on 100% of occasions)
13 but compliance was poor.²¹² Expert opinion recommends that face and eye protection reduce the risk
14 of occupational exposure of healthcare practitioners to splashes of blood, body fluids, secretion or
15 excretions.^{45,95,211}

7.6.161 Recommendations

17 **19.Face masks and eye protection must^{aa} be worn where there is a risk of blood, body fluids,**
18 **secretions or excretions splashing into the face and eyes. [2003]**

19 **20.Respiratory protective equipment, for example a particulate filter mask, must^{aa} be used**
20 **when clinically indicated. [2003]**

^{aa} In accordance with current health and safety legislation (at the time of pre-publication of the guideline [December 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

4 The updated review questions in this chapter are:

- 5 • choice of safety cannulae
- 6 • choice of safety needles.

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

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

12 No new review questions included in this chapter.

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

15 Specific recommendations on disposal of sharps are included in this chapter and have been updated
16 following changes to legislation.^{64,67} General waste disposal recommendations are in chapter 9.
17 Waste disposal recommendations for personal protective equipment are in chapter 7.

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

8.2 Sharps injuries – what’s the problem?

22 The safe handling and disposal of needles and other sharp instruments should form part of an overall
23 strategy of clinical waste disposal to protect staff, patients and visitors from exposure to blood borne
24 pathogens.¹¹⁹ The incidence of injuries caused by sharps varies across clinical settings and is difficult
25 to compare due to different denominators for data collection. Audit data suggests that of the
26 occupational injuries that occur in hospitals, 16% are attributable to sharps injuries.¹⁷⁹ National
27 surveillance of occupational exposure to bloodborne viruses from 1997-2001 indicates that 68% of
28 percutaneous exposures were caused by sharps. Of the exposures followed up at 6 weeks, 7 percent
29 involved healthcare workers working in community and primary care settings.⁸⁵ In the first year of
30 data collection the UK EpiNet sharps injury surveillance project provides data on 888 injuries
31 occurring in 12 NHS Trusts identifying that 80% of injuries involve contaminated sharps, with 43% of
32 injuries sustained by nursing staff and 24% by medical staff.²²³ In general clinical settings, sharps
33 injuries are predominantly caused by needle devices and associated with venepuncture,
34 administration of medication via intravascular lines and recapping of needles during the disassembly
35 of equipment.³⁶ All sharps injuries are considered to be potentially preventable.

36 The average risk of transmission of bloodborne pathogens following a single percutaneous exposure
37 from a positive source has been estimated to be²¹⁴:

- | | | |
|----|--------------------------------------|-------------------------|
| 38 | • Hepatitis B Virus (HBV) | 33.3 percent (1 in 3) |
| 39 | • Hepatitis C Virus (HCV) | 3.3 percent (1 in 30) |
| 40 | • Human Immunodeficiency Virus (HIV) | 0.31 percent (1 in 319) |

1 The GDG acknowledge that there is existing guidance on HIV post-exposure prophylaxis from the
 2 Department of Health.⁶⁶

8.2.131 Recommendations

4 **21. Sharps should^{bb} not be passed directly from hand to hand, and handling should be kept to a**
 5 **minimum. [2003, amended 2012]**

6	22. Used needles:
Recommendations	<ul style="list-style-type: none"> • must not be bent or broken before disposal • must not be recapped. <p>In dentistry, if recapping or disassembly is unavoidable, a risk assessment must be undertaken and appropriate safety devices should be used. [new 2012]</p>
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	<p>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.</p> <p>The GDG were aware that a new EU Directive (2010/32/EU⁴⁸) 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...”.</p> <p>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.⁶⁴</p>
Economic considerations	<p>No relevant economic considerations were identified for this issue. Where avoidable, recapping and disassembly is not considered a valid alternative.</p> <p>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 will be associated with minimal cost.</p>
Quality of evidence	<p>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</p>

^{bb} 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).

	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.

1

Recommendations	23. Used sharps must be discarded immediately into a sharps container conforming to current standards^{cc} 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 9.
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. ²²⁴
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). ¹⁸² 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 noted that the person generating the sharps waste in a dental setting is the clinician (therefore, dentist, dental therapist or hygienist), and that most sharps injuries in dental surgeries are sustained by dental nurses. ²³⁸ 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

2

^{cc} At the time of pre-publication of the consultation on the guideline (December 2011): UN3291 and BS 7320.

Recommendations	<p>24. Sharps containers:</p> <ul style="list-style-type: none"> • must^{dd} 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^{dd} be used for any other purpose than the disposal of sharps • must not^{dd} be filled above the fill line • must^{dd} 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	<p>There was no clinical evidence review for this section.</p> <p>The GDG noted that any amendments to the original recommendation should conform to the Safe Management of Healthcare Waste guidelines⁷² and the relevant EU and UK regulations⁶⁴ 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.²²⁴</p>
Other considerations	<p>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).¹⁸²</p> <p>The GDG discussed and considered the following aspects when making the recommendations:</p> <ul style="list-style-type: none"> • Patients cared for at home: The Safe Management of Healthcare Waste⁷² 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.

^{dd} For guidance see (at the time of pre-publication of the guideline [December 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^{16,213}, and one RCT comparing active safeguarded needles with standard cannulae.⁴⁷

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 ^{16,213}	2	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Catheterised on first attempt ^{16,47,213}	3	RCT	Serious limitations ^(c)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Blood contamination of patients or healthcare workers (HCWs) ^{16,47,213}	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.

1 **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

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

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury ^{16,213}	2	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Catheterised on first attempt ^{16,213}	2	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	No serious imprecision
Blood contamination of patients or HCWs ^{16,213}	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				

3 (a) Lack of blinding and unclear randomisation and allocation in 1 study.

4 (b) Hospital setting rather than community.

5 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
6 difficult to know the true effect size for this outcome.

7 **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

8.3.182 Cost-effectiveness evidence

9 No cost-effectiveness evidence was identified.

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

11 In the absence of any published cost-effectiveness evidence, estimates about the cost and quality of
12 life associated with needle stick injury was obtained from several review articles¹⁴⁸⁻¹⁵⁰ identified

1 through the economic literature search and presented to the GDG to inform decision making. The
 2 GDG were also presented with the current UK cost of standard cannulae and safety cannulae.

3 **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

4 *Source/Note: Based on average 2010 Supply Chain¹⁸⁷ prices. Individual trusts may negotiate different contracts and*
 5 *prices with suppliers.*

8.3.163 Evidence statements

- 7 Clinical It is unlikely that there is any difference in success of cannulation on first attempt
 8 between active or passive safety cannulae compared to standard cannulae (LOW
 9 QUALITY).
- 10 There were no sharps injuries for active or passive safety cannulae or standard
 11 cannulae (LOW QUALITY).
- 12 There is a statistically significant and clinically important increase in blood
 13 contamination of patients or HCWs with active safety cannulae compared to
 14 standard cannulae (LOW QUALITY).
- 15 It is uncertain whether there is any difference in blood contamination of patients or
 16 HCWs with passive safety cannulae compared to standard cannulae (VERY LOW
 17 QUALITY).
- 18 No studies were identified that reported infection related mortality and morbidity,
 19 user preference or compliance.
- 20 Economic No cost-effectiveness studies were identified.

8.3.114 Recommendations and link to evidence

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

25

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

2

8.4.1 Review question

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

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

8.4.1.1 Clinical evidence

10 Five observational studies were identified. Three studies were before and after implementation
11 studies of safety devices for phlebotomy procedures.^{38,171,221} One study investigates the
12 implementation of a disposable safety syringe for dentistry²⁸⁶ compared to a non-disposable metal
13 syringe. The final study investigates the implementation of a self-retracting glucometer lancet
14 compared to a straight stick non-retracting lancet.¹⁹⁸

15 Three studies from the previous 2003 guideline met the inclusion criteria for this review
16 question.^{38,198,286}

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

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

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury ^{171(d)}	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(a)	No serious imprecision
Needle stick injury ²²¹	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(a)	No serious imprecision
Needlestick injury - Winged steel needle ³⁸	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(a)	No serious imprecision
Needlestick injury - Bluntable vacuum tube ³⁸	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(a)	No serious imprecision
Needlestick injury - Vacuum tube with recapping sheath ³⁸	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
User preference ³ ₈	1	Observational studies	No serious limitations	No serious inconsistency	Serious indirectness ^(a)	No serious imprecision
User preference ¹ _{71(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				

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

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

Outcome	Safety device	Standard device	Relative risk	Absolute effect	Quality
Needle stick injury ^(a)	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 ^(b)	-	-	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

- 8 (a) Denominator is the total number of needles delivered to the department.
 9 (b) Relative risk taken directly from paper. Total events and population not given for study period.
 10

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

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Needle stick injury ²⁸⁶	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				

2 (a) Dental school setting rather than community.

3 **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

4 **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 ¹⁹⁸	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				

6 (a) The denominator used for needlestick injury was worker years rather than the actual number of lancets used.

7 (b) Wide confidence and low event number lead to low confidence in the effect size.

8 **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

10

8.4.112 Cost-effectiveness evidence

2 The update search conducted as part of this review identified two studies; neither met inclusion
3 criteria. A cost analysis by Glennard et al (2009)¹⁰³ was excluded because costs were presented
4 nationally rather than individually and were considered specific to Sweden. A cost-effectiveness
5 analysis from Madagascar⁷⁸ was excluded because neither the comparator nor the setting was
6 relevant to this question.

7 One study identified by the clinical evidence review in the previous 2003 guideline met inclusion
8 criteria for the update economic review. Peate and colleagues (2001)¹⁹⁸ conducted a basic cost
9 analysis in their comparison of the use of self-retracting glucometer lancets to straight stick non-
10 retracting lancets among emergency medical system workers in the United States.

11 Additional estimates of the cost and quality of life impact associated with needle stick injury were
12 obtained from several review articles¹⁴⁸⁻¹⁵⁰ identified through the economic literature search and
13 presented to the GDG to inform decision making. The GDG were also presented with the current UK
14 cost of various standard and safety needles.

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

Study	Limitations	Applicability	Other Comments
Peate 2001 ¹⁹⁸	Potentially serious limitations ^(a)	Partial applicability ^(b)	

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

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

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Peate 2001 ¹⁹⁸	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

21 **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

22 *Source: Based on average 2010 Supply Chain¹⁸⁷ prices. Individual trusts may negotiate different contracts and prices with*
23 *suppliers.*

24

8.4.113 Evidence statements

2	Clinical	<u>Phlebotomy devices</u>
3		There is a statistically significant and clinically important reduction in needlestick injuries with the safety devices compared to standard devices (VERY LOW QUALITY).
4		
5		There is a statistically significant and clinically important increase in user preference with the safety devices compared to standard devices (VERY LOW QUALITY).
6		
7		<u>Dental syringe</u>
8		There is a statistically significant and clinically important reduction in needlestick injuries with the safety devices compared to standard devices (VERY LOW QUALITY).
9		
10		No studies were identified that reported blood borne infection, infection related mortality and morbidity, or compliance.
11		
12		<u>Safety lancet</u>
13		It is uncertain whether there is any difference in needlestick injuries with the safety devices compared to standard devices (VERY LOW QUALITY).
14		
15	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.
16		
17		

8.4.124 Recommendations and link to evidence

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	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
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 ²⁸⁶ 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 ¹⁹⁸ 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 ¹¹⁶ and how it might contribute to supporting the implementation of risk assessment in the following areas: <ul style="list-style-type: none"> • 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 and sharps safety devices. [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.
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 ¹⁷¹ ; and training sessions and pamphlets in each ward ²²¹ .
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

1

9 Waste disposal

9.1 Introduction

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

6 New legislation relating to waste disposal has been introduced since the previous guideline. The
7 Department of Health have published a guidance document; Safe Management of Healthcare Waste
8 version 1.0⁷² as a best practice guide to the management of healthcare waste. Healthcare waste
9 refers to any waste produced by, and as a consequence of, healthcare activities. The document
10 replaces the Health Services Advisory Committee's (1999) guidance document "Safe Disposal of
11 Clinical Waste" and HTM07-01 Safe Management of healthcare waste⁶⁴, which has revised and
12 updated the previous documents to take into account the changes in legislation governing the
13 management of waste, its storage, carriage, treatment and disposal, and health and safety.

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

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

9.1.181 Review questions

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

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

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

9.1.152 Clinical evidence

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

40 The Department of Health guidance; Safe Management of Healthcare Waste version 1.0⁷² was
41 reviewed.

9.1.113 Recommendations and link to evidence

Recommendations	<p>27. Healthcare waste must be segregated immediately by the person generating the waste into appropriate colour-coded storage or waste disposal bags or containers defined as compliant with current national legislation^{ee} and local policies. [new 2012]</p>
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	<p>No clinical evidence review was conducted.</p> <p>This recommendation was developed based on the consideration of current best practice guidance from Department of Health; Safe Management of Healthcare Waste version 1.0⁷² and the relevant EU and UK legislation.</p>
Other considerations	<p>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).</p> <p>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).¹⁸²</p> <p>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 appropriate choice of waste disposal bags or receptacles takes into account among other factors, the type of waste and capacity of the containers.</p> <p>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.</p> <p>See recommendations regarding sharps and waste disposal in chapters 7 and 8, respectively.</p>

Update 2012

2

^{ee} For guidance see (at the time of pre-publication of the guideline [December 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

1

28. Healthcare waste must be labelled, stored, transported and disposed of in accordance with current national legislation^{ff} and local policies. [new 2012]	
Recommendations	
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). ¹⁸² 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.
29. Educate patients and carers about the correct handling, storage and disposal of healthcare waste. [new 2012]	
Recommendations	
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 Healthcare Waste ⁷² and the relevant EU and UK regulations.

Update 2012

^{ff} For guidance see (at the time of pre-publication of the guideline [December 2011]): 'Safe management of healthcare waste' (2011); available from www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_126345

Other considerations	<p>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. 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.</p> <p>Also see recommendations regarding sharps and waste disposal in chapters 7 and 8, respectively.</p>
----------------------	--

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

9.1.2 Research recommendations

- 4 The GDG did not identify any research recommendations.

10 Long term urinary catheters

10.1 Introduction

3 The updated review questions in this chapter are:

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

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

9 The evidence and text from the previous guideline that has been superseded by this update is
10 included in Appendix D.6. and D.9. No new review questions are included in this chapter.

11 Sections *not* updated in this chapter are:

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

17 The GDG recognised that hand decontamination is an important part of catheter management. See
18 Section 6 for further details.

19 In addition the GDG acknowledged that Medical Device Regulations¹⁶⁹ implement the EC Medical
20 Devices Directives into UK law. They place obligations on manufacturers to ensure that their devices
21 are safe and fit for their intended purpose before they are CE marked and placed on the market in
22 any EC member state. The GDG noted that guidance¹⁶⁸ on the MHRA's adverse incident reporting
23 system is available for reporting adverse incidents involving medical devices.

24 The GDG has prioritised three recommendations in this chapter as a key priorities for
25 implementation, see recommendations 39, 42 and 58.

26 In the community and primary healthcare settings, long-term (>28 days) urinary catheterisation (LTC)
27 is most commonly used in the management of the elderly and patients with neurological conditions.
28 The prevalence of LTC in the United Kingdom (UK) has been estimated as 0.5 percent in those over
29 75 years old¹³⁵ and 4 percent in people undergoing domiciliary care.⁹⁸ Some patients may require
30 continuous bladder drainage using urethral or suprapubic catheters. Alternatively, patients or carers
31 may insert and remove urethral catheters at regular intervals (intermittent catheterisation).

32 Catheter care in the community is time consuming and expensive.^{98,135,230} LTC should be regarded as
33 a 'method of last resort' in the management of urinary problems as the burden both to the health
34 service and to individual patients is high.⁸⁴ However, there will remain a group of patients for whom
35 LTC is the best option.

36 The method of catheterisation will depend on each patient's individual requirements, available
37 clinical expertise and services. Infection is a major problem in LTC although there are other non-
38 infectious complications associated with LTC, including physiological/structural damage,²⁷¹ urological
39 cancer⁶¹ and psycho-social problems.²⁰⁹ In selecting particular strategies to manage urinary
40 problems, healthcare practitioners must take account of all of these complications. These guidelines

- 1 focus on preventing infection. However, because infection has a complex inter-relationship with
2 encrustation and blockage, these aspects of catheter management are also addressed.
- 3 These guidelines apply to adults and children and should be read in conjunction with the guidance on
4 Standard Principles (see chapters 7 to 8). These recommendations are broad principles of best
5 practice and are not detailed procedural protocols. They need to be adapted and incorporated into
6 local practice guidelines. The recommendations are divided into five distinct interventions:
- 7 1. Education of patients, their carers and healthcare workers
 - 8 2. Assessing the need for catheterisation
 - 9 3. Selection of catheter type and system
 - 10 4. Catheter insertion
 - 11 5. Catheter maintenance.
- 12 The systematic review process is described in Appendix D.1.

10.2 Education of patients, carers and healthcare workers

- 14 Given the prevalence of LTC and the associated risk of clinical urinary tract infection, it is important
15 that everyone involved in catheter management is educated about infection prevention. As many
16 people, including children, will manage their own catheters, they must be confident and proficient in
17 the procedure, aware of the signs and symptoms of clinical infection and how to access expert help
18 when difficulties arise.^{79,97,140,283}

10.2.191 Recommendations

- 20 **30. Patients and carers should be educated about and trained in techniques of hand**
21 **decontamination, insertion of intermittent catheters where applicable, and catheter**
22 **management before discharge from hospital. [2003]**
- 23 **31. Community and primary healthcare workers must be trained in catheter insertion, including**
24 **suprapubic catheter replacement and catheter maintenance. [2003]**
- 25 **32. Follow-up training and ongoing support of patients and carers should be available for the**
26 **duration of long-term catheterisation. [2003]**

10.3 Assessing the need for catheterisation

- 28 Catheterising patients increases the risk of acquiring a urinary tract infection. The longer a catheter is
29 in place, the greater the danger.
- 30 The highest incidence of healthcare-associated infection is associated with indwelling urethral
31 catheterisation.²⁴⁷ Many of these infections are serious and lead to significant morbidity. In acute
32 care facilities, 20-30% of catheterised patients develop bacteriuria, of whom 2-6 percent develop
33 symptoms of urinary tract infection (UTI).²⁴⁷ The risk of acquiring bacteriuria is approximately 5
34 percent for each day of catheterisation,^{92,94} and therefore most patients with LTC are bacteriuric
35 after 20 days of catheterisation.²⁷²
- 36 A study of patients in long-term care facilities demonstrated significantly higher morbidity and
37 mortality in catheterised patients than in matched non-catheterised controls.¹⁴⁰ Duration of
38 catheterisation is strongly associated with risk of infection, i.e., the longer the catheter is in place,
39 the higher the incidence of UTI.²⁴⁷

- 1 Best practice emphasises that all procedures involving the catheter or drainage system and the
- 2 related batch codes of these devices are recorded in the patient's records.²⁸³ Patients should be
- 3 provided with adequate information in relation to the need, insertion, maintenance and removal of
- 4 their catheter by the person planning their care.²⁸³

10.3.151 Recommendations

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

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

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

10.4 Catheter drainage options

10.4.1 How to select the right system

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

- 15 Our search identified one systematic review²³⁹ concerning the approaches to catheterisation. This
- 16 reported a higher rate of infection associated with indwelling rather than intermittent
- 17 catheterisation. This finding is reflected in a recent position paper¹⁸⁹ on urinary tract infections in
- 18 long-term care facilities by the Society for Healthcare Epidemiology of America (SHEA) who
- 19 recommended that "where clinically appropriate, intermittent catheterisation should be used for
- 20 urinary drainage rather than a chronic indwelling catheter."

