

Infection Control

Prevention of healthcare-associated infections in primary and community care

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SECTION 1 - Summary

Guidelines for preventing healthcare-associated infections in primary and community care: summary of the recommendations and the development of the guidelines

Summary of Recommendations

The following guidance is evidence based and the grading for each recommendation is shown.

This guideline makes recommendations on both the standard principles for preventing healthcare-associated infections and measures for preventing infections associated with three specific aspects of care – the use of long-term urinary catheters, enteral feeding systems and central venous catheters.

Standard principles

The recommendations on standard principles provide guidance on infection control precautions that should be applied by all healthcare personnel to the care of patients in community and primary care settings.

The recommendations are divided into four distinct interventions:

- hand hygiene
- the use of personal protective equipment
- the safe use and disposal of sharps
- education of patients, their carers and healthcare personnel.

Hand hygiene

- | | | |
|-------------|---|---|
| SP1. | Hands must be decontaminated immediately before each and every episode of direct patient contact or care and after any activity or contact that could potentially result in hands becoming contaminated. | B |
| SP2. | Hands that are visibly soiled, or potentially grossly contaminated with dirt or organic material, must be washed with liquid soap and water. | A |
| SP3. | Hands must be decontaminated, preferably with an alcohol-based hand rub unless hands are visibly soiled, between caring for different patients or between different care activities for the same patient. | A |

- SP4.** Before regular hand decontamination begins, all wrist and ideally hand jewellery should be removed. Cuts and abrasions must be covered with waterproof dressings. Fingernails should be kept short, clean and free from nail polish. D
- SP5.** An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water **before** applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with **all** of the surfaces of the hand. The hands must be **rubbed** together vigorously for a minimum of 10-15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels. D
- SP6.** When decontaminating hands using an alcohol handrub, hands should be free from dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be **rubbed** together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry. D
- SP7.** An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted. D

Use of personal protective equipment

- SP8.** Selection of protective equipment must be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare practitioners' clothing and skin by patients' blood, body fluids, secretions or excretions. D
H&S
- SP9.** Gloves must be worn for invasive procedures, contact with sterile sites and non-intact skin or mucous membranes, and all activities that have been assessed as carrying a risk of exposure to blood, body fluids, secretions or excretions, or sharp or contaminated instruments. D
H&S
- SP10.** Gloves must be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient. D
H&S
- SP11.** Gloves must be disposed of as clinical waste and hands decontaminated after the gloves have been removed. D
H&S

| | |
|--|----------|
| SP12. Gloves that are acceptable to healthcare personnel and that conform to European Community (CE) standards must be available. | H&S |
| SP13. Sensitivity to natural rubber latex in patients, carers and healthcare personnel must be documented, and alternatives to natural rubber latex gloves must be available. | H&S |
| SP14. Neither powdered gloves nor polythene gloves should be used in healthcare activities. | D H&S |
| SP15. Disposable plastic aprons should be worn when there is a risk that clothing may become exposed to blood, body fluids, secretions or excretions, with the exception of sweat. | D H&S |
| SP16. Full-body fluid-repellent gowns must be worn where there is a risk of extensive splashing of blood, body fluids, secretions or excretions, with the exception of sweat, onto the skin or clothing of healthcare personnel (for example when assisting with childbirth). | D H&S |
| SP17. Plastic aprons should be worn as single-use items, for one procedure or episode of patient care, and then discarded and disposed of as clinical waste. | D H&S |
| SP18. Face masks and eye protection must be worn where there is a risk of blood, body fluids, secretions or excretions splashing into the face and eyes. | D H&S |
| SP19. Respiratory protective equipment, for example a particulate filter mask, must be used when clinically indicated. | D H&S |

Safe use and disposal of sharps

| | |
|---|----------|
| SP20. Sharps must not be passed directly from hand to hand, and handling should be kept to a minimum. | D H&S |
| SP21. Needles must not be recapped, bent, broken or disassembled before use or disposal. | D H&S |
| SP22. Used sharps must be discarded into a sharps container (conforming to UN3291 and BS 7320 standards) at the point of use by the user. These must not be filled above the mark that indicates that they are full. | D H&S |
| SP23. Containers in public areas must be located in a safe position, and must not be placed on the floor. They must be disposed of by the licensed route in accordance with local policy. | D H&S |

SP24. Needle safety devices must be used where there are clear indications that they will provide safer systems of working for healthcare personnel.

D
H&S

SP25. Everyone involved in providing care in the community should be educated about standard principles and trained in hand decontamination, the use of protective clothing and the safe disposal of sharps.

D

SP26. Adequate supplies of liquid soap, handrub, towels and sharps containers should be made available wherever care is delivered.

D

Care of patients with long-term urinary catheters

These guidelines apply to adults and children and should be read in conjunction with the guidance on Standard Principles. These guidelines focus on preventing infection. However, because infection has a complex inter-relationship with encrustation and blockage, these aspects of