- 21 Two studies were identified in our search which compared catheter options.^{125,258} The first focussed
- 22 on the risk of Meticillin-resistant *Staphylococcus aureus* (MRSA) colonisation and infection in nursing
- 23 home patients.²⁵⁸ This study concluded that indwelling catheters posed a greater risk of infection
- 24 than intermittent catheters. The second studied men with prostatic enlargement and reported a
- 25 significantly lower rate of infection in those with suprapubic rather than urethral catheters, despite
- 26 the former being used for two weeks longer.¹²⁵ A non-comparative study of patients with
- 27 neuropathic bladder demonstrated a low rate of infection (6 percent) associated with the use of
- 28 long-term suprapubic catheters.²⁴⁰ However, 30% of patients in this study reported other catheter-
- 29 related complaints. Economic opinion suggests that if staff and resource use are the same,
- 30 suprapubic catheterisation is more cost effective.^{229,240}

- 31 Eight studies were identified which focussed exclusively on the use of intermittent catheterisation.
- 32 The study populations encompassed a wide range of patient groups and ages.^{17-19,42,79,174,200,274} One
- 33 theme emerging from these studies was that the prevalence of bacteriuria is equal between men and
- 34 women^{17,18} though the incidence of clinical UTI appears to be higher in women.^{18,19} There is also
- 35 some evidence that bacteriuria rates are similar between adults and children.⁵⁷

- 36 Generally, large studies indicated that the rates of infection associated with intermittent
- 37 catheterisation were low,^{200,274} 1 per 87 months,²⁷⁴ and that hydrophilic catheters were associated
- 38 with a further reduction in infection risk.^{19,42}

- 39 A possible alternative to indwelling and intermittent catheterisation is the penile sheath (condom
- 40 catheter). Whilst our systematic review did not include a specific question related to the use of
- 41 penile sheath catheters, there is evidence that this type of device may be preferable in men who are

- 1 able to empty their bladder and are unlikely to manipulate the system.^{57,229} To date there are no
2 controlled studies comparing penile sheaths with indwelling devices.

10.4.131 Recommendations

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

7 **37.Intermittent catheterisation should be used in preference to an indwelling catheter if it is**
8 **clinically appropriate and a practical option for the patient. [2003]**
9

10.5 Types of long-term catheters

10.5.1 Review question – intermittent catheters

12 Long-term urinary catheterisation is considered an important area where updated guidance is
13 required.

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

- 17 1. What is the clinical and cost effectiveness of different types of long-term intermittent urinary
18 catheters (non-coated, hydrophilic or gel reservoir) on symptomatic urinary tract infections,
19 bacteraemia, mortality, and patient preference?
20
21 2. In patients performing intermittent catheterisation, what is the clinical and cost effectiveness
22 of non-coated catheters reused multiple times compared to single-use on urinary tract
23 infections, bacteraemia, mortality, and patient preference?

10.5.241 Clinical evidence

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

26 Six studies were identified, five of which investigated hydrophilic catheters compared to non-coated
27 catheters^{35,59,193,254,265} and one that compared non-hydrophilic gel reservoir catheters to non-coated
28 catheters.⁹⁹ None of the studies from the previous 2003 guideline met the inclusion criteria for this
29 review question.

30 The non-coated catheters were used as a single-use product in Cardenas et al., 2009,³⁵ as a multi use
31 product (reused up to 5 times a day, with a new catheter used each day) in Vapnek et al., 2003²⁶⁵ and
32 Pachler et al., 1999¹⁹³ and not stated in Gianntoni et al., 2001⁹⁹ and Sutherland et al., 1996²⁵⁴ and
33 DeRidder et al., 2005.⁵⁹ In order to allow accurate incorporation of the data from these studies into
34 the economic model, the authors of these studies were contacted for clarification. DeRidder et al.,
35 replied that the catheters used in the study were single-use. No reply was obtained from Gianntoni
36 et al., and Sutherland et al., it was assumed that these studies also used single-use non-coated
37 catheters.

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

1 **Table 46: Hydrophilic coated vs. non-coated catheters for long term intermittent self**
 2 **catheterisation – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Mean monthly urinary tract infection - 12 months ²⁶⁵	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 ^{35,59}	2	RCT	Serious limitations ^(b, d)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Patients/helpers very satisfied with the catheter – 6 months ⁵⁹	1	RCT	Serious limitations ^(d)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Patients/helpers very satisfied with the catheter – 1 year ⁵⁹	1	RCT	Serious limitations ^(d)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Patient satisfaction ²⁵⁴ (visual analogue scale, 10 = least favourable)	1	RCT	Serious limitations ^(e, g)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Problems introducing catheter ¹⁹³	1	RCT	Serious limitations ^(f)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Burning sensation when introducing the catheter ¹⁹³	1	RCT	Serious limitations ^(f)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Pain when introducing the catheter ¹⁹³	1	RCT	Serious limitations ^(f)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Burning sensation or pain after removal of the catheter ¹⁹³	1	RCT	Serious limitations ^(f)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Bacteraemia	0	RCT				
Mortality	0	RCT				

- 3 (a) Method of randomisation not stated. Number of urinary tract infections at baseline is higher in intervention compared
 4 to the control. Catheters re-used up to 5 times a day for control, where as intervention did not reuse catheters.
 5 (b) Method of randomisation not stated and unclear allocation concealment. Higher number of women in control group
 6 compared to the intervention³⁵.
 7 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
 8 difficult to know the true effect size for this outcome.
 9 (d) High dropout rate in DeRidder et al., 2005⁵⁹ (54%) due to restored urinary function and thus no further need for
 10 catheterisation, change of bladder management to an indwelling catheter and withdrawal of consent.
 11 (e) Sutherland et al., 1996²⁵⁴ population is all male mean age 12 years old.
 12 (f) Unclear allocation concealment.
 13 (g) Crossover study. No details of allocation concealment or assessor blinding.

1 **Table 47: Hydrophilic coated vs. non-coated catheters for long term intermittent self**
2 **catheterisation - Clinical summary of findings**

Outcome	Hydrophilic	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 - 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

Update 2012

3 **Table 48: Gel reservoir vs. non-coated catheters for long term intermittent self catheterisation –**
4 **Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Patients with ≥1 urinary tract infection – 7 weeks ⁹⁹	1	RCT	Very serious ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Patient comfort (visual analogue scale, low = more comfortable) ⁹⁹	1	RCT	Very serious ^(b)	No serious inconsistency	No serious indirectness	No serious imprecision
Bacteraemia	0	RCT				
Mortality	0	RCT				

5 (a) Crossover study, the outcomes measured 3 times per patient and reported for 3x the number of total patients in the
6 group i.e. 54 instead of 18. No details of allocation concealment or assessor blinding.
7 (b) Crossover study. No details of allocation concealment or assessor blinding. Small number of patients in each arm.

1 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
2 difficult to know the true effect size for this outcome.

3 **Table 49: Gel reservoir vs. non-coated catheters for long term intermittent self catheterisation -**
4 **Clinical summary of findings**

Outcome	Gel reservoir	Non-coated	Relative risk	Absolute effect	Quality
Patients with 1 or more urinary tract infection – 7 weeks	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 (visual analogue scale, low = more comfortable)	18	18	-	MD 2.39 higher (1.29 to 3.49 higher)	VERY LOW

5 **Question 2. Single-use non-coated vs. multiple-use non-coated catheters (see section 10.5.1):**

6 Two RCTs were identified for inclusion comparing multiple-use non-coated catheters to single-use
7 catheter for intermittent catheterisation, where the multiple-use arm had new catheters once a
8 week⁷⁹ or every 24 hours.¹³⁴ None of the studies from the previous 2003 guideline met the inclusion
9 criteria for this review question.

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

11 **Table 50: 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				

12 (a) Unclear randomisation, allocation concealment and blinding. The length of follow up varied from 1-107 days.

13 (b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
14 difficult to know the true effect size for this outcome.

15 **Table 51: 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

10.5.16 **Cost-effectiveness evidence**

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

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

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

10.5.133 Cost-effectiveness evidence – original economic model

4 **Methods**

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

11 **Population & comparators**

12 The population evaluated in the base case analysis was people with bladder dysfunction caused by
13 spinal cord injury (SCI). This population was chosen for the base case as it most closely matched the
14 population considered by the majority (4/5) of the RCTs included in the clinical review and because
15 this group of patients is one of the largest users of intermittent catheters. The average age of the
16 population entering the model was 40 years and 80% were assumed to be male; this is the average
17 age at injury and gender composition of the UK population of people with SCI.

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

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

- 22 • Single-use hydrophilic catheters
- 23 • Single-use gel reservoir catheters
- 24 • Single-use non-coated catheters
- 25 • Clean multiple-use non-coated catheters

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

31 The GDG also noted that in children and young people (≤ 16 years old), symptomatic UTI can cause
32 progressive renal scarring which may lead to renal failure later in life. Renal failure carries a high risk
33 of mortality and morbidity, is associated with very high cost and decreased quality of life. The most
34 recent NICE guideline for Urinary Tract Infection in Children¹⁸¹ concluded that it was not possible to
35 estimate the true risk of renal failure as a result of childhood UTI, did not identify any quality of life
36 values for children with UTI, and did not consider economic modelling a valid option in this
37 population. The current GDG agreed with this decision and noted that none of the studies included in
38 the clinical review which contained symptomatic UTI as an outcome were conducted in children.
39 Given the uncertain risk of harm as a result of symptomatic UTI in childhood, the GDG decided to
40 employ the precautionary principle in their approach to intermittent self-catheterisation (ISC) in
41 children. Therefore, only single-use catheters were considered an option for ISC in children and
42 modelling was not explicitly undertaken in this population.

1 **Approach to modelling**

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

8 The main simplifying assumption of the model was that the probability of antibiotic resistance does
 9 not change over time. This assumption was necessary due to a lack of available data about current
 10 and historical resistance rates, the complexity of forecasting antibiotic resistance trends over time
 11 and within populations, and a lack of examples on which to base methodological approaches.⁴⁹
 12 Different rates of resistance were explored in sensitivity analysis.

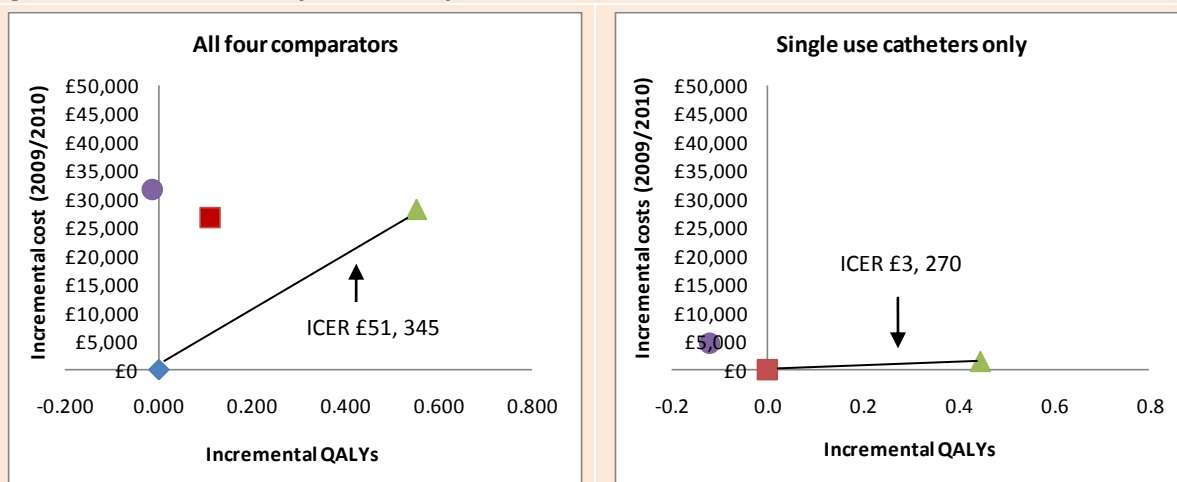
13 **Results**

14 This analysis found that clean multiple-use non-coated catheters are the most cost-effective type of
 15 intermittent catheter. Although gel reservoir catheters were found to be slightly more effective than
 16 clean non-coated catheters, they were associated with a much greater cost. Dividing the incremental
 17 cost by the incremental effectiveness results gives a cost-effectiveness ratio of £51,345 per QALY
 18 gained. This value far exceeds the £20,000 per QALY threshold set by NICE. By taking into account the
 19 standard error of each model input, probabilistic analysis revealed that clean multiple-use non-
 20 coated catheters are the most cost-effective option in 99.6% of model iterations.

21 In patients who are unable to use clean non-coated catheters, gel reservoir catheters were found to
 22 be the most cost-effective option, at approximately £3,270 per QALY gained. Compared to
 23 hydrophilic catheters, gel reservoir catheters are most cost-effective in 84.2% of model iterations.

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

30 **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.

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

4 **Table 52: 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	£11, 984	11.896	Baseline	Baseline	Baseline	99.6%
Hydrophilic	£38, 883	12.005	£26, 899	0.109	ED	0.00%
Gel reservoir	£40, 346	12.449	£28, 326	0.552	£51, 345	0.4%
Non-coated used once only	£43, 611	11.882	£31, 627	-0.014	D	0.00%
In cases where non-coated catheters cannot be washed and reused						
Hydrophilic	£38, 936	12.002	Baseline	Baseline	Baseline	15.1%
Gel reservoir	£40, 391	12.446	£1, 454	0.445	£3, 270	84.2%
Non-coated used once only	£43, 642	11.879	£4, 705	-0.122	D	0.7%

5 The health gain to individuals using ISC is presented in terms of total and incremental QALYs. Cost is presented as total and
6 incremental cost per catheter strategy. These values are used to calculate the ICER. Because single-use non-coated catheters
7 are less effective and more expensive than non-coated catheters used multiple times, they are said to be dominated and are
8 eliminated from further analysis. Similarly, hydrophilic catheters are excluded by extended dominance. QALYs = quality
9 adjusted life years; ICER = incremental cost-effectiveness ratio; ED = extended dominated; D = dominated; CE = cost-effective
10 at a threshold of £20,000.

11 *Incremental costs and QALYs are calculated compared to the option with the lowest cost – non-coated multiple-use
12 catheters and hydrophilic catheters, respectively.

13 Scenario and sensitivity analyses

14 **Intermittent self-catheterisation (ISC) in patients with bladder dysfunction not due to spinal cord** 15 **injury**

16 A separate set of probabilities and utilities was collected in order to run a scenario analysis for
17 patients with bladder dysfunction that is not caused by SCI. Assuming that each type of catheter
18 exhibits the same relative efficacy in this population, the conclusion of this scenario analysis is the
19 same as that for patients with SCI: where it is possible to wash and re-use non-coated catheters (in
20 this population gel reservoir catheters are associated with a cost of £149, 559 per QALY gain and so
21 do not represent an efficient use of NHS resources); however, when re-use of non-coated catheters
22 is not an option, gel reservoir catheters represent the most cost-effective option. In both cases,
23 single-use non-coated catheters are excluded from the analysis by dominance and hydrophilic
24 catheters by extended dominance.

25 **Urethral complications**

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

31 **Antimicrobial resistance**

32 The conclusions of the model were robust to simultaneously varying the probability of the risk of
33 treatment failure and multidrug resistant UTI to the upper limit of each input's 95% confidence

1 interval. This shows that given current understanding of the scope of antibiotic resistance, multiple-
2 use non-coated catheters are the most cost cost-effective option for ISC.

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

10 **Number of non-coated catheters used**

11 The number of clean non-coated catheters used per year was varied between an average of 60 per
12 year (average 5 per *month*) and 1825 per year (average 5 per *day*) in a threshold analysis. Clean ISC
13 ceases to be the most cost-effective option when an average of 208 non-coated catheters is used per
14 year; this equivalent to approximately 17.3 catheters per month or 4 per week.

15 **Interpretation and limitations**

16 This analysis combines the best available evidence about the costs and consequences of each type of
17 catheter used for intermittent catheterisation. Based on the results of the model, we can conclude
18 that the small decrease in symptomatic infections associated with single-use gel reservoir and
19 hydrophilic catheters is not enough to justify the large increase in the cost of these catheters
20 compared to multiple-use non-coated catheters. As a result, clean multiple-use non-coated catheters
21 represent the most cost-effective type of catheter for ISC. This conclusion was robust to a wide range
22 of sensitivity analyses, including the increased probability of urethral complications that may be
23 associated with the use of non-coated catheters. However, multiple-use non-coated catheters cease
24 to be the most cost-effective choice when patients use *an average* of more than two catheters per
25 day. Compliance and behaviour are therefore important factors for healthcare workers to consider
26 when prescribing an ISC regime.

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

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

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

10.5.114

Evidence statements

2 Clinical

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

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

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

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

14 There is a statistically significant decrease of uncertain clinical importance in the
15 number of patients with 1 or more urinary tract infection(s) at 7 weeks for gel
16 reservoir catheters compared to non-coated catheters for long-term intermittent
17 catheterisation (VERY LOW QUALITY).

18 There is a statistically significant increase of uncertain clinical importance in patient
19 comfort for gel reservoir catheters compared to non-coated catheters for long-term
20 intermittent catheterisation (VERY LOW QUALITY).

21 No studies were identified that reported bacteraemia or mortality.

22 **Question 2. Single-use non-coated vs. multiple-use non-coated catheters**

23 It is unlikely that there is any difference in symptomatic urinary tract infections with
24 clean vs. sterile uncoated catheters for long-term intermittent catheterisation
25 (MODERATE QUALITY).

26 It is uncertain whether there is any difference in frequency of catheterisations per
27 day with clean vs. sterile non-coated catheters for long-term intermittent
28 catheterisation (LOW QUALITY).

29 No studies were identified that reported bacteraemia, mortality or patient
30 preference and comfort.

31 Economic

32 New economic analyses comparing single-use hydrophilic, single-use gel reservoir,
33 single-use non-coated, and clean multiple-use non-coated catheters found that
34 washing and re-using non-coated catheters is the most cost-effective option for
35 intermittent self-catheterisation. In situations where it may not be feasible or
36 appropriate to wash and reuse non-coated catheters, gel reservoir catheters appear
37 to be the most cost-effective catheter type. However, if patients prefer hydrophilic
38 catheters to gel reservoir catheters, they may also be considered cost-effective.
39 Single-use non-coated catheters are never a cost-effective option for intermittent
40 self-catheterisation. The conclusion was robust to a wide range of scenario and
41 sensitivity analyses, including varying the probability and cost of urethral
42 complications (MINOR LIMITATIONS AND DIRECTLY APPLICABLE).

10.5.115 Recommendations and link to evidence

Recommendations	38. Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent self-catheterisation. [new 2012]
Relative values of different outcomes	<p>The GDG considered the most important outcomes to be symptomatic UTIs (recurrent and total), patient preference or comfort and mortality. The risk of long-term complications as a result of childhood UTI was considered the most important outcome in people under 16. Other outcomes also searched for were allergic reactions and bacteraemia.</p>
Trade off between clinical benefits and harms	<p>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 as to whether the effect is of clinical significance. The risk ratio for one or more UTIs for hydrophilic vs. single-use non-coated is 0.80 (95% CI 0.65 – 0.99);^{35,59} gel reservoir vs. single-use non coated is 0.33 (95% 0.11 – 0.97);⁹⁹ and multiple-use non-coated vs. single-use non-coated is 0.98 (95% 0.77 – 1.25).^{79,134}</p> <p>Although there was a statistically significant increase in scores for comfort using gel reservoir catheters compared to single-use non-coated catheters,⁹⁹ it is uncertain if this is clinically important as the scores are un-validated. No difference was reported between hydrophilic and single-use non-coated catheters;^{59,193,254} and there was no evidence for single-use non-coated compared to multiple-use non-coated catheters in terms of patient comfort or preference.</p> <p>A probabilistic model was constructed to take into account the uncertainty surrounding the relative efficacy of each catheter at preventing infection, the cost of each type of catheter regime, the cost of catheter-associated infections, and quality of life associated with catheter-associated urinary tract infection.</p> <p>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. For patients in whom single-use catheters represent the most appropriate option, the strategy for multiple-use non coated catheters was removed from the model.</p> <p>The GDG noted that symptomatic UTI in childhood carries the risk of serious kidney damage in the long-term. 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.</p> <p>The GDG discussed the health economic evidence at length and acknowledged the model findings. The GDG felt it important to reflect the strength of the low quality clinical evidence in drafting their recommendation. They felt it appropriate to recommend that this choice of catheter is therefore ‘considered’ rather than ‘offered’ in line with advice that is defined in the NICE guidelines manual (2009)¹⁸² for ‘recommendations on interventions that ‘could’ be used, i.e. the GDG is confident that the intervention will do more good than harm for most patients, and will be cost effective’.</p> <p>This recommendation states that those patients in residential or nursing homes should be offered a choice of single-use hydrophilic or gel reservoir catheters and not be offered single-use non-coated catheters. There may be a higher risk of infections in settings where patients share facilities and as such the GDG considered that a cautionary approach be followed. The GDG</p>

considered that in residential or nursing homes the healthcare workers care for many patients during their work and there is consequently a greater risk of infection and reusable catheters would therefore not be appropriate. The GDG felt that healthcare workers should consider using single-use intermittent catheters in this setting.

The GDG discussed the clinical and cost-effectiveness evidence and acknowledged the model findings. The GDG drafted a recommendation for consultation which reflected the results of the clinical review and cost-effectiveness evaluation. This recommendation proposed that non-coated intermittent catheters for multiple-use be prescribed providing the following conditions were met: this is considered clinically appropriate after assessment; the patient is aged 16 years or over; the patient is able to wash and dry catheters; suitable facilities to wash, dry and store catheters are readily available; catheterisation is performed by the patient or a close family member; and the patient is not in a residential or nursing home.

Following stakeholder consultation, the GDG reviewed this recommendation in light of comments received. Stakeholders expressed concern that it would not be possible to implement the recommendation due to the MHRA designation of intermittent catheters as single-use items. Despite advice received from the NICE legal counsel in advance of consultation, stakeholders were concerned that the re-use of these items would make practitioners liable for any catheter-associated infections caused by the multiple-use of a catheter intended for single-use (see other considerations below). There was also concern that recommending that patients disregard the single-use symbol for this device may lead to confusion and safety implications in other areas. Therefore, it was agreed that this recommendation would be amended for the current guideline update, as the GDG feel that too many barriers remain in practice to achieve successful implementation of the consultation recommendation at this time. Multiple-use catheters remain in the clinical and health economic write up of this guideline and were considered by the GDG when developing the original recommendation.

Reusing a device labelled as single-use in this context is considered similar to making an “off label” recommendation where robust clinical and cost-effectiveness evidence is required. The GDG noted that although the results of the cost-effectiveness evaluation suggest that multiple-use catheters are the most cost effective option for ISC, the model was based on low or very low quality clinical evidence.

In addition to concerns regarding the single-use symbol, two other areas (frequency of catheter change and cleaning and drying of catheters for reuse) which were not included within the scope of this update were highlighted as relevant to the implementation of this recommendation. Further work is required in future updates of this guidance to clarify some of the 2003 recommendations related to catheters. For example, the original 2003 recommendations state that ‘catheters should be changed only when clinically necessary or according to manufacturer’s current recommendations [2003]’, but the GDG are aware that manufacturer’s instructions vary. This is also the case with the recommendation that states ‘reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer’s instructions [2003]’. As such the GDG feel it important at this time to remove the recommendation about cleaning and storing reusable catheters from this update, to minimise confusion in practice.

If the MHRA review their designation of intermittent catheters as single-use devices or if higher quality clinical evidence is published prior to the next scheduled review for update, then this recommendation may be revisited again. A research recommendation has been made to gain higher quality clinical evidence in this area (see section 10.12). If the results of additional research support the conclusions reached by the current clinical and cost-

	<p>effectiveness evaluation, then the use of non-coated catheters for multiple-use represents a significant cost saving to the NHS.</p>
Economic considerations	<p>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 £51, 345. 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, including exploratory analysis surrounding the issue of urethral trauma and strictures. The base case model assumed that patients use an average of five catheters per month (1.2 per week). When a threshold analysis was run for this parameter, multiple-use non-coated catheters cease to be the most cost effective option when patients use more than an average of 17.3 per month (4 per week).</p> <p>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, 270 compared to hydrophilic catheters. However, not all patients find gel reservoir catheters suitable, so flexibility is needed to allow the use of hydrophilic catheters in this situation. The NICE guideline 'Urinary Tract Infection in Children'¹⁸¹ 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 GDG for this partial update 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.</p>
Quality of evidence	<p>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.</p> <p>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.</p> <p>Several of the outcomes for this recommendation were imprecise and although, for example, there is a statistically significant decrease in the 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 for 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.</p> <p>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 children²⁵⁴ which investigated hydrophilic catheters versus non-coated PVC catheters in children (mean age 12 years).²⁵⁴ This study did suggest that there</p>

	<p>is no difference in patient satisfaction between the catheter types although this evidence was low quality. In the absence of evidence, the GDG made a consensus recommendation that people under 16 should not use non-coated catheters.</p>
Other considerations	<p>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:</p> <ul style="list-style-type: none"> • 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. <p>However, the GDG considered this to be contradictory for several reasons:</p> <ul style="list-style-type: none"> • Some manufacturers provide instructions for cleaning non-coated catheters. • There is no evidence to suggest that re-use of non-coated catheters is unsafe. On the contrary, the only direct 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. <p>Discussion of these issues informed the GDG's consultation recommendation for multiple-use of non-coated intermittent catheters. Following the stakeholder consultation and the NICE guideline review panel feedback (GRP) the GDG reviewed their recommendation for non-coated intermittent catheters for multiple-use and made revisions. The reasons for this are discussed in the trade off between clinical benefits and harms section above. If the MHRA review their decision for including a single-use logo on these catheters and their interpretation of that logo or if higher quality clinical evidence is published prior to the next scheduled review for update, then this recommendation maybe reviewed, given the strong economic findings.</p> <p>In drafting the revised recommendation, the GDG noted the following issues of importance:</p> <p>The GDG feel it important to consider privacy and dignity issues when recommending a type of intermittent catheter and considered issues such as shared toilets in work places or other public spaces.</p> <p>The GDG considered that during the healthcare worker's assessment of the patient (see recommendation 36), they would discuss the choice of catheter that would appropriately maintain their patient's independence and not restrict their everyday activities.</p> <p>The GDG thought the patient's physical ability, including problems with manual dexterity or mobility, including wheelchair users, should be taken into consideration. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter, when assessing the patient for type of catheterisation,(see recommendation 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]). The GDG acknowledged that patient preference is an important issue and this was clearly highlighted as an important outcome in the evidence review; and that recommendation 36 is worded to prompt discussion between clinician and patient so that they may both decide which type of catheter is best suited to an individual's needs and circumstances. Patient preference, clinical assessment, clinical and cost effectiveness should all be considered when</p>

selecting an intermittent catheter.

Although the results of the economic model indicate that gel reservoir catheters are more cost effective than hydrophilic, the GDG considered that patients should be able to choose a less effective, less expensive option if it is their preference. The GDG have therefore recommended that healthcare workers 'offer a choice of single-use hydrophilic or gel reservoir catheters'. This is in line with the NHS constitution which details that patients "have the right to make choices about [their] NHS care and to information to support these choices. The options available to you will develop over time and depend on your individual needs."⁶⁹ The GDG also took this into account when cross referring to an earlier recommendation about clinician assessment, which includes patient preference (see recommendation 36).

No evidence was reviewed regarding the frequency of change for non-coated catheters. The GDG did not feel it was appropriate to make a recommendation regarding the frequency of change of 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.

Patient compliance was also identified as an important factor when deciding which type of intermittent catheter to recommend. No clinical evidence was identified regarding this; however it was felt that this could also form part of the discussion with the patient regarding clinically appropriate options.

Urinary tract infection in childhood may carry special significance, as discussed in the Urinary Tract Infection in Children guideline.¹⁸¹ This includes the risks of acute clinical deterioration and long-term renal damage. Although the vast majority of children who have a urinary tract 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.

The GDG have also made a research recommendation in this area, see section 10.12.

1

10.5.2 Review question – long-term indwelling catheters

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

10.5.2.1 Clinical evidence

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

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

11 **Table 53: Hydrophilic coated vs. silicone catheters for long term indwelling catheterisation –**
12 **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 preference and comfort	0	RCT				

13 (a) Unclear allocation concealment and selective outcome reporting where full data is not provided.

14 (b) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
15 difficult to know the true effect size for this outcome.

16 **Table 54: Hydrophilic coated vs. silicone catheters for long term indwelling catheterisation -**
17 **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

10.5.212 Cost-effectiveness evidence

- 2 No cost-effectiveness evidence was identified in the update search.
- 3 No cost-effectiveness evidence was identified in the previous 2003 guideline.
- 4 In the absence of any published cost-effectiveness analyses, current UK catheter and infection-
 5 related costs were presented to the GDG to inform decision making. The GDG were also presented
 6 with the costs and quality of life associated with UTI and UTI-associated complications (see economic
 7 model in Appendix J and K).

8 **Table 55: 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

9 *Source: Based on average 2010 Supply Chain¹⁸⁷ prices.*

10 *Abbreviations: PTFE = polytetrafluoroethylene*

10.5.213 Evidence statements

- 12 Clinical There is a statistically significant and clinically important increase in mean catheter
 13 time *in situ* for hydrophilic catheters compared to silicone catheters for long-term
 14 indwelling catheterisation (MODERATE QUALITY).
- 15 It is uncertain whether there is any difference in encrustations leading to catheter
 16 change for hydrophilic catheters compared to silicone catheters for long-term
 17 indwelling catheterisation (LOW QUALITY).
- 18 It is unlikely that there is any difference in catheter related adverse events for
 19 hydrophilic catheters compared to silicone catheters for long-term indwelling
 20 catheterisation (LOW QUALITY).
- 21 No studies identified reported symptomatic urinary tract infections, bacteraemia,
 22 frequency of catheter change, mortality or patient preference and comfort.
- 23 Economic No relevant economic studies were identified.
 24

10.5.214 Recommendations and link to evidence

Recommendations	<p>39. Select the type and gauge of an indwelling urinary catheter based on an assessment of the patient's individual characteristics, including:</p> <ul style="list-style-type: none"> • 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 if 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).
Other considerations	<p>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.</p> <p>This list was largely made by GDG consensus and the reasoning behind the inclusion of each factor is discussed below:</p> <ul style="list-style-type: none"> • 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, see section 4.1.

10.5.3 Is one catheter better than another?

2 There is some evidence that the balloon material on all silicone Foley catheters has a greater
3 tendency to “cuff” on deflation than latex catheters, particularly when used suprapubically. Cuffing
4 can cause distress and injury to patients when the catheter is removed.¹⁶⁵ Our systematic review
5 showed that smaller gauge catheters (12-14 Ch) with a 10 ml balloon minimise urethral trauma,
6 mucosal irritation and residual urine in the bladder, all factors which predispose to catheter-
7 associated infection.^{220,229} A non-systematic review of the literature confirmed this.²⁴⁸ For suprapubic
8 catheterisation, a 16 Ch gauge catheter is usually preferable to avoid blockage.¹⁶² Where there is no
9 difference in the quality of the catheter, the least expensive option should be used.⁷³

10 One study²⁸⁰ identified by our systematic review compared the use of catheter valves with a standard
11 drainage system and found no significant difference in urinary tract infection but a patient
12 preference for the catheter valve. The Medical Device Agency (now Medicines and Healthcare
13 products Regulatory Agency) suggests patients need to be assessed for their mental acuity, manual
14 dexterity, clothing preferences and use of night drainage bags when considering using catheter
15 valves.¹⁶⁴

10.5.3.1 Recommendations

17 **40. In general, the catheter balloon should be inflated with 10 ml of sterile water in adults and**
18 **3-5 ml in children. [2003]**

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

21

10.6 Asepsis

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

10.6.1 Review question

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

10.6.101 Clinical evidence

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

10.6.122 Cost-effectiveness evidence

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

10.6.153 Recommendations

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

19

10.7 Catheter Insertion

10.7.1 Catheterisation is a skilled procedure

3 Principles of good practice, clinical guidance^{270,284} and expert opinion^{74,75,131,141,247} agree that urinary
4 catheters must be inserted using sterile equipment and an aseptic technique. Expert opinion
5 indicates that there is no advantage in using antiseptic preparations for cleansing the urethral
6 meatus prior to catheter insertion.^{93,139} Urethral trauma and discomfort will be minimised by using an
7 appropriate sterile, single-use lubricant or anaesthetic gel. The insertion of urinary catheters by
8 healthcare workers who are competent in the procedure will minimise trauma, discomfort and the
9 potential for catheter-associated infection.^{75,93,141,270}

10 With regard to self-catheterisation, our systematic review found that in a study examining the safety
11 of clean versus sterile intermittent catheterisation in male adults aged 36-96 years, no significant
12 differences were found in infection rates, time to first infection or number of episodes.⁷⁹ A
13 systematic review identified three controlled trials regarding the benefits of sterile or “non-touch
14 techniques” for intermittent catheterisation vs. conventional clean intermittent catheterisation.²³⁹
15 Data “neither supports nor refutes the need to utilize sterile, as opposed to clean, intermittent
16 catheterisation.” Economic analysis suggests that clean intermittent catheterisation is unlikely to
17 lead to additional infections and the additional cost of sterile catheterisation is unlikely to be
18 justified.^{79,274}

10.7.191 Recommendations

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

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

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

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

10.8 Catheter Maintenance

10.8.1 Leave the closed system alone!

31 Maintaining a sterile, continuously closed urinary drainage system is central to the prevention of
32 catheter-associated infection.^{75,101,141,261,270,284} The risk of infection reduced from 97% with an open
33 system to 8-15% when a sterile closed system was employed as standard practice.^{93,100,139} However,
34 breaches in the closed system such as unnecessary emptying of the urinary drainage bag or taking a
35 urine sample increase the risk of catheter-related infection and should be avoided.^{139,208,270} Hands
36 must be decontaminated and healthcare workers should wear clean, non-sterile gloves before
37 manipulation.

38 Reflux of urine is associated with infection and, consequently, best practice suggests catheters are
39 secured to avoid trauma and drainage bags should be positioned in a way that prevents back-flow of

1 urine.^{75,270} Expert opinion also recommends that urinary drainage bags should be supported in such a
2 way that prevents contact with the floor.¹³⁹ For night drainage, a link system should be used to
3 maintain the original closed system, i.e., a bag attached to the end of the day system.²⁴⁹

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

10.8.181 Recommendations

9 **46. Indwelling catheters should be connected to a sterile closed urinary drainage system or**
10 **catheter valve. [2003]**

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

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

17 **49. Patients managing their own catheters, and their carers, must be educated about the need**
18 **for hand decontamination⁸⁸ before and after manipulation of the catheter, in accordance**
19 **with the recommendations in the standard principles section (chapter 6.). [2003, amended**
20 **2012]**

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

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

24 **52. A link system should be used to facilitate overnight drainage, to keep the original system**
25 **intact. [2003]**

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

10.8.2 Appropriate maintenance minimises infections

10.8.291 Meatal cleansing with antiseptic solutions is unnecessary

30 One systematic review considered six acceptable studies that compared meatal cleansing with a
31 variety of antiseptic/antimicrobial agents or soap and water.²¹¹ No reduction in bacteriuria was
32 demonstrated when using any of these preparations for meatal care compared with routine bathing
33 or showering. Expert opinion^{75,139,284} and another systematic review²²⁹ support the view that vigorous
34 meatal cleansing is not necessary and may increase the risk of infection. Washing the meatus with
35 soap and water during daily routine bathing or showering is all that is needed.

⁸⁸ The text 'Patients managing their own catheters, and their carers, must be educated about the need for hand decontamination...' has replaced 'Carers and patients managing their own catheters must wash their hands...' in the 2003 guideline.

10.8.212 Recommendation

2 **54.The meatus should be washed daily with soap and water. [2003]**

10.9 Do bladder instillations or washouts reduce catheter associated symptomatic urinary tract infections?

4
5 The terminology regarding bladder instillations, irrigations and washouts can be confusing. Bladder
6 irrigation refers to the continuous introduction of a sterile fluid into the bladder for the purpose of
7 draining blood and debris; bladder instillation refers to the introduction of a sterile fluid into the
8 bladder and leaving it there for a variable period of time in order to dissolve encrustations, alter
9 bladder pH, or suppress bacterial growth; bladder washout refers to the introduction of a sterile fluid
10 which is allowed to drain immediately for the purpose of diluting bladder contents or unblocking an
11 obstruction. Bladder irrigation is not performed in primary and community settings and is therefore
12 outside the scope of this guideline. However, in the literature the term 'irrigation' is sometimes used
13 to refer to what is actually an instillation. Therefore, the term 'irrigation' was included as a search
14 term to ensure that studies in which the terminology may have been confused were identified. These
15 papers were also reviewed by a GDG member to ensure that only studies reporting on bladder
16 instillations were included.

10.9.1 Review question

18 What is the clinical and cost effectiveness of bladder instillations or washouts on reduction of
19 catheter associated symptomatic urinary tract infections and encrustations and blockages?

10.9.201 Clinical evidence

21 Four studies were identified. The terms instillations, washouts and irrigations were not defined or
22 used consistently in the studies. The studies have been categorised into those that compare one type
23 of washout to another and those that compare a washout to no washout.

24 One randomised crossover trial, which was included in the previous guideline, compared saline,
25 Solution G (active ingredients: citric acid, magnesium oxide and sodium bicarbonate) and Solution R
26 (active ingredients: citric acid, magnesium carbonate and gluconolactone)¹³³ instillations/washouts
27 twice a week. One RCT compared saline and acetic acid instillations/washouts twice a week.²⁶⁹ One
28 RCT compared Solution G and saline instillations/washouts once a week to no instillation/washout.¹⁷³
29 One randomised crossover trial compared saline once a day to no instillation/washout.¹⁷⁶

30 Only one study¹³³ from the previous 2003 guideline met the inclusion criteria for this review
31 question.

32 See Evidence Tables G.5.3, Appendix G, Forest Plots in Figure 43-59, Appendix I.
33

1 **Comparison of solutions for instillation/washout**

2 **Table 56: Solution G vs. saline washout (twice a week) – 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				

3 (a) Crossover trial. Allocation concealment and blinding not reported

4 (b) Randomised catheters rather than patients, therefore patients were included in the study more than once.

5 (c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

6 **Table 57: Solution G vs. saline washout (twice a week)- 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

7 (a) Catheters outcomes reported per number of catheters rather than number of study participants

8

1 **Table 58: Solution R vs. saline washout (twice a week) – 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				

2 (a) Crossover trial. Allocation concealment and blinding not reported.

3 (b) Randomised catheters rather than patients, therefore patients were included in the study more than once.

4 (c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

5 **Table 59: Solution R vs. saline washout (twice a week) - 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

6 (a) Catheters outcomes reported per number of catheters rather than number of study participants.

7

1 **Table 60: Solution G vs. solution R washout (twice a week) – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations ^(a, b)	Inconsistency	Indirectness	Imprecision ^(c)
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	Serious imprecision ^(c)
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				

2 (a) Crossover trial. Allocation concealment and blinding not reported.

3 (b) Randomised catheters rather than patients, therefore patients were included in the study more than once.

4 (c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

5 **Table 61: Solution G vs. solution R washout (twice a week) - 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

6 (a) Catheters outcomes reported per number of catheters rather than number of study participants.

7

1 **Table 62: Acetic acid vs. saline washout (twice a week) – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI ²⁶⁹	1	RCT	Serious limitations ^(a, b)	No serious inconsistency	No serious indirectness	Serious imprecision ^(c)
Adverse effects ²⁶⁹	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				

- 2 (a) Randomised non-controlled trial. Sequence generation not clear and allocation concealment not reported.
3 (b) Blinding not clear.
4 (c) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

5 **Table 63: Acetic acid vs. saline washout (twice a week) - 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

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6 **Table 64: Solution G vs. saline washout (once a week) – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI ¹⁷³	1	RCT	Very serious limitations ^{(a)(b)}	No serious inconsistency	No serious indirectness	Very serious imprecision ^(c)
Mean time to first catheter change (weeks) ¹⁷³	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				

- 7 (a) Open label study. Blinding not possible due to nature of sterile packaging.

- 1 (b) 2-3 patients in each group did not complete data collection due to self reported UTI and initiation of antibiotic
2 treatment, but none met study criteria for symptomatic UTI.
3 (c) Very low number of patients in each study arm, likely to be underpowered.

4 **Table 65: Solution G vs. saline washout (once a week) - 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

5 **Comparison of solutions for instillation/washout vs. no instillation/washout**

6 **Table 66: Solution G (once a week) vs. no washout – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI ¹⁷³	1	RCT	Very serious limitations ^(a)	No serious inconsistency	No serious indirectness	Very serious imprecision ^(b)
Mean time to first catheter change (weeks) ¹⁷³	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				

- 7 (a) Open label study - blinding not possible due to nature of sterile packaging
8 (b) Very low number of patients in each study arm, likely to be underpowered.

9 **Table 67: Solution G (once a week) 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

10

1 **Table 68: Saline washout (once a week) vs. no washout – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI ¹⁷³	1	RCT	Very serious limitations ^(a, b)	No serious inconsistency	No serious indirectness	Very serious imprecision ^(c)
Mean time to first catheter change (weeks) ¹⁷³	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				

2 (a) Open label study - blinding not possible due to nature of sterile packaging.

3 (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.

4 (c) Very low number of patients in each study arm, likely to be underpowered.

6 **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

7 **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 ¹⁷⁶	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 comfort	0	RCT				
Symptomatic UTI	0	RCT				

8 (a) Crossover trial. Sequence generation and allocation concealment not clear.

- 1 (b) 23 patients participated in full duration of trial, but 32 patients (crossover and partial crossover patients) included in
2 analysis.
3 (c) Blinding not reported.
4 (d) Wide confidence intervals crossing MID. This makes it difficult to know the true effect size for this outcome.

5 **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

- 6 (a) Value not estimated as SD not reported.

10.9.172 Cost-effectiveness evidence

- 8 No cost-effectiveness evidence was identified.
9 No cost-effectiveness evidence was identified in the previous 2003 guideline.
10 In the absence of any published cost-effectiveness analyses, the current UK cost of bladder
11 instillations and washouts, nurse time, and catheter-related infections were presented to the GDG to
12 inform decision making.

13 **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

- 14 Source: NHS Drug Tariff 2010¹⁸⁶; Infection-related costs – see economic model in Appendix J. Acetic acid (used in the
15 included clinical trials) was not identified in either the BNF or NHS Drug Tariff and was therefore not included in this table.

10.9.163 Evidence statements

- 17 Clinical It is uncertain whether there is any difference between saline, Solution G or
18 Solution R washout (twice a week) for catheter encrustations, catheter blockage and
19 catheter removal or replacement (LOW QUALITY).
20 It is uncertain whether there is any difference between saline and acetic acid (twice a
21 week) for symptomatic UTI or adverse effects (LOW QUALITY).
22 It is uncertain whether there is any difference between saline washout and Solution
23 G (once a week) and no washout for symptomatic UTI and mean time to first
24 catheter change (VERY LOW QUALITY).
25 It is uncertain whether there is any difference between saline washout (daily) and no
26 washout in the number of catheter replacements per 100 days of catheterisation
27 (VERY LOW QUALITY).
28 No studies were identified that reported bacteraemia, mortality and patient
29 preference or comfort.
30 Economic No evidence of the cost-effectiveness of instillations or washouts was identified.

- 1
 - 2
 - 3
- 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.

10.9.144 Recommendations and link to evidence

Recommendations	<p>55. To minimise the risk of blockages, encrustations and catheter-associated infections for patients with a long-term indwelling urinary catheter:</p> <ul style="list-style-type: none"> • develop a patient-specific care regimen • 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	<p>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 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.</p> <p>The GDG considered that the use of bladder instillations and washouts as a prophylactic measure to prevent infections was not appropriate. After careful consideration, the GDG acknowledged that there is insufficient evidence to make a recommendation regarding the use of instillations and washouts to minimise the risk of blockages and encrustations.</p>
Economic considerations	<p>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.</p> <p>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 as a prophylactic measure to prevent infections.</p> <p>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.</p>
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 that 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 patients undergoing chemotherapy, was an area beyond the scope of the guideline.

Patient preference and quality of life were considered important.

1 **56. Bladder instillations or washouts must not be used to prevent catheter-associated**
 2 **infections. [2003]**

10.9.2 Changing catheters

4 There is no definitive evidence as to the optimal interval for changing catheters in patients
 5 undergoing long-term urinary drainage via either the urethral or suprapubic route. Our search
 6 identified a study which suggested that a higher rate of infection was associated with frequent
 7 catheter changes, though evidence is not definitive.²⁷⁷ Expert opinion suggests changing the catheter
 8 according to the clinical needs of the patient or as recommended by the catheter manufacturer
 9 (usually every 12 weeks).^{270,284} Our systematic review identified a study that showed if catheter
 10 blockage occurs within a shorter interval, catheters should be changed more frequently to avert a
 11 future clinical crisis.⁹⁷ An economic analysis suggested that there may be a cost saving in changing a
 12 catheter at six weeks when there is an increased likelihood of blockage (>50%).¹⁸⁵

10.9.2.31 Recommendations

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

10.10 Use of antibiotics when changing long-term urinary catheters

17 Antibiotic use when changing indwelling catheters is considered an area of disparity and associated
 18 with mixed views regarding antibiotic resistance and patient safety. This update aims to determine
 19 the need for prophylactic antibiotics and their impact on the reduction of urinary tract infections.

10.10.1 Review question

21 In patients with long-term urinary catheters (more than 28 days), what is the clinical and cost
 22 effectiveness of prophylactic antibiotics (single dose or short course) during catheter change on
 23 reduction of urinary tract infections?

10.10.1.1 Clinical evidence

25 One RCT conducted in elderly patients using an open urinary collecting catheter system and silicone
 26 coated catheters was identified.⁸⁹ No studies from the previous 2003 guideline met the inclusion
 27 criteria for this review question.

28 See Evidence Table G.5.1, Appendix G, Forest Plots in Figure 60-62, Appendix I.

29 **Table 73: Antibiotic prophylaxis vs. no treatment - Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Antibiotic resistance ⁸⁹	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Very serious imprecision ^(c)
Mortality ⁸⁹	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Very serious imprecision ^(c)
Bacteraemia ⁸⁹	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Very serious imprecision ^(c)

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Symptomatic UTI	0	RCT				
Upper UTI (pyelonephritis)	0	RCT				
Patient preference	0	RCT				

- 1 (a) Randomisation allocation and concealment method not reported. Not double blinded.
 2 (b) The patients in the study were elderly in a home, and used an open urinary collecting catheter system; the antibiotic
 3 prophylaxis used was meropenem (1gm given intravenously 30 minutes prior to catheterisation). Meropenem is a broad
 4 spectrum antibiotic normally reserved as a second line treatment in the UK. It is highly uncertain whether this evidence is
 5 applicable to prophylaxis in the community for UK patients.
 6 (c) Sparse data and confidence intervals crossed MID. Sample size was too small to detect statistical significance for rare
 7 events.

8 **Table 74: Antibiotic prophylaxis vs. no treatment - Clinical summary of findings**

Outcome	IV meropenem	No treatment	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

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10.10.2 Cost-effectiveness evidence

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

12 From an economic perspective, questions surrounding the use of antibiotic prophylaxis are very
 13 complex. A recent Health Technology Assessment performed a literature search in order to develop a
 14 conceptual evaluative framework for the economic evaluation of policies against MRSA⁴⁹. Many of
 15 the considerations discussed within this review were relevant to the current question and provided a
 16 useful background for GDG discussions related to the cost-effectiveness of antibiotic prophylaxis for
 17 changing long-term indwelling urethral catheters.

18 The GDG were also presented with current UK antibiotic and infection-related costs (see economic
 19 model in Appendix J).

20 **Table 75: Cost of antibiotics commonly used for prophylaxis when changing long-term indwelling**
 21 **urinary catheters**

Antibiotic	Standard prophylactic dose	Cost per dose (£)
Gentamicin	80mg intramuscular	1.48
Ciprofloxacin	20mg x 2 per oral	0.22
Nitrofurantoin	50mg x 4 per oral	0.38
Trimethoprim	200mg x 2 per oral	0.02

22 Source: Drug and dosing data based on expert advice; costs obtained from the NHS Drug Tariff¹⁸⁶ prices.
 23

10.10.3 Evidence statements

2	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).
3		
4		
5		No studies were identified that reported symptomatic lower UTI, symptomatic upper UTI, or patient preference.
6		
7	Economic	No evidence comparing the cost-effectiveness of providing antibiotic prophylaxis vs. not providing prophylactic antibiotics while changing urinary catheters was identified.
8		
9		

10.10.301 Recommendations and link to evidence

	<p>58. When changing catheters in patients with a long-term indwelling urinary catheter:</p> <ul style="list-style-type: none"> • do not offer antibiotic prophylaxis routinely • consider antibiotic prophylaxis^{hh} for patients who: <ol style="list-style-type: none"> i. have a history of symptomatic urinary tract infection after catheter change or ii. experience traumaⁱⁱ during catheterisation. [new 2012]
Relative values of different outcomes	Prevention of symptomatic UTI was considered the most important outcome. UTI-associated mortality, bacteraemia and pyelonephritis or upper UTIs were also considered important outcomes.
Trade off between clinical benefits and harms	<p>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.</p> <p>Antibiotics also carry a risk of adverse reaction in individual patients.</p> <p>The recommendation was based on GDG consensus as the strength of evidence was insufficient to indicate an overall benefit from routine antibiotic prophylaxis.</p>
Economic considerations	<p>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.</p> <p>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</p>

^{hh} At the time of pre-publication of the guideline (December 2011), no antibiotics have a UK marketing authorisation for this indication. Informed consent should be obtained and documented.

ⁱⁱ The GDG defined trauma as frank haematuria following catheterisation or two or more attempts of catheterisation.

	<p>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.</p>
<p>Quality of evidence</p>	<p>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.</p> <p>No cost-effectiveness evidence was identified.</p>
<p>Other considerations</p>	<p>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.</p> <p>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).</p> <p>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.</p> <ul style="list-style-type: none"> • 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. <p>For these groups, the concerns about patient safety were paramount.</p> <p>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.</p> <p>The GDG also discussed patients with a high risk of bacteraemia, such as immunosuppressed patients, and that they could also be considered for antibiotic prophylaxis.</p> <p>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.</p> <p>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.</p> <p>Other linked recommendations:</p> <p>Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional</p>

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.

10.11 Areas for Further Research

2 In developing the recommendations we identified several areas that were inadequately addressed in
3 the literature. The following recommendations for research are therefore made.

4 **Assessing the need for catheterisation**

5 Epidemiological studies of the prevalence and incidence of bacteriuria/clinical urinary tract infection
6 during long-term catheterisation in different populations and different care settings. These should at
7 least encompass the predominant populations; older people and those with neurological deficits in
8 both institutional and domiciliary settings. There needs to be clear definition of the 'cases' and the
9 populations from which they are drawn.

10 **Catheter drainage options**

11 Randomised controlled trials of different approaches to urinary drainage. These should compare
12 urethral indwelling catheterisation with and without a drainage bag (i.e., a valve); urethral
13 intermittent catheterisation; suprapubic catheterisation; penile sheath drainage and incontinence
14 pads in appropriate populations. Outcome measures need to include rates of bacteriuria/clinical UTI;
15 tissue damage; patient/carer satisfaction; and cost-benefit.

16 Randomised controlled trials of the efficacy of antimicrobial impregnated urethral catheters for long-
17 term use.

18 **Catheter maintenance**

19 Randomised controlled trials of strategies to reduce/prevent/manage encrustation and blockage.
20 These need to determine whether catheter maintenance solutions (washouts/installations) are
21 effective in reducing encrustation; blockage; urethral trauma; frequency of catheter replacement;
22 and interventions/visits by healthcare practitioners. The rates of these complications when catheter
23 valves are used in place of drainage bags also needs to be compared.

24 Cohort studies to determine whether monitoring of urinary pH can be used to predict time to
25 blockage. These need to be undertaken in defined and representative groups.

26 Randomised controlled trials to establish the optimum time interval between changing equipment.
27 There is a particular need to determine whether the frequency of changing leg bags or catheter
28 valves influences the rates of bacteriuria/clinical UTI.

29

10.12 Research Recommendations

2 **3. For patients performing intermittent self-catheterisation over the long term, what is the clinical**
3 **and cost effectiveness of single-use non-coated versus single-use hydrophilic versus single-use**
4 **gel reservoir versus reusable non-coated catheters with regard to the following outcomes:**
5 **symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality,**
6 **patient comfort and preference, quality of life, and clinical symptoms of urethral damage?**

7 Why is this important?

8 Long-term (more than 28 days) intermittent self-catheterisation is performed by many people living
9 in the community. It is important that the choice between intermittent catheters is informed by
10 robust evidence on clinical and cost effectiveness.

11 The cost-effectiveness model developed for this guideline combined evidence of clinical
12 effectiveness, costs and quality of life with respect to symptomatic urinary tract infection and
13 associated complications. The results of the analysis showed that reusable non-coated catheters
14 were the most cost-effective option for intermittent self-catheterisation. However, the clinical
15 evidence informing this model was of low to very low quality. Currently, non-coated catheters are
16 considered to be single-use devices by the MHRA. In order to make an 'off-licence' recommendation
17 for the use of these catheters, better quality evidence is needed.

18 A four-arm randomised controlled trial is required. The trial population should be diverse, including
19 wheelchair users, people with spinal cord injuries and people over 16 who regularly self-catheterise.
20 The primary outcome measures should be incidence of symptomatic urinary tract infections, urinary
21 tract infection-associated bacteraemia, mortality, patient comfort and preference, quality of life,
22 clinical symptoms of urethral damage, and costs.

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

26 Why is this important?

27 Long-term indwelling catheters (both urethral and suprapubic) are commonly used in both hospital
28 and community care settings. Long-term catheterisation carries a significant risk of symptomatic
29 urinary tract infection, which can lead to more serious complications. Several different types of
30 impregnated and hydrophilic long-term indwelling catheters on the market claim to be more
31 effective than non-coated catheters, but are also more expensive.

32 The clinical evidence review for the guideline revealed an absence of evidence for the effectiveness
33 of indwelling catheters over the long-term. A comparison of impregnated (for example, with silver)
34 catheters, hydrophilic catheters and silicone catheters is needed. The primary outcome measures
35 should be symptomatic urinary tract infections, encrustations, blockages, cost/resource use and
36 quality of life. Secondary outcome measures should include the mean number of days the catheter
37 remains in situ (mean dwell time) and patient comfort.

38

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

5 Why is this important?

6 The immediate clinical and economic impact of urinary tract infection is so great that patients at risk
7 of infection are sometimes offered the option to receive prophylactic antibiotics. However, the
8 widespread use of antibiotics, including their prophylactic use, has been identified as a major factor
9 in the increasing levels of antibiotic resistance observed across England and Wales. There is currently
10 an absence of evidence about the short-term and long-term effects of prophylactic antibiotic use
11 during catheter change. The GDG identified this as an important area for research to establish the
12 benefits and harms of this practice in order to develop future guidance (the recommendation on this
13 topic in the current guideline was based on GDG consensus).

14 A randomised controlled trial or cohort trial to compare single-dose antibiotic prophylaxis with
15 selected major antibiotic groups is needed. The primary outcome measures should be symptomatic
16 urinary tract infection, cost and quality of life. This is an important area for patients as it could
17 minimise the inappropriate use of antibiotics.

11 Enteral feeding

11.1 Introduction

2 The updated review questions in this chapter are:

- 3 • aseptic techniques
4 • care of the enteral feeding tube.

5 Asepsis was considered as a priority to be included in this update as this area was not included in the
6 previous guideline. The previous guideline did refer to aseptic techniques in the recommendations,
7 but the terminology was considered to be incorrect or out-of-date by the scoping group. This area
8 was also highlighted many times by various stakeholders during the consultation as an area that
9 should be included in the scope. The use of syringes (single-use syringes vs. single patient use
10 (reusable) syringes) was also highlighted during the scoping phase as an area for update.

11 No new evidence was found, however changes were made to recommendations in section 11.4.2.3
12 and 11.5.2.4.

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

15 No new review questions are included in this chapter.

16 The GDG recognised that hand decontamination is an important part of enteral feeding. See chapter
17 6 for further details.

18 Sections not updated in this chapter are:

- 19 • preparation of storage feeds
20 • administration of feeds
21 • care of the insertion site.

22 In addition the GDG acknowledge that Medical Device Regulations¹⁶⁹ implement the EC Medical
23 Devices Directives into UK law. They place obligations on manufacturers to ensure that their devices
24 are safe and fit for their intended purpose before they are CE marked and placed on the market in
25 any EC member state. The GDG noted that guidance on the MHRA's adverse incident reporting
26 system is available for reporting adverse incidents involving medical devices.¹⁶⁸

27

28 Once enteral feeding (EF) in hospital became common practice in the late 1980s, it was inevitable
29 that those requiring prolonged feeding would continue this treatment at home. Enteral feeding is
30 usually prescribed for patients in hospital requiring artificial nutrition support (ANS) for 7-10 days
31 and long-term feeding/home enteral tube feeding (HETF) may be considered for patients needing
32 ANS for more than 30 days.⁸ HETF has expanded rapidly and by the end of 2000, 11,817 adult patients
33 receiving HETF were registered with the British Artificial Nutrition Survey (BANS).⁸² Of these, 46.5%
34 were over 70 years of age. Over 60% of the patients were receiving tube feeds because of disorders
35 of the central nervous system, of which cerebral vascular accident accounted for 34%. It was
36 reported that over half the adult patients and virtually all children starting home enteral feeding lived
37 in their own home and 40% of adults lived in nursing homes.

38 Nutrition Support Teams (NST) are recommended to support patients receiving artificial nutrition.⁸²
39 However, only 22% of NST stated that they were responsible for HETF and 47% stated that they were
40 never responsible.⁸² In addition, only one third felt that they had sufficient time to train patients on

1 HETF prior to discharge from hospital. It is therefore not surprising that enteral feeding places a
2 growing workload on community healthcare workers¹⁵⁸ and an audit of patients on HETF highlighted
3 a need for continuing support.¹⁴² Contamination of feeds is a key concern in HETF as it has been
4 found that more than 30% of feeds in hospital and home are contaminated with a variety of
5 microorganisms, largely due to the preparation or administration of feeds,¹⁰ and this has been linked
6 to serious clinical infection.²⁰³ The rates of contamination are highest in home settings and reinforces
7 the need for infection prevention guidelines.¹⁰

8 Despite searching for infection prevention measures associated with nasogastric and jejunostomy
9 feeding, most of the evidence related to gastrostomy or percutaneous endoscopic gastrostomies
10 (PEG feeds). Although these guidelines have been developed for gastrostomy feeding, the Guideline
11 Development Group felt that most of these principles could also be applied to other feeding systems.

12 These guidelines apply to adults and children over 1 year old and should be read in conjunction with
13 the guidance on Standard Principles. These recommendations are broad principles of best practice
14 and are not detailed procedural protocols. They need to be adapted and incorporated into local
15 practice guidelines. The recommendations are divided into four distinct interventions:

- 16 1. Education of patients, their carers and healthcare workers
- 17 2. Preparation and storage of feeds
- 18 3. Administration of feeds
- 19 4. Care of insertion site and enteral feeding tube.

11.2 Education of patients, carers and healthcare workers

21 Although not a specific question for our systematic review, it has become evident from our research
22 that the responsibility for preparing and administering HETF lies usually with the patient, their carers
23 and in some cases, community healthcare workers. An audit of the nursing knowledge of
24 percutaneous endoscopic gastrostomy (PEG)¹²⁶ of hospital nurses in a district general hospital
25 identified gaps in their knowledge and management of enteral feeding systems and a similar
26 situation was noted in the community.²⁷⁶ The BANS survey noted the less than optimum support
27 people on HETF receive⁸² despite expert opinion stressing the need for education and training.^{2,166}
28 Given that nutrition is a key Department of Health patient-focused benchmark for healthcare
29 practitioners,⁶³ it is of concern that this does not include those receiving artificial nutrition and
30 consequently support and preparation for these patients is not widely available.

31 A system known as Hazard Analysis and Critical Control Point (HACCP) is employed widely in the food
32 industry to highlight areas where food safety may be at risk. The Parenteral & Enteral Nutrition
33 Group of the British Dietetic Association supports the use of HACCP in enteral feeding to increase
34 safety and as an educational tool.⁹

11.2.3.1 Recommendations

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

39 **60. Healthcare workers should be trained in enteral feeding and management of the**
40 **administration system. [2003]**

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

11.3 Preparation and storage of feeds

11.3.1 Select the right system

- 3 Our systematic review identified two randomised controlled trials, which demonstrated that closed
4 systems (i.e., sterile prefilled ready-to-use feeds that do not expose feed to the air during assembly)
5 as available from all major manufacturers, have lower contamination rates than open systems.^{120,268}
6 The design of the system is also important in order to minimise handling.^{22,161,275}

11.3.171 Recommendations

- 8 **62. Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds**
9 **requiring decanting, reconstitution or dilution. [2003]**
- 10 **63. The system selected should require minimal handling to assemble, and be compatible with**
11 **the patient's enteral feeding tube. [2003]**

11.3.2 Hygienic preparation of feeds is essential

- 13 Hand hygiene is critical and hand decontamination is discussed more fully in Standard Principles
14 (chapter 6). The International Scientific Forum on Home Hygiene has also published comprehensive
15 guidance on food preparation and cleanliness in the home.²³⁵ Our systematic review identified three
16 studies^{11,12,147} concerned with feed preparation. The evidence on the use of gloves is contradictory.
17 Two studies^{11,12} suggested that gloves were preferable and one suggested bare hands if properly
18 decontaminated were acceptable.¹⁴⁷ However all three studies linked contamination to the amount
19 of manipulation a system required and reinforces the guidance above.
- 20 Standard principles stress the importance of hand decontamination and expert opinion^{9,166,242}
21 stresses the need to prepare the work surface and, where necessary the equipment for
22 reconstituting or diluting the feed. Equipment used for either opening sterile feeds or preparing
23 feeds should be dedicated for enteral feeding use only. It should be cleaned in a dishwasher or
24 washed with hot soapy water, rinsed and then dried and stored covered until required. Cooled boiled
25 water or freshly opened sterile water should be used to prepare feeds in the home.^{9,278}

11.3.261 Recommendations

- 27 **64. Effective hand decontamination must be carried out before starting feed preparation. [2003]**
- 28 **65. When decanting, reconstituting or diluting feeds, a clean working area should be prepared**
29 **and equipment dedicated for enteral feed use only should be used. [2003]**
- 30 **66. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-**
31 **touch technique. [2003]**

11.3.3 Store feeds safely

- 33 Expert opinion²⁴² and manufacturers^{5,91} advise that ready-to-use, prepackaged feeds should be
34 stored in a clean environment, protected from extremes of temperature. Stock should be rotated to
35 avoid feeds exceeding their best before date.

- 1 Where feeds need to be reconstituted or diluted they can be made up for 24 hours. All feeds not
2 required for immediate use must be stored in a refrigerator at a temperature not exceeding 4
3 degrees Celsius and discarded after 24 hours.^{5,91}

11.3.341 Recommendations

- 5 **67. Feeds should be stored according to manufacturer's instructions and, where applicable, food**
6 **hygiene legislation. [2003]**
- 7 **68. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a**
8 **refrigerator, and used within 24 hours. [2003]**

11.4 Administration of feeds

11.4.1 Minimal handling reduces risk

- 11 Four reports,^{108,147,160,197} which studied enteral feeds delivered in a variety of settings, demonstrated
12 that the risk of contamination is related to the manipulation of the system and the system design.
13 This reinforces earlier guidance about selecting a system that requires minimal handling.
- 14 When assembling the system, first assess the condition of the connection. A no-touch technique
15 should be used to connect the feed container to the administration set using the minimum number
16 of connectors possible. Contact with the patient's clothes should be avoided when attaching the
17 administration set to the enteral feeding tube.⁹
- 18 Administering feeds for the maximum time possible reduces handling to a minimum. Sterile ready-to-
19 hang feeds can be left for a maximum time 24 hours and non-sterile (reconstituted) feeds for 4
20 hours.^{9,227} However even closed systems can become contaminated if hands are not adequately
21 decontaminated.¹⁹⁷
- 22 Bacterial contamination has been associated with the re-use of feed bags and administration sets.⁸
23 One study in a long-term care facility¹⁰⁸ suggested that administration set changes could be left up to
24 72 hours but other studies^{83,136,227,232} suggested that 24 hours is the maximum time acceptable. Three
25 experimental, in vitro studies^{13,109,244} considered the re-use of equipment but none identified a
26 satisfactory system for disinfecting equipment that might be acceptable in practice. As evidence
27 suggests re-use is not advisable, the administration system should be considered single-use only and
28 discarded after each session.
- 29 Currently there appears to be a debate on the re-use of single-use syringes used to flush enteral
30 feeding tubes. Our systematic review found no evidence to either support or refute the reuse of
31 syringes. The Medicines and Healthcare Products Regulatory Agency's current guidance is that
32 medical devices labelled single-use must not be reused under any circumstances and the reuse of
33 such medical devices has legal implications.¹⁶⁷
34

11.4.2 Review question

2 The following question was asked to determine which technique should be used when handling PEGs
 3 as this was identified as an area where there is confusion in terminology. The GDG identified
 4 diarrhoea, vomiting, peritonitis and gastrostomy site infection as the primary outcomes of interest.

5 What is the most clinically and cost effective technique (such as aseptic technique, non-touch
 6 technique, aseptic non touch technique or a clean technique) when handling PEGs to reduce
 7 healthcare-associated infections?

11.4.2.1 Clinical evidence

9 No clinical evidence was identified in this update. No clinical evidence was identified in the previous
 10 2003 guideline.

11.4.2.2 Cost-effectiveness evidence

12 No cost-effectiveness evidence was identified in this update. No cost-effectiveness evidence was
 13 identified in the previous 2003 guideline.

11.4.2.3 Recommendations

Recommendations	69. Use minimal handling and an aseptic 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 an aseptic technique, in which no key parts are touched, 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 an aseptic 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 'no-touch' was removed. The GDG noted that this terminology can cause confusion. The GDG chose the term 'aseptic technique' as its preferred option for describing this approach. It was acknowledged that connecting the administration system to the enteral feeding tube is a procedure that should be carried out in a manner that maintains and promotes the principles of asepsis. See also the sections on asepsis discussed in LTC (section 10.6) and VAD (section 12.3) chapters.

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

17 **71. Administration sets and feed container are for single-use and must be discarded after each**
 18 **feeding session. [2003]**

11.5 Care of insertion site and enteral feeding tube

11.5.1 Keep the tube clear

3 Our systematic review searched for evidence regarding the stoma site as a source of infection.
 4 Although some evidence related to infection immediately after insertion of the first tube, we have
 5 found no evidence relating to infections in a healed stoma.^{137,253} However, after the stoma site has
 6 healed, usually 10-12 days after placement, no dressings are necessary. Instead the site should be
 7 inspected and cleaned daily, and dried thoroughly. The tube should be rotated 360 degrees regularly
 8 to avoid infections related to 'buried bumper syndrome'.²⁴²

11.5.191 Recommendations

10 **72. The stoma should be washed daily with water and dried thoroughly. [2003]**

11.5.2 Review question

12 The following recommendation was prioritised for update to determine the most suitable type of
 13 syringe for flushing enteral tubes. The GDG identified the most important outcomes for the question
 14 as the number of blockages/ tube occlusions and fungal colonisation.

15 What is the clinical and cost effectiveness of single vs. reusable syringes used to flush percutaneous
 16 endoscopic gastrostomy tubes on reduction of tube blockages, diarrhoea, fungal colonisation,
 17 gastrostomy site infection, peritonitis and vomiting?

11.5.281 Clinical evidence

19 No clinical evidence was identified in this update. No clinical evidence was identified in the previous
 20 2003 guideline.

11.5.212 Cost-effectiveness evidence

22 No cost-effectiveness evidence was identified in this update. No cost-effectiveness evidence was
 23 identified in the previous 2003 guideline.

24 In the absence of any published cost-effectiveness analyses, current UK syringe and infection-related
 25 costs were presented to the GDG to inform decision making.

26 **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

27 (a) Estimate only - based on the assumption that each reusable syringe is used for up to one week and five single use
 28 syringes are used per day.

29 Source: Based on average 2010 NHS Drug Tariff¹⁸⁶ prices.

30 Possible infections arising from PEG tubes include: fungal colonisation, gastrostomy site infection,
 31 and peritonitis, with symptoms ranging from vomiting and diarrhoea to bloodstream infection and
 32 sepsis. Cost and quality of life implications are potentially large.
 33

11.5.213 Evidence statements

2	Clinical	No clinical studies were identified.
3	Economic	No economic studies were identified.

11.5.244 Recommendations and link to evidence

Recommendation	<p>73.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:</p> <ul style="list-style-type: none"> • freshly drawn 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/enteral 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 immunosuppressed 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	<p>Since March 2007 the National Patient Safety Agency (NPSA)¹⁸⁴ 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.</p> <p>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.</p> <p>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.</p> <p>The GDG considered the wording of the recommendation in the previous</p>

infection control guideline and felt that restructuring the recommendation would make the advice for immunosuppressed patients clearer. The GDG considered that the term 'immunosuppressed' included people with a jejunostomy as the natural protective effect of gastric acid is bypassed when administering feeds or medication.

11.6 Areas for Further Research

2 In developing the recommendations we identified several areas that were inadequately addressed in
3 the literature. The following recommendations for research are therefore made.

4 Although comprehensive data is available on the use of HETF in the United Kingdom, very little
5 information is documented about enteral feeding practices. Anecdotal reports suggest a wide
6 variation in practice that may or may not be safe. The use of risk assessment, including HACCP has
7 been reported as a means of reducing risks but little is known about healthcare workers' knowledge
8 and use of risk assessment tools.

9 Descriptive studies of enteral feeding practices in a range of primary care trusts. This should include
10 healthcare workers, patients and carers, their preparation to undertake enteral feeding and ongoing
11 support, availability and use of equipment. Data should also be collected on the incidence of stoma
12 site infections.

13 A qualitative study of healthcare practitioners' understanding and use of risk assessment in practice.
14 Ideally this should be a series of interviews with a range of healthcare workers about their
15 knowledge of risk assessment and the tools they use. This could be applied to other areas where risk
16 assessment is used.

17 Randomised controlled trials to assess the effectiveness of HACCP in reducing the incidence of
18 enteral feeding related infection. These should focus on HETF in a variety of settings and involving a
19 range of patients and healthcare workers.

11.6.1 Preparation and storage of feeds

21 Epidemiological studies of the incidence of clinical infection associated with reconstituting enteral
22 feeds for different populations and in different care settings. These should at least encompass the
23 predominant populations - older people and those with neurological deficits in both institutional and
24 domiciliary settings and children. There needs to be clear definition of the 'cases' and the
25 populations from which they are drawn.

11.6.2 Administration of feeds

27 Randomised controlled trials of single-use, single patient use and reusable syringes. Outcome
28 measures need to include rates of clinical infection, patient/carers satisfaction and cost effectiveness.

29 Randomised controlled trial comparing the use of cooled boiled water versus sterile water to flush
30 enteral feeding tubes. Outcome measures need to include rates of clinical infection; patient/carers
31 satisfaction, and cost effectiveness.

12 Vascular access devices

12.1 Introduction

3 The updated review questions in this chapter are:

- 4 • aseptic techniques
5 • types of dressings
6 • frequency of dressing change
7 • decontamination of skin when changing dressings (central and peripheral vascular access devices
8 (VADs).
9 • decontamination of inserted catheter ports and hubs before access (central and peripheral VADs).

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

12 New review questions included in this chapter are:

- 13 • skin decontamination prior to insertion of peripheral VADs
14 • single versus multiuse vials.

15 Sections not updated in this chapter are:

- 16 • in line filters
17 • antibiotic lock solutions
18 • system anticoagulation.

19 Community based infusion therapy is an increasingly viable option as technology, treatment regimes
20 and healthcare policy advances. The various vascular access devices; peripheral cannulae (VAD
21 inserted into an extremity whereby the catheter tip does not sit in a centrally located vein), midline
22 catheters and central venous access devices (the catheter sits within a centrally located vein with the
23 tip residing in the vena cava), provide options that can meet the clinical and lifestyle requirements of
24 patients. Furthermore, in the community the insertion of peripheral VADs such as cannulae and
25 midlines is rising. Central lines are not inserted in community settings and therefore have not been
26 included in the review of evidence for skin decontamination prior to insertion. However, patients in
27 the community may have long-term central VADs, and therefore all other questions related to
28 vascular catheter management, such as skin decontamination during dressing changes and type of
29 dressing and frequency of dressing change, have been updated to reflect this. As a result, the care
30 and management of both peripheral and central VADs is pertinent.

31 VADs are one of the most important causes of healthcare acquired infection. Millions of vascular
32 catheters are used each year, putting large numbers of patients at risk of phlebitis and catheter-
33 related blood stream infection. The attributable mortality of catheter-related blood stream infections
34 is approximately 15%, and catheter-related bloodstream infections have been associated with
35 significant costs.^{157,266} The aim of this chapter was to review the clinical and cost-effectiveness
36 evidence for several strategies that have been found to decrease the incidence of catheter-
37 associated infections. The GDG has prioritised three recommendations in this chapter as key
38 priorities for implementation, see recommendations 74, 75 and 79.

39 Note: Since the publication of the guideline in 2003, a newer version of the CDC guideline had been
40 published.¹⁹⁰

1 Two recommendations from the 2003 version of this guideline have been removed in this update
2 (see Appendix D.10). These deleted recommendations are already covered by recommendations in
3 the hand decontamination (see 6.3) and PPE (see 7.4) chapters.

4 In addition the GDG acknowledged that Medical Device Regulations¹⁶⁹ implement the EC Medical
5 Devices Directives into UK law. They place obligations on manufacturers to ensure that their devices
6 are safe and fit for their intended purpose before they are CE marked and placed on the market in
7 any EC member state. The GDG noted that guidance on the MHRA's adverse incident reporting
8 system is available for reporting adverse incidents involving medical devices.¹⁶⁸

12.1.1 Expert review of evidence

10 These guidelines are primarily based upon an expert review of evidence-based guidelines for
11 preventing intravascular device-related infections developed at the Centers for Disease Control and
12 Prevention (CDC) in the United States of America by the Healthcare Infection Control Practices
13 Advisory Committee (HICPAC).^{39,191} Using a validated guideline appraisal instrument developed by
14 the AGREE collaboration,²⁵⁹ three experienced appraisers independently reviewed these guidelines,
15 taking into consideration supplementary information provided by HICPAC at our request (see
16 Appendix D.5). We concluded that the development processes were valid and that the guidelines
17 were: evidence-based; categorised to the strength of the evidence examined; reflective of current
18 concepts of best practice; and acknowledged as the most authoritative reference guidelines currently
19 available. They were subsequently recommended as the principal source of evidence for developing
20 the guidance below.

12.2 Education of patients, carers and healthcare professionals

22 To improve patient outcomes and reduce healthcare costs, it is essential that everyone involved in
23 caring for patients with a vascular access device is educated about infection prevention. Healthcare
24 workers, patients and their carers need to be confident and proficient in infection prevention
25 practices and to be equally aware of the signs and symptoms of clinical infection and how to access
26 expert help when difficulties arise. Well-organised educational programmes that enable healthcare
27 workers to provide, monitor, and evaluate care and to continually increase their competence are
28 critical to the success of any strategy designed to reduce the risk of infection. Evidence reviewed by
29 HICPAC consistently demonstrated that the risk for infection declines following the standardisation of
30 aseptic care and increases when the maintenance of intravascular catheters is undertaken by
31 inexperienced healthcare workers.¹⁹¹

12.2.321 Recommendations

33 **74. Before discharge from hospital, patients and their carers should be taught any techniques**
34 **they may need to use to prevent infection and safely manage a vascular access device^{jj}.**
35 **[2003, amended 2012]**

36 **75. Healthcare workers caring for a patient with a vascular access device^{jj} should be trained,**
37 **and assessed as competent, in using and consistently adhering to the infection prevention**
38 **practices described in this guideline. [2003, amended 2012]**

39 **76. Follow-up training and support should be available to patients with vascular access**
40 **devices^{jj} and their carers. [2003, amended 2012]**

41

^{jj} 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.

12.3 Aseptic technique

2 Asepsis was considered as a priority to be included in this update as this area was not included in the
 3 previous guideline. The previous guideline did refer to aseptic techniques in the recommendations,
 4 but the terminology was considered to be incorrect or out-of-date by the scoping group. This area
 5 was also highlighted many times by various stakeholders during the consultation as an area that
 6 should be included in the scope.

12.3.1 Review question

8 What is the most clinically and cost effective technique (such as aseptic technique, non-touch
 9 technique, aseptic non-touch technique or a clean technique) when handling vascular access devices
 10 to reduce infection related bacteraemia, phlebitis, compliance, MRSA or *C. diff* reduction and
 11 mortality?

12.3.121 Clinical evidence

13 No clinical evidence was identified in this update. No clinical evidence was identified in the previous
 14 2003 guideline.

12.3.152 Cost-effectiveness evidence

16 No cost-effectiveness evidence was identified in this update. No cost-effectiveness evidence was
 17 identified in the previous 2003 guideline.

12.3.183 Recommendations

Recommendations	77.Hands must be decontaminated before accessing or dressing a vascular access device. [new 2012]
Relative values of different outcomes	As stated in the hand decontamination 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 decontamination 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 decontamination 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

	<p>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 settings. These studies all had relatively small sample sizes and an imprecise estimate of effect.</p>
Other considerations	<p>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).¹⁸²</p> <p>The GDG decided to update this recommendation to be consistent with the evidence reviewed in the hand decontamination chapter and to emphasise the importance of hand decontamination for VAD management.</p> <p>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 decontamination chapter (see section 6.3) are directly relevant to this recommendation. The product that should be used to decontaminate hands is discussed in recommendation 6.3 of the hand decontamination chapter. Please refer to the hand decontamination chapter for a detailed explanation of products to use for hand decontamination.</p> <p>This recommendation is in line with the recommendations in the hand decontamination chapter and is included in the VAD chapter to emphasise the importance of hand decontamination. 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’.</p> <p>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.</p> <p>A recommendation from the earlier 2003 guideline 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.</p>

1

	<p>78. 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]</p>
Recommendations	
Relative values of different outcomes	The GDG considered bacteraemia, phlebitis and MRSA and <i>C. diff</i> 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	<p>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.</p> <p>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.</p>
Quality of evidence	No clinical or economic evidence was identified.

Other considerations	<p>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).¹⁸²</p> <p>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.</p> <p>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.</p> <p>See also recommendations regarding asepsis discussed in the Long term urinary catheters and Enteral feeding chapters.</p>
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12.4 Skin decontamination prior to insertion of peripheral vascular access devices

2

3 This is a new section added to the guideline as peripheral VADs are inserted in the community.
4 Central VADs are not inserted in the community and therefore are not within the remit of this
5 guideline. Care of VAD sites (such as changing dressings), both peripheral and central, is included in
6 section 12.5.

7 The following review question was prioritised for update to determine the most effective
8 decontamination solution for skin decontamination prior to insertion of peripheral vascular access
9 devices, as it was felt there are more types of decontamination products are available since 2003. In
10 particular, stakeholders highlighted uncertainty regarding what is the most appropriate
11 concentration for chlorhexidine gluconate (CHG).

12.4.1 Review question

13 What is the most clinical and cost effective product or solution for decontamination of the skin prior
14 to insertion of peripherally inserted VADs on catheter tip colonisation, infection related mortality,
15 frequency of line removal, septicaemia, bacteraemia, local or soft tissue infection and phlebitis?

12.4.1.1 Clinical evidence

17 Three RCTs were found comparing the effectiveness of different antiseptic solutions for the insertion
18 of peripheral VADs.^{46,60,243} These studies provide different levels of detail about the type of antiseptic
19 used, and the descriptions used in this section reflect the information provided in the papers. For
20 examples, in some comparisons, the type and concentration of alcohol used is specified whereas
21 others just noted “alcohol”.

22 See Evidence Table G.7.5, Appendix G, Forest Plots in Figure 63-64, Appendix I.

1 **2% Iodine in 70% alcohol vs. 70% alcohol**

2 **Table 77: 2% Iodine in 70% alcohol vs. 70% alcohol – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related phlebitis ^{46,60,243}	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				

- 3 (a) Open label study, but randomisation and allocation concealment methods were clearly reported.
 4 (b) Downgrading for indirectness (population among hospitalised COPD patients receiving prednisolone).
 5 (c) Confidence intervals crossed MIDs.

6 **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
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

7 **0.5% Chlorhexidine gluconate(CHG) in 70% alcohol vs. povidone iodine(PVP-I) and 70% alcohol**

8 **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 ⁴⁶	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Serious imprecision ^(c)
Catheter tip colonisation ⁴⁶	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				

- 10 (a) Number of patients analysed or lost to follow up not reported. Study not blinded because interventions are physically different.
 11 (b) Large proportion of hospitalised patients in study; actual proportion of inpatients in the study not reported.
 12 (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.
 13
 14

1 **Table 80: 0.5% Chlorhexidine gluconate(CHG) in 70% isoprophyl alcohol (IPA) vs. povidone**
2 **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	Quality
Catheter tip colonisation	N/R	N/R	N/R	N/R	P=0.62 (reported by authors)	VERY LOW
VAD related phlebitis	1.2%	12.5%	9.88%	N/R	P=0.008 overall (reported by authors)	VERY LOW

3 **2% Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl alcohol (IPA)**

4 **Table 81: 2% Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl**
5 **alcohol (IPA) - Clinical study characteristics**

Outcome	Number of studies	Design	Limitations ^(a, b)	Inconsistency	Indirectness	Imprecision
Infection related mortality ²⁴³	1	RCT	Serious ^(a, b)	No serious inconsistency	Serious indirectness ^(c)	Serious imprecision ^(d)
VAD related blood bacteraemia ²⁴³	1	RCT	Serious ^(a, b)	No serious inconsistency	Serious indirectness ^(c)	Serious imprecision ^(d)
VAD related local infection ²⁴³	1	RCT	Serious ^(a, b)	No serious inconsistency	Serious indirectness ^(c)	Serious imprecision ^(d)
Catheter tip colonisation ²⁴³	1	RCT	Serious ^(a, b)	No serious inconsistency	Serious indirectness ^(c)	No serious imprecision
VAD line removal ²⁴³	1	RCT	Serious ^(a, b)	No serious inconsistency	Serious indirectness ^(c)	Serious imprecision ^(d)
VAD related phlebitis	0	RCT				
Septicaemia	0	RCT				

6 (a) *Methods of randomisation and allocation concealment not reported. Study not blinded because interventions are*
7 *physically different.*

8 (b) *The paper reported “no evidence of infection found”. Communication with authors clarified that they looked for VAD*
9 *related blood stream infection but there were no cases.*

10 (c) *Patients were hospitalised and undergoing elective cardiology interventions.*

11 (d) *Small sample size – not powered to detect a difference that reaches the minimal important difference.*

12 **Table 82: 2% Chlorhexidine gluconate (CHG) in 70% isopropyl alcohol (IPA) vs. 70% isopropyl**
13 **alcohol (IPA) - Clinical summary of findings**

Outcomes	2% CHG in 70% IPA	70% IPA	Relative risk (95% CI)	Absolute risk or mean difference	Quality
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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12.4.12 Cost-effectiveness evidence

- 2 No cost-effectiveness evidence was identified in the previous 2003 guideline related to this topic.
- 3 One cost-effectiveness analysis by Chaiyakunapruk and colleagues (2003)⁴⁰ was identified in this
4 update. However, the majority of the studies used to inform clinical effectiveness parameters in this
5 model had evaluated central VADs; the remainder were either unpublished posters or conference
6 abstracts. Therefore, this study was excluded.
- 7 In the absence of any economic evidence which met inclusion criteria, current UK decontamination
8 product costs and estimated infection-related costs and quality of life data were presented to the
9 GDG to inform decision making.

10 **Table 83: Skin decontamination product costs**

Decontamination product	Total product cost	Unit cost
7% Povidone Iodine in aqueous solution	£2.50 per 500ml bottle + £0.27 per sterile dressing pack	£0.32 ^(a)
10% Povidone Iodine in aqueous solution	£2.50 per 500ml bottle + £0.27 per sterile dressing pack	£0.32 ^(a)
0.5% Chlorhexidine in 70% isopropyl alcohol	£1.94 per 600ml bottle + £0.27 per sterile dressing pack	£0.30 ^(a)
2.0% Chlorhexidine in 70% isopropyl alcohol	£71.13 for 200 0.67ml preparations	£0.36

11 Source: NHS Supply Catalogue 2010.¹⁸⁷

12 (a) Assumes that each application uses approximately 10ml of solution.

13 **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, ⁵³ NHS Drug Tariff, ¹⁸⁶ 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

14 Source: The resource use used to calculate cost estimates was based on the input of the GDG and co-opted expert advisors.

15 **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.	Marcianite 2003 ¹⁵⁷
Site infection/phlebitis	N/R	No estimates of quality of life in people with VAD site infection or phlebitis were identified.	N/R

Health state	Utility estimate	Note	Source
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 catheter model.	Halton 2009 ¹¹²

1 Source: These values were presented to the GDG as rough estimates only and were not identified systematically.

12.4.123 Evidence statements

- 3 **Clinical** It is uncertain whether there is any difference between 2% iodine in 70% alcohol
 4 compared to 70% alcohol in VAD related phlebitis (LOW QUALITY).
- 5 None of the studies identified reported infection related mortality, septicaemia, VAD
 6 related bacteraemia, VAD related local infection, VAD line removal and catheter tip
 7 colonisation for 2% iodine in 70% alcohol compared to 70% alcohol.
- 8 There was no statistically significant difference in the number of catheter tip
 9 colonisation between 0.5% chlorhexidine gluconate (CHG) in 70% isopropyl alcohol
 10 (IPA) compared to povidone iodine (PVP-I) and alcohol applied one after another
 11 (VERY LOW QUALITY).
- 12 There were statistically significant fewer VAD related phlebitis for 0.5% CHG in 70%
 13 IPA compared to PVP-I and alcohol applied one after another (VERY LOW QUALITY).
- 14 None of the studies identified reported infection related mortality, septicaemia, VAD
 15 related bacteraemia, and VAD related local infection and VAD line removals for 0.5%
 16 CHG in 70% IPA compared to PVP-I and alcohol applied one after another.
- 17 There is a statistically significant and clinically important reduction in catheter tip
 18 colonisation among patients receiving 2% CHG in 70% IPA compared to 70% IPA.
- 19 It is uncertain whether there is any difference in infection related mortality, VAD
 20 related blood stream infections, VAD related location infections and VAD related line
 21 removal between 2% CHG in 70% IPA compared to 70% IPA.
- 22 None of the studies identified reported septicaemia, VAD related bacteraemia and
 23 VAD related phlebitis for 2% CHG compared to 70% IPA.
- 24 **Economic** No economic studies were included.
 25

12.4.114 Recommendations and link to evidence

Recommendations	79. 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 0.5% chlorhexidine gluconate in 70% alcohol. Compared to alcohol on its own, there were significantly fewer 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 was very limited. For each comparison, low or very low quality evidence from one small RCT 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 is 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 optimal concentration for the best balance of efficacy against 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 greater at higher concentrations of chlorhexidine gluconate. However, the GDG decided 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 latest American Healthcare Infection Control Practices Advisory Committee (HICPAC) guidance from CDC (available from: http://www.cdc.gov/hicpac/BSI/BSI-guidelines-2011.html) ¹⁹⁰ had also not specified the concentration of chlorhexidine gluconate for peripheral venous catheter insertion but specified that the >0.5% CHG in alcohol used for peripheral arterial catheter insertion. 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	79. 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]
	<p>recognised this remains a pertinent issue for clinical practice and as such made a research recommendation (see section 12.11).</p> <p>The correct technique and volume of decontamination solution was considered critical to achieve skin decontamination, see section 6.6.</p> <p>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.</p> <p>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.</p> <p>The GDG discussed what to use if the patient is allergic to chlorhexidine and thought that alternatives, including iodine, could be discussed with the patient taking into account patient history.</p> <p>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, see section 4.1.</p>

Update 2012

12.5 Types of vascular access device dressing

2 Dressings for peripherally and centrally inserted vascular access devices have been highlighted as an
 3 area for updating as it was considered that more types of dressings are now available for use, since
 4 2003. The following question aims to determine which types of dressing for peripherally or centrally
 5 inserted vascular access device sites is the most effective at preventing healthcare-associated
 6 infections.

12.5.1 Review question

8 What is the clinical and cost effectiveness of dressings (transparent semipermeable, impregnated or
 9 gauze and tape) covering peripherally or centrally inserted vascular access device insertion sites,
 10 including those that are bleeding or oozing, on catheter tip colonisation, frequency of dressing
 11 change, infection related mortality, septicaemia, bacteraemia and phlebitis?

12.5.1.1 Clinical evidence

13 Four RCTs were identified for peripherally inserted VADs.^{50,124,154,262} Three studies investigated
 14 transparent semipermeable membrane (TSM) dressing vs. gauze and tape, and one study compared
 15 TSM dressings with iodophor antiseptic adhesive vs. gauze and tape.¹⁵⁴ No studies from the previous
 16 2003 guideline met the inclusion criteria for this review question.

1 Five RCTs were identified for centrally inserted VADs.^{25,154,262,279} One study was identified comparing
2 highly permeable transparent membrane dressings with gauze and tape.²⁵ One study was identified
3 comparing highly permeable transparent membrane dressings with TSM dressings.²⁷⁹ Three studies
4 were identified comparing TSM dressings vs. gauze and tape.^{146,202,241} No studies from the previous
5 2003 guideline met the inclusion criteria for this review question.

6 No evidence was found relating to insertion sites that were bleeding or oozing.

7 See Evidence Table G.7.1-G.7.2, Appendix G, Forest Plots in Figure 65-76, Appendix I.

8

9 Clinical evidence for peripherally inserted VADs

10 **Table 86: Transparent semi permeable membrane vs. gauze and tape – Clinical study**
11 **characteristics; peripherally inserted VADs**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter tip colonisation ^{50,124}	2	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Serious imprecision ^(c)
Phlebitis ^{124,154,262}	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				

12 (a) Unclear allocation concealment and blinding. Craven 1985⁵⁰ randomised catheter sites rather than patients, therefore
13 patients were included in the study up to 8 times.

14 (b) The studies are all hospital based rather than community settings.

15 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
16 difficult to know the true effect size for this outcome.

17 (d) Unclear allocation concealment and blinding. Maki 1987¹⁵⁴ randomised catheter sites rather than patients, therefore
18 patients were included in the study more than once.

19 **Table 87: Transparent semi permeable membrane vs. gauze and tape - Clinical summary of**
20 **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

21 **Table 88: Transparent semi permeable membrane with iodophor antiseptic vs. gauze and tape –**
22 **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				

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Mortality	0	RCT				
Bacteraemia	0	RCT				

- 1 (a) Randomised catheter sites rather than patients, therefore patients were included in the study more than once.
 2 (b) The studies are all hospital based rather than community settings.
 3 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
 4 difficult to know the true effect size for this outcome.

5 **Table 89: Transparent semi permeable membrane with iodophor antiseptic vs. gauze and tape -**
 6 **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

7 **Clinical evidence for centrally inserted VADs**

8 **Table 90: Highly permeable transparent membrane vs. gauze and tape – Clinical study**
 9 **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				

- 10 (a) Unclear randomisation, allocation concealment and blinding.
 11 (b) The study is hospital based rather than community settings.
 12 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
 13 difficult to know the true effect size for this outcome.

14 **Table 91: Highly permeable transparent membrane vs. gauze and tape - Clinical summary of**
 15 **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

1 **Table 92: Highly permeable transparent membrane vs. transparent semi permeable membrane –**
2 **Clinical study characteristics; centrally inserted VADs**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter related sepsis ²⁷⁹	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				

3 (a) Unclear randomisation, allocation concealment and blinding.

4 (b) The study is hospital based rather than community settings.

5 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
6 difficult to know the true effect size for this outcome.

7 **Table 93: Highly permeable transparent membrane vs. transparent semi permeable membrane -**
8 **Clinical summary of findings; centrally inserted VADs**

Outcome	Highly permeable	Semi permeable	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

9 **Table 94: Transparent semi permeable membrane vs. gauze and tape – Clinical study**
10 **characteristics; centrally inserted VADs**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Catheter related sepsis ²⁴¹	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Serious imprecision ^(c)
Exit site infection ^{146,202,241}	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				

11 (a) Unclear allocation concealment, blinding and randomisation.

12 (b) The studies are all hospital based rather than community settings.

13 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
14 difficult to know the true effect size for this outcome.

15 (d) Unclear allocation concealment and blinding.

16

1 **Table 95: Transparent semi permeable membrane vs. gauze and tape - Clinical summary of**
2 **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

12.5.132 Cost-effectiveness evidence for peripherally inserted VADs

4 No economic evidence was identified in the update search. No studies from the previous 2003
5 guideline met the inclusion criteria for this review question.

6 This topic was originally identified as a high-priority area for original economic modelling. However,
7 after reviewing the clinical evidence it was decided that there was insufficient comparative clinical
8 evidence to inform a cost-effectiveness model. In addition, the GDG did not consider each of the
9 dressings to represent true alternatives; certain dressings were considered to be more appropriate
10 for certain clinical indications than others.

11 In the absence of cost-effectiveness evidence, the GDG were presented with current UK dressing
12 costs and estimates of infection-related costs (see Table 84) to inform decision making.

13 **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

14 *(a) For mid-size dressings measuring approximately 10cm x 12cm (transparent, gauze) or 2.4cm in diameter (chlorhexidine).*

15 *Source: Based on average 2010 NHS Drug Tariff¹⁸⁶ and Supply Chain¹⁸⁷ prices.*

12.5.163 Cost-effectiveness evidence for centrally inserted VADs

17 Three studies were identified in the update search. One study was a cost analysis by Crawford et al
18 (2004)^{51,51} comparing chlorhexidine dressings to 'standard' dressings in patients with central venous
19 catheters. The other two were RCTs comparing the use of TSM dressings and gauze dressings in
20 patients undergoing bone marrow transplant^{241,241} and haemodialysis.^{146,146}

21 For a list of excluded studies and reasons for exclusion, refer to Appendix L.

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

23 **Table 97: Chlorhexidine dressing vs. transparent semi permeable membrane dressing - Economic**
24 **summary of findings; centrally inserted VADs**

Study	Limitations	Applicability	Other Comments
Crawford 2004 ⁵¹	Potentially serious ^(a)	Partially applicable ^(b)	Central line dressing Hospital setting

25 *(a) Clinical evidence based on an unpublished, industry funded trial which is not publicly available, time horizon is unclear,*
26 *risk of mortality from CRBSI is not accounted for, costs not reported incrementally.*

27 *(b) Hospital based setting (specific ward and patient population not reported), definition of 'standard' dressing unclear and*
28 *assumed to refer to transparent dressings, USA hospital perspective, industry funded study.*

1 **Table 98: Transparent semi permeable membrane dressing vs. gauze dressing - Economic**
 2 **summary of findings; centrally inserted VADs**

Study	Limitations	Applicability	Other Comments
Shivnan 1991 ²⁴¹	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

3 (a) Cost of infection not accounted for, industry funded study.

4 (b) Hospital based setting, USA hospital perspective.

5 (c) Cost of infection not accounted for, industry funded study.

6 (d) Hospital based setting, Canadian healthcare system perspective.

7 **Table 99: Chlorhexidine vs. transparent - Economic summary of findings; centrally inserted VADs**

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Crawford 2004 ⁵¹	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)

8 (a) Cost of transparent dressing not reported, therefore it was not possible to analyse costs incrementally.

9 (b) Note that cost of transparent dressings is not reported, therefore it is not possible to determine true incremental costs;
 10 costs adjusted to 2009/10 GBP; four scenario analyses were run in which the cost of treating a blood stream infection
 11 was alternated.

12 **Table 100: Transparent vs. gauze - Economic summary of findings; centrally inserted VADs**

Study	Incremental cost (£)	Incremental effects	ICER	Uncertainty
Shivnan 1991 ²⁴¹	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

13

1 **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

2 *Source: The resource use used to calculate cost estimates was based on the input of the GDG and co-opted expert advisors.*

12.5.134 **Evidence statements**

- 4 Clinical It is uncertain whether there is any difference in catheter tip colonisation or phlebitis
 5 with transparent semipermeable membrane dressing compared to gauze and tape
 6 for peripherally inserted VADs (VERY LOW QUALITY).
- 7 It is uncertain whether there is any difference in phlebitis with transparent
 8 semipermeable membrane with iodophor antiseptic in the adhesive compared to
 9 gauze and tape for peripherally inserted VADs (VERY LOW QUALITY).
- 10 It is uncertain whether there is any difference in catheter related sepsis, exit site
 11 infection, bacteraemia/fungaemia with highly permeable transparent membrane
 12 compared to gauze and tape for centrally inserted VADs (VERY LOW QUALITY).
- 13 It is uncertain whether there is any difference in catheter related sepsis with highly
 14 permeable transparent membrane compared to transparent semipermeable
 15 membrane dressings for centrally inserted VADs (VERY LOW QUALITY).
- 16 It is uncertain whether there is any difference in catheter related sepsis, exit site
 17 infection or bacteraemia with transparent semipermeable membrane compared to
 18 gauze for centrally inserted VADs (VERY LOW QUALITY).
- 19 No studies were identified that reported frequency of dressing change or VAD
 20 related mortality.
- 21 Economic No studies were identified for peripherally inserted VADs
- 22 In patients with centrally inserted VADs, transparent semipermeable membrane
 23 dressings appear to be cost-saving in terms of materials and nursing time
 24 (POTENTIALLY SERIOUS LIMITATIONS AND PARTIAL APPLICABILITY).
- 25 Chlorhexidine dressings may be cost-effective compared to transparent
 26 semipermeable membrane dressings (POTENTIALLY SERIOUS LIMITATIONS AND
 27 PARTIAL APPLICABILITY).
 28

12.5.115 Recommendations and link to evidence

Recommendations	80. 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	<p>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.</p> <p>No clinical evidence was identified for dressings on bleeding or oozing VAD insertion sites.</p> <p>No clinical evidence was identified for silver- or chlorhexidine-impregnated dressings.</p> <p>Cost-effectiveness evidence from two low quality studies was considered. Neither study included all relevant comparators, costs, or outcomes.</p>
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

2
3

Recommendations	<p>81. Consider a sterile gauze dressing covered with a sterile transparent semipermeable membrane dressing only if the patient has profuse perspiration, or if the vascular access device insertion site is bleeding or oozing. If a gauze dressing is used:</p> <ul style="list-style-type: none"> • 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, septicemia, 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

1

2

12.6 Vascular access device frequency of dressing change

4 The following question aims to determine the most appropriate frequency of dressing change for
 5 peripherally or centrally inserted vascular access device sites with the aim of preventing healthcare-
 6 associated infections.

12.6.1 Review question

8 What is the clinical and cost effectiveness of frequency of dressing change (from daily up to 7 days)
 9 on catheter tip colonisation, infection related mortality, septicemia, bacteraemia and phlebitis?

12.6.1.1 Clinical evidence

11 One RCT was identified for frequency of dressing change that compared semipermeable transparent
 12 polyurethane dressing changed once weekly vs. twice weekly.²⁶⁷ No studies from the previous 2003
 13 guideline met the inclusion criteria for this review question.

14 See Evidence Table G.7.3, Appendix G, Forest Plots in Figure 75-76, Appendix I.

1 **Table 102: Once weekly vs. twice weekly dressing changes – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
Positive blood culture ²⁶⁷	1	RCT	Serious limitations ^(a)	No serious inconsistency	Serious indirectness ^(b)	Serious imprecision ^(c)
CVC insertion site inflammation ²⁶⁷	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				

2 (a) Only 58% of the dressing changes were performed to protocol for the intervention (mean interval was 5.4 days, instead
3 of 7 days) and 80% of the changes were performed to protocol for the control/twice weekly change (with a mean
4 interval of 3.8 days.

5 (b) The study is hospital based rather than community settings.

6 (c) The relatively few events and few patients give wide confidence intervals around the estimate of effect. This makes it
7 difficult to know the true effect size for this outcome.

8 **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

12.6.192 Cost-effectiveness evidence

10 No cost-effectiveness evidence was identified in this update. No cost-effectiveness evidence was
11 identified in the previous 2003 guideline. In the absence of any published cost-effectiveness analyses,
12 current UK dressing costs, staff costs and infection-related cost estimates (Table 84 and Table 101)
13 were presented to the GDG to inform decision making.

14 **Table 104: Healthcare staff costs**

Healthcare professional	Cost per home visit (£)
Community health visitor	35
GP practice nurse	13
Community clinical support nurse	9

15 Source: PSSRU 2007^{53,55}.

12.6.163 Evidence statements

17 Clinical There is a statistically significant decrease of uncertain clinical importance in central
18 venous catheter insertion site inflammation when changing transparent
19 semipermeable membrane dressings once weekly compared to twice weekly (VERY
20 LOW QUALITY).

21 It is uncertain whether there is any difference in positive blood cultures when
22 changing transparent semipermeable membrane dressings once weekly compared to
23 twice weekly (VERY LOW QUALITY).

1 No studies were identified that reported catheter tip colonisation, phlebitis or VAD
 2 related mortality.

3 Economic No economic studies were identified.

12.6.144 Recommendations and link to evidence

Recommendations	82.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 ²⁶⁷ 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.

5

Recommendations	83. 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.
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 ⁶⁵ also recommends that cannulae should be replaced in a new site after 72-96 hours or earlier if indicated clinically.

Update 2012

- 1 **84. Dressings used on tunnelled or implanted central venous catheter sites should be replaced**
- 2 **every 7 days until the insertion site has healed, unless there is an indication to change**
- 3 **them sooner. [2003]**
- 4

12.7 Decontaminating skin when changing dressings

2 The following review question was prioritised for update to determine the most effective
3 decontamination solution for skin when changing dressings, as it was felt there are more types of
4 decontamination products available since 2003. In particular, stakeholders highlighted uncertainty
5 regarding what is the most appropriate concentration for chlorhexidine gluconate (CHG).

12.7.1 Review question

7 What is the most clinical and cost effective product or solution for skin decontamination when
8 changing VAD dressings on catheter tip colonisation, infection related mortality, frequency of line
9 removal, septicaemia, bacteraemia and phlebitis?

10 What is the most clinical and cost effective duration of application of decontamination
11 product/solution to the skin prior to insertion of peripherally inserted VAD on catheter tip
12 colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia, local
13 or soft tissue infection and phlebitis?

12.7.1.1 Clinical evidence

15 Five RCTs which compared the effectiveness of different antiseptic solutions for the decontamination
16 of skin during dressing changes were found. This included studies conducted in patients receiving
17 central venous catheters. See Evidence Table G.7.4, Appendix G, Forest Plots in Figure 77-95,
18 Appendix. The comparisons identified are shown below.

19 These studies provide different levels of details about the type of antiseptic used, and the
20 descriptions used in this section reflect the information provided in the papers. For examples, in
21 some comparisons, the type and concentration of alcohol used is specified whereas others just noted
22 "alcohol".

23 **Table 105: Number of RCTs comparing different types of antiseptic solutions**

	2% CHG in aqueous	0.5% CHG in alcohol	0.25% CHG in aqueous*	10% PVP-I in aqueous	5% PVP-I in 70% alcohol
0.5% CHG in alcohol	1 ²⁶⁴				
0.25% CHG in aqueous*	None	None			
10% PVP-I in aqueous	2 ^{155,264}	2 ^{127,264}			
5% PVP-I in 70% alcohol	None	None	1 ¹⁷²	1 ¹⁹⁴	
70% isopropyl alcohol (IPA)	1 ¹⁵⁵	None	None	1 ¹⁵⁵	None

24 * This aqueous solution contains 0.25% chlorhexidine gluconate, 0.025 benzalkonium chloride, and 4% benzylic alcohol
25 (Biseptine TM, Bayer).
26

1 **2% Chlorhexidine gluconate (CHG) in aqueous vs. 10% Povidone Iodine (PVP-I) in aqueous**

2 **Table 106: 2 % Chlorhexidine gluconate (CHG) in aqueous vs. 10% Povidone Iodine (PVP-I) in**
3 **aqueous – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia ^{155,264}	2	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
VAD related septicaemia ²⁶⁴	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
Catheter tip colonisation ^{155,264}	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				

4 (a) Block randomisation followed by physically different interventions (not blinded) – unclear whether there were adequate
5 allocation concealment methods,²⁶⁴ randomisation (done per catheter instead of patients) sequence generation and
6 allocation concealment unclear.¹⁵⁵

7 (b) Confidence intervals wide- crossed threshold(s) of clinically important harms and benefits.

8 **Table 107: 2% Chlorhexidine gluconate (CHG) in aqueous vs. 10% Povidone Iodine (PVP-I) in**
9 **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

10 (a) Studies reported outcomes per catheter, instead of per patient.

11 **2% Chlorhexidine gluconate (CHG) in aqueous vs. 70% Isopropyl alcohol (IPA)**

12 **Table 108: 2% Chlorhexidine gluconate (CHG) in aqueous vs. 70% isopropyl alcohol (IPA) – Clinical**
13 **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	0	RCT				

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
mortality						
Septicaemia	0	RCT				
VAD line removal	0	RCT				

- 1 (a) Randomisation sequence generation and allocation concealment methods unclear, randomised per catheter instead of
2 per patient.
3 (b) Confidence intervals wide - crossed threshold(s) of clinically important harms and benefits.

4 **Table 109: 2% chlorhexidine gluconate (CHG) in aqueous vs. 70% Isopropyl alcohol (IPA) - Clinical**
5 **summary of findings**

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

- 6 (a) Studies reported outcomes per catheter, instead of per patient.

7 **2 % Chlorhexidine gluconate (CHG) in aqueous vs. 0.5% CHG in alcohol**

8 **Table 110: 2% Chlorhexidine gluconate (CHG) in aqueous vs 0.5% CHG in alcohol - Clinical study**
9 **characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia ²⁶⁴	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
VAD related septicaemia ²⁶⁴	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
Catheter tip colonisation ²⁶⁴	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				

- 10 (a) Block randomisation followed by physically different interventions (not blinded) – unclear whether there were adequate
11 allocation concealment methods.
12 (b) Confidence intervals wide - crossed threshold of clinically important harms and benefits.

13 **Table 111: 2 % Chlorhexidine gluconate (CHG) in aqueous vs. 0.5% CHG in alcohol– Clinical**
14 **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

1 (a) Studies reported outcomes per catheter, instead of per patient.

2 **0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in aqueous**

3 **Table 112: 0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in**
4 **aqueous – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia ^{127,264}	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 ^{127,264}	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				

5 (a) Randomisation sequence generation and allocation concealment methods unclear.

6 (b) Confidence intervals wide - crossed threshold(s) of clinically important harms and benefits.

7 **Table 113: 0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% Povidone Iodine (PVP-I) in**
8 **aqueous – Clinical summary of findings**

Outcome	0.5% CHG in alcohol	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

9 (a) Studies reported outcomes per catheter, instead of per patient.

10 **10% Povidone iodine (PVP-I) in aqueous vs. 5% PVP-I in 70% ethanol**

11 **Table 114: 10% Povidone iodine (PVP-I) in aqueous vs. 5% PVP-I in 70% ethanol – Clinical study**
12 **characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia ¹⁹⁴	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
Catheter tip colonisation ¹⁹⁴	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
VAD related local infection ¹⁹⁴	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				
VAD line removal	0	RCT				

- 1 (a) Number of patients randomised into each arm unclear (only reported a total of 125 patients). The denominators
2 reported in this study are number of catheters, instead of number of patients.
3 (b) Confidence intervals wide- crossed threshold of clinically important harms and benefits.

4 **Table 115: 10% Povidone iodine (PVP-I) in aqueous vs. 5% PVP-I in 70% ethanol - Clinical**
5 **summary of findings**

Outcome	10% PVP-I in aqueous	5% PVP-I in 70% ethanol	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

- 6 (a) The denominators reported in this study are number of catheters, instead of number of patients.

7 **10% Povidone iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA)**

8 **Table 116: 10% Povidone iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA) - Clinical study**
9 **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				

- 10 (a) Randomisation sequence generation and allocation concealment methods unclear.
11 (b) Confidence intervals wide- crossed threshold(s) of clinically important harms and benefits.

12 **Table 117: 10% Povidone Iodine (PVP-I) in aqueous vs. 70% Isopropyl alcohol (IPA) - Clinical**
13 **summary of findings**

Outcome	10% PVP-I in aqueous	70% IPA	Relative risk	Absolute effect	Quality
Catheter tip colonisation ^(a)	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 ^(a)	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

- 14 (a) Studies reported outcomes per catheter, instead of per patient.
15

- 16
17

1 **0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkonium chloride, and 4% benzylic alcohol in**
2 **vs. 5% povidone Iodine(PVP-I) in 70% alcohol**

3 **Table 118: 0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkonium chloride, and 4% benzylic**
4 **alcohol in aqueous vs. 5% PVP-I in 70% alcohol – Clinical study characteristics**

Outcome	Number of studies	Design	Limitations	Inconsistency	Indirectness	Imprecision
VAD related bacteraemia ¹⁷²	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
Catheter tip colonisation ¹⁷²	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
VAD related phlebitis ¹⁷²	1	RCT	Serious limitations ^(a)	No serious inconsistency	No serious indirectness	Serious imprecision ^(b)
VAD line removal ¹⁷²	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				

5 (a) Unit of randomisation is catheter, instead of patient. The study randomised consecutively inserted central venous
6 catheters, stratified by insertion site in blocks of 8. Allocation concealment potentially compromised.

7 (b) Confidence intervals wide- crossed threshold(s) of clinically important harms and benefits.

8 **Table 119: 0.25 % Chlorhexidine gluconate (CHG), 0.025% benzalkonium chloride, and 4% benzylic**
9 **alcohol in aqueous vs. 5% povidone iodine (PVP-I) 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

10 (a) The study randomised and reported outcomes per catheter, instead of per patient.

11

12.7.112 Evidence statements

2	Clinical	2% Chlorhexidine gluconate (CHG) in aqueous vs. 10% povidone iodine (PVP-I) in aqueous
3		
4		There is a statistically significant reduction of uncertain clinical importance in the number of catheter tip colonisation for 2% CHG in aqueous compared to 10% PVP-I in aqueous (LOW QUALITY).
5		
6		
7		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).
8		
9		
10		None of the studies identified reported VAD related phlebitis, VAD related local infection, VAD line removal frequency, and infection related mortality for 2% CHG aqueous compared to 10% PVP-I in aqueous.
11		
12		
13		2% Chlorhexidine gluconate (CHG) in isopropyl aqueous vs. 70% isopropyl alcohol
14		
15		It was uncertain whether there is any difference in the number of VAD related bacteraemia and catheter tip colonisation for 2% CHG in aqueous compared to 70% isopropyl alcohol (LOW QUALITY).
16		
17		
18		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.
19		
20		
21		2% chlorhexidine gluconate (CHG) in aqueous vs. 0.5% chlorhexidine gluconate (CHG) in alcohol
22		
23		It was uncertain whether there is any difference in the number of VAD related bacteraemia, VAD related septicaemia and catheter tip colonisation for 2% CHG in aqueous compared to 0.5% CHG in alcohol (LOW QUALITY).
24		
25		
26		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.
27		
28		
29		0.5% Chlorhexidine gluconate (CHG) in alcohol vs. 10% povidone iodine (PVP-I) in aqueous
30		
31		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).
32		
33		
34		There is a statistically significant decrease of uncertain clinical importance in the number of patients with catheter tip colonisation for 0.5% CHG in alcohol compared to 10% PVP-I in aqueous (LOW QUALITY).
35		
36		
37		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.
38		
39		
40		

1		10% Povidone iodine (PVP-I) in aqueous vs. 5% povidone iodine(PVP-I) in
2		70% ethanol
3		It was uncertain whether there is any difference in the number of VAD
4		related bacteraemia and VAD related local infection for 10% PVP-I in aqueous
5		compared to 5% PVP-I in 70% ethanol (LOW QUALITY).
6		There is a statistically significant and clinically important increase in the
7		number of patient with catheter tip colonisation for 10% PVP-I in aqueous
8		compared to 5% PVP-I in 70% ethanol (LOW QUALITY).
9		None of the studies identified reported VAD related phlebitis, septicaemia,
10		VAD line removal frequency, and infection related mortality for 10% PVP-I in
11		aqueous compared to 5% PVP-I in 70% ethanol.
12		10% Povidone iodine (PVP-I) vs. 70% isopropyl alcohol (IPA)
13		It was uncertain whether there is any difference in the number of VAD
14		related bacteraemia and catheter tip colonisation for 10% PVP-I in aqueous
15		compared to 70% isopropyl alcohol (LOW QUALITY).
16		None of the studies identified reported VAD related phlebitis, VAD related
17		local infection, septicaemia, VAD line removal frequency, and infection
18		related mortality for 10% PVP-I in aqueous compared to 70% isopropyl
19		alcohol.
20		0.25% Chlorhexidine gluconate (CHG), 0.025% benzalkonium chloride and
21		4% benzylic alcohol in aqueous vs. 5% povidone iodine (PVP-I) in 70%
22		alcohol
23		It is uncertain whether there is any difference in number of VAD related
24		bacteraemia or VAD related phlebitis, or in the VAD line removal (measured
25		as duration of catheter placement) for a proprietary solution containing a
26		combination of 0.25% CHG and other disinfectants compared to 5% PVP-I in
27		alcohol (LOW QUALITY).
28		There is a statistically significant decrease of uncertain clinical importance in
29		the number of patient with catheter tip colonisation for a proprietary
30		solution containing a combination of 0.25% CHG and other disinfectants
31		compared to 5% PVP-I in alcohol (LOW QUALITY).
32		None of the studies identified reported VAD related local infection, VAD
33		related phlebitis, VAD line removal frequency, and infection related mortality
34		for 0.25% CHG and other disinfectants compared to 5% PVP-I in alcohol.
35	Economic	No economic evidence was identified.
36		

12.7.113 Recommendations and link to evidence

- 2 **85. Healthcare workers should ensure that catheter-site care is compatible with catheter**
 3 **materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully**
 4 **check compatibility with the manufacturer’s recommendations. [2003]**
 5

Recommendations	86. 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	<p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>In addition, the clinical importance of the results observed was difficult to</p>

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	interpret because most of the studies had been randomised by catheters, and reported the outcomes per catheter, rather than per patient.
Other considerations	<p>The GDG noted that the discussions that they had relating 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.</p> <p>In particular when 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 around 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 to accessing ports and hubs.</p> <p>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.</p>

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87. 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 management of vascular access devices

12.8.1 Decontaminating peripheral and centrally inserted catheter ports and hubs before access

3

4 The following review question was prioritised for update to determine the most effective
 5 decontamination solution for decontaminating peripheral and centrally inserted catheter ports and
 6 hubs before access, as it was felt there are more types of decontamination products available
 7 since 2003. In particular, stakeholders highlighted uncertainty regarding what is the most
 8 appropriate concentration to use for chlorhexidine gluconate.

12.8.2 Review question

10 What is the most clinical and cost effective product or solution for decontaminating VAD ports and
 11 hubs prior to access on catheter tip colonisation, infection related mortality, septicaemia,
 12 bacteraemia and frequency of line removal?

12.8.231 Clinical evidence

14 No clinical studies were identified in this update. No clinical evidence was identified in the previous
 15 2003 guideline.

12.8.262 Cost-effectiveness evidence

17 No cost-effectiveness evidence was identified in this update. No cost-effectiveness evidence was
 18 identified in the previous 2003 guideline.

19 In the absence of any published cost-effectiveness analyses, current UK decontamination product
 20 costs, estimated infection-related costs (Table 84 and Table 101) and quality of life data (Table 85)
 21 were presented to the GDG to inform decision making.

22 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)

23 Source/Note: NHS Supply Catalogue 2010¹⁸⁷

12.8.243 Evidence statements

25 Clinical No clinical evidence was identified.

26 Economic No economic studies were identified.

27

12.8.214 Recommendations and link to evidence

Recommendations	88. 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 the 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 around 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 and recommendation 87). 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 that showed there were fewer catheter tips with colonisation when using 2% chlorhexidine gluconate in aqueous solution rather than 10% povidone iodine in aqueous,

Recommendations	88. 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]
	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. Considerations about the use of alcohol in infection control was also taken into account, and discussed at length in the recommendation about hand decontamination. Please see section 6.4 for more details.

12.8.3 Inline filters do not help prevent infections

2 Although in-line filters reduce the incidence of infusion-related phlebitis, HICPAC could find no
3 reliable evidence to support their efficacy in preventing infections associated with intravascular
4 catheters and infusion systems. Infusate-related BSI is rare and HICPAC concluded that filtration of
5 medications or infusates in the pharmacy is a more practical and less costly way to remove the
6 majority of particulates. Furthermore, in-line filters might become blocked, especially with certain
7 solutions, e.g., dextran, lipids, mannitol, thereby increasing the number of line manipulations and
8 decreasing the availability of administered drugs.¹⁹¹ In our systematic review we found no additional
9 good quality evidence to support their use for preventing infusate-related BSI. However, there may
10 be a role for the use of in-line filtration of parenteral nutrition solutions for reasons other than the
11 prevention of infection but these are beyond the scope of these guidelines.

12.8.321 Recommendation

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

12.8.4 Antibiotic lock solutions have limited uses in preventing infection

15 Antibiotic lock prophylaxis, i.e., flushing and then filling the lumen of the CVC with an antibiotic
16 solution and leaving it to dwell in the lumen of the catheter, is sometimes used in special
17 circumstances to prevent CRBSI, e.g., in treating a patient with a long-term cuffed or tunneled
18 catheter or port who has a history of multiple CRBSI despite optimal maximal adherence to aseptic
19 technique. Evidence reviewed by HICPAC¹⁹¹ demonstrated the effectiveness of this type of
20 prophylaxis in neutropenic patients with long-term CVCs. However, they found no evidence that
21 routinely using this procedure in all patients with CVCs reduced the risk of CRBSI and may lead to
22 increasing numbers of antimicrobial resistant microorganisms.

12.8.431 Recommendation

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

12.8.5 Systemic antibiotic prophylaxis does not reliably prevent CRBSI

27 No studies appraised by HICPAC demonstrated that oral or parenteral antibacterial or antifungal
28 drugs might reduce the incidence of CRBSI among adults. However, among low birth weight infants,
29 two studies reviewed by HICPAC had assessed vancomycin prophylaxis; both demonstrated a
30 reduction in CRBSI but no reduction in mortality. They noted that because the prophylactic use of

- 1 vancomycin is an independent risk factor for the acquisition of vancomycin-resistant enterococcus
2 (VRE), the risk for acquiring VRE probably outweighs the benefit of using prophylactic vancomycin.¹⁹¹

12.8.531 Recommendation

- 4 **91.Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter**
5 **colonisation or CRBSI, either before insertion or during the use of a central venous catheter.**
6 **[2003]**

12.8.6 A dedicated catheter lumen is needed for parenteral nutrition

- 8 HICPAC reviewed evidence from a prospective epidemiologic study examining the risk for CRBSI in
9 patients receiving Total Parenteral Nutrition (TPN). They concluded that either using a single lumen
10 CVC or a dedicated port in a multilumen catheter for TPN would reduce the risk for infection.¹⁹¹

12.8.611 Recommendation

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

12.8.7 Maintaining catheter patency and preventing catheter thrombosis may help prevent infections

- 18 Indwelling central venous and pulmonary artery catheters are thrombogenic. Thrombus forms on
19 these catheters in the first few hours following placement¹²² and may serve as a nidus for microbial
20 colonization of intravascular catheters.²¹⁷ Thrombosis of large vessels occurs after long-term
21 catheterisation in 35 to 65% of patients.^{14,43,138,255,263} Prophylactic heparin and warfarin have been
22 widely used to prevent catheter thrombus formation and catheter related complications, such as
23 deep venous thrombosis (DVT).^{191,218}

- 24 Two types of heparin can be used: unfractionated (standard) heparin and low molecular weight
25 heparins. Although more expensive, low molecular weight heparins have a longer duration of action
26 than unfractionated heparin and are generally administered by subcutaneous injection once daily.
27 The standard prophylactic regimen of low molecular weight heparins are at least as effective and as
28 safe as unfractionated heparin in preventing venous thrombo-embolism and does not require
29 laboratory monitoring.¹⁷⁰

12.8.8 Systemic Anticoagulation

- 31 A meta-analysis of randomised controlled trials²¹⁸ evaluating the benefit of infused prophylactic
32 heparin through the catheter, given subcutaneously or bonded to the catheter in patients with CVCs
33 found that prophylactic heparin:

- 34 • was associated with a strong trend for reducing catheter thrombus (RR, 0.66; 95% confidence
35 interval [CI], 0.42,1.05). The test for heterogeneity of variance was not significant (p=0.681);
36 • significantly decreased central venous catheter-related venous thrombosis by 57% (RR, 0.43; 95%
37 CI, 0.23,0.78). The test for heterogeneity of variance was not significant (p=0.526). Significant
38 reduction of deep venous thrombosis was still present after excluding one trial of heparin-bonded
39 catheters (RR, 0.44; 95% CI, 0.22,0.87);

40

- 1 • significantly decreased bacterial colonisation of the catheter (RR, 0.18; 95% CI, 0.06, 0.60). The
2 test for heterogeneity of variance was not significant ($p=0.719$). The significant benefit for heparin
3 remained after excluding one trial of heparin-bonded catheters (RR, 0.19; 95% CI, 0.04, 0.86).
- 4 • showed a strong trend for a reduction in CRBSI (RR, 0.26; 95% CI, 0.07,1.03). The test for
5 heterogeneity of variance was not significant ($p=0.859$); This trend decreased when one trial of
6 heparin-bonded catheters was excluded (RR,0.33; 95% CI, 0.07,1.56

7 The authors of this meta-analysis concluded that heparin administration effectively reduces
8 thrombus formation and may reduce catheter-related infections in patients who have central venous
9 and pulmonary artery catheters in place. They suggest that various doses of subcutaneous and
10 intravenous unfractionated and low molecular weight heparins and new methods of heparin bonding
11 need further comparison to determine the most cost-effective strategy for reducing catheter-related
12 thrombus and thrombosis.

13 There are many different preparations and routes of administration of heparin, and as yet there is no
14 definite evidence that heparin reduces the incidence of CRBSI, but this may reflect the heterogeneity
15 of heparin and its administration.

16 Warfarin has also been evaluated as a means for reducing catheter-related thrombosis. A controlled
17 trial of 82 patients with solid tumours randomised to receive or not to receive low-dose warfarin (1
18 mg a day) beginning 3 days prior to catheter insertion and continuing for 90 days, warfarin was
19 shown to be effective in reducing catheter-related thrombosis.²¹ The rates of venogram-proved
20 thrombosis 4 of 42 in the treatment group versus 15 of 40 in the control group with 15 having
21 symptomatic thromboses. In this study, warfarin was discontinued in 10% of patients due to
22 prolongation of the prothrombin time.

22.8.9 Heparin versus normal saline intermittent flushes

24 Although many clinicians use low dose intermittent heparin flushes to fill the lumens of CVCs locked
25 between use in an attempt to prevent thrombus formation and to prolong the duration of catheter
26 patency, the efficacy of this practice is unproven. Despite its beneficial antithrombotic effects,
27 decreasing unnecessary exposure to heparin is important to minimise adverse effects associated with
28 heparin use, e.g., autoimmune-mediated heparin-induced thrombocytopenia, allergic reactions and
29 the potential for bleeding complications following multiple, unmonitored heparin flushes.¹⁹⁶ The risks
30 of these adverse effects can be avoided by using 0.9 percent sodium chloride injection instead of
31 heparin flushes. A systematic review and meta-analysis of randomised controlled trials evaluating the
32 effect of heparin on duration of catheter patency and on prevention of complications associated with
33 the use of peripheral venous and arterial catheters concluded that heparin at doses of 10 U/ml for
34 intermittent flushing is no more beneficial than flushing with normal saline alone.²¹⁹ This finding was
35 in agreement with two other meta-analyses.^{105,201} Manufacturers of implanted ports or opened-
36 ended catheter lumens may recommend heparin flushes for maintaining catheter patency and many
37 clinicians feel that heparin flushes are appropriate for flushing CVCs that are infrequently accessed.

38 HICPAC reviewed all of the evidence^{14,21,43,105,122,138,196,201,217-219,255,263} for intermittent heparin flushes
39 and systemic heparin and warfarin prophylaxis and concluded that no data demonstrated that their
40 use reduces the incidence of CRBSI and did not recommend them.¹⁹¹ Although their use for
41 preventing CRBSI remains controversial, patients who have CVCs may also have risk factors for DVT
42 and systemic anticoagulants may be prescribed for DVT prophylaxis.

43

12.8.911 Recommendations

- 2 **93. Preferably, a sterile 0.9 percent sodium chloride injection should be used to flush and lock**
3 **catheter lumens. [2003]**
- 4 **94. When recommended by the manufacturer, implanted ports or opened-ended catheter**
5 **lumens should be flushed and locked with heparin sodium flush solutions. [2003]**
- 6 **95. Systemic anticoagulants should not be used routinely to prevent CRBSI. [2003]**

12.8.10 Needleless devices require vigilance

- 8 Needleless infusion systems have been widely introduced into clinical practice to reduce the
9 incidence of sharp injuries and the potential for the transmission of blood borne pathogens to
10 healthcare workers. HICPAC examined evidence that these devices may increase the risk for CRBSI
11 and concluded that when they are used according to the manufacturers' recommendations, they do
12 not substantially affect the incidence of CRBSI.¹⁹¹

12.8.1031 Recommendations

- 14 **96. If needleless devices are used, the manufacturer's recommendations for changing the**
15 **needleless components should be followed. [2003]**
- 16 **97. When needleless devices are used, healthcare workers should ensure that all components of**
17 **the system are compatible and secured, to minimise leaks and breaks in the system. [2003]**
- 18 **98. When needleless devices are used, the risk of contamination should be minimised by**
19 **decontaminating the access port with either alcohol or an alcoholic solution of chlorhexidine**
20 **gluconate before and after using it to access the system. [2003]**
- 21 See also recommendation 89. (Decontaminate the injection port or catheter hub using chlorhexidine
22 gluconate in 70% alcohol before and after it has been used to access the system unless
23 contraindicated by manufacturer).

12.8.11 Change intravenous administration sets appropriately

- 25 The optimal interval for the routine replacement of intravenous (IV) administration sets has been
26 examined in three well-controlled studies reviewed by HICPAC. Data from each of these studies
27 reveal that replacing administration sets no more frequently than 72 hours after initiation of use is
28 safe and cost-effective. When a fluid that enhances microbial growth is infused, e.g., lipid emulsions,
29 blood products, more frequent changes of administration sets are indicated as these products have
30 been identified as independent risk factors for CRBSI.¹⁹¹

12.8.1311 Recommendations

- 32 **99. In general, administration sets in continuous use need not be replaced more frequently than**
33 **at 72 hour intervals unless they become disconnected or if a catheter-related infection is**
34 **suspected or documented. [2003]**
- 35 **100. Administration sets for blood and blood components should be changed every 12 hours, or**
36 **according to the manufacturer's recommendations. [2003]**

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

12.9 Administering infusions or drugs

12.9.1 Review question

- 7 What is the clinical and cost effectiveness of multi dose vials vs. single-use vials for administering
 8 infusions or drugs on preventing contamination of the infusate and healthcare-associated infection?

12.9.2 Clinical evidence

- 10 No clinical evidence was identified.
 11 This review question was not covered in the previous 2003 guideline.

12.9.3 Cost-effectiveness evidence

- 13 No cost-effectiveness evidence was identified.
 14 This review question was not covered in the previous 2003 guideline.
 15 The co-opted expert advisors were approached about the likely costs of single- compared to
 16 multiple- use vials. They indicated that single-use vials were generally more expensive than multiple-
 17 use, but did not think it would represent a good use of time to evaluate the costs of individual
 18 infusion medications. Similarly, the infections which may arise as a consequence of infusate
 19 contamination are many and varied. It was not considered an effective use of time to calculate the
 20 costs and quality of life associated with all possible infections. Instead, the GDG was encouraged to
 21 use their clinical experience to consider the most likely costs of single versus multiple-use vials and
 22 the likely consequences arising from their contamination.

12.9.4 Evidence statements

- 24 Clinical No clinical studies were identified
 25 Economic No economic studies were identified

12.9.5 Recommendations and link to evidence

Recommendations	102. 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 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.

Recommendations	102. Avoid the use of multidose vials, in order to prevent the contamination of infusates. [new 2012]
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 detailed 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 multidose vials can lead to loss of integrity of the vial through puncturing the bung multiple times.

12.10 Areas for Further Research

- 2 This is a well researched area and few realistic research needs were identified in developing these
 3 guidelines. The following investigations, along with a health economic assessment, may inform
 4 future clinical practice.

12.10.1 Current issues

- 6 The effectiveness of subcutaneous low molecular weight heparins or low dose warfarin to prevent
 7 catheter thrombus, colonisation and CRBSI.

12.10.2 Emerging Technologies

- 9 The efficacy of antimicrobial impregnated CVCs and catheters with new forms of heparin bonding to
 10 provide sustained protection against CRBSI in patients with long-term CVCs in the community.

12.11 Research recommendations

- 12 **6. What is the clinical and cost effectiveness of 2% chlorhexidine in alcohol versus chlorhexidine**
 13 **0.5% in alcohol versus 2% chlorhexidine aqueous solution versus 0.5% chlorhexidine aqueous**
 14 **solution for cleansing skin (before insertion of peripheral vascular access devices [VADs] and**
 15 **during dressing changes of all VADs) on reducing VAD related bacteraemia and VAD site**
 16 **infections?**

17 Why is this important?

- 18 The effective management of vascular access devices (VADs) is important for reducing phlebitis and
 19 bacteraemia. In the community, compliance is improved when a single solution is used for all aspects
 20 of VAD related skin care. There is no direct evidence comparing different percentages of
 21 chlorhexidine in aqueous and alcohol solutions, and little evidence on the use of such solutions in the
 22 community. A randomised controlled trial is required to compare the clinical and cost effectiveness
 23 of the different solutions available. The trial should enrol patients in the community with a VAD. The
 24 protocol would need to use the same skin preparation technique regardless of solution, and could
 25 also investigate decontamination technique and drying time. The primary outcome measures should
 26 be rate of VAD related bacteraemia, rate of VAD site infections, mortality, cost and quality of life.
 27 Secondary outcomes measures should include Visual Infusion Phlebitis (VIP) score, insertion times
 28 and skin irritation.

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 an 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	Asepsis prevents microbial contamination during procedures where the body's natural defences are bypassed. Asepsis can be defined as medical or surgical. Medical asepsis aims to reduce the number of organisms and prevent their spread by key principles such as decontaminating hands, use of PPE and not touching key parts. Surgical asepsis is a strict process and includes procedures to eliminate micro-organisms from an area (thus creating a sterile environment) and is practised in operating theatres and for invasive procedures such as the insertion of a central venous catheter. See also 'aseptic techniques'.
Aseptic non touch technique (ANTT™)	A specific type of aseptic technique with a unique theory and practice framework (www.antt.co.uk).
Aseptic techniques	An aseptic technique ensures that only uncontaminated equipment and fluids come into contact with susceptible body sites. It should be used during any clinical procedure that bypasses the body's natural defences. Using the principles of asepsis minimises the spread of organisms from one person to another. See 'asepsis'.
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 ≥ 200 mm/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 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 decontamination.

Term	Definition
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.
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.
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.
<i>C.diff</i> cross infection	The transmission of <i>Clostridium difficile</i> from one person to another because of a breach in a barrier.
<i>C.diff</i> reduction	A reduction in the incidence (number of new cases) of <i>Clostridium difficile</i> .
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 cut off 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	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

Term	Definition
Infection	urinary tract as the source). Infection may arise: <ul style="list-style-type: none"> • 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.
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 ⁴¹ .
Clinical waste	Clinical waste is defined as: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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

Term	Definition
	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 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 be 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).
Catheter-related bloodstream infection (CRBSI)	The patient has one or more recognized pathogens cultured from a single blood culture OR If the microorganism is a common skin organism then... <ul style="list-style-type: none"> • 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: fever of >38°C, chills, or hypotension AND <ul style="list-style-type: none"> • 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:

Term	Definition
	<p>i. a positive semiquantitative (>15 CFU/catheter segment) or quantitative (>10³ CFU/ml or >10³ 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;</p> <p>ii. simultaneous quantitative blood cultures with a >5:1 ratio CVC versus peripheral.</p>
Credible Interval	The Bayesian equivalent of a confidence interval.
Decision analysis	An explicit quantitative approach to decision making under uncertainty, based on 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, these 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, and 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

Term	Definition
	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.
Fill line	The manufacturer's mark on the sharps bin that relates to the bin being $\frac{3}{4}$ 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. Also known as 'pre-gelled'.
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.
Hazard analysis and critical control point (HACCP)	A system to identify potential hazards in food preparation.
Hand decontamination	The use of handrub or handwashing to reduce the number of bacteria on the hands. In this guideline this term is interchangeable with 'hand hygiene'.
Hand hygiene	See "Hand decontamination".
Hand decontamination compliance	A measure of compliance to best practice ideals or policy related to hand decontamination.
Handrub (compliant with EN 1500)	A preparation applied to the hands to reduce the number of viable microorganisms. This guideline refers to handrubs compliant with British standards (BS EN1500; standard for efficacy of hygienic handrubs using a reference of 60% isopropyl

Term	Definition
	alcohol).
Hand washing	Washing hands with plain (i.e. nonantimicrobial) soap and water.
Hand to hand	The act of passing (a sharp) from one person to another.
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.
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: <ul style="list-style-type: none"> • 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	Dressing permeated with a chemical, usually with antimicrobial properties, to

Term	Definition
dressings	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 effectiveness ratio (ICER)	The difference in the mean costs in the population of interest divided by the 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

Term	Definition
	everyday activities. This includes nursing homes and residential homes.
Long-term catheterisation	Long-term catheterisation: The use of a catheter (indwelling or intermittent) for a period greater than 28 days.
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 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 ^{129,233,234} . 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.
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

Term	Definition
	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 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 gastrostomy 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 (e.g. 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.
Peripherally inserted central catheter (PICC)	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.

Term	Definition
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 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. It is 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.

Term	Definition
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 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 into 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 reduces the risk of 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: e.g. 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 ($p < 0.05$).

Term	Definition
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 or reused.
Single-patient use	Items that can be used several times but are reserved for the use of one patient only.
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. These 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-organisms, 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'.

Term	Definition
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 tissue infection	Presence and growth of a pathogenic micro-organism in the soft tissue around the 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 thrombophlebitis	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 (e.g. 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
<i>C.diff</i>	<i>Clostridium difficile</i>
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
MCID	Minimal clinical important difference
MHRA	Medicines and Healthcare products Regulatory Agency
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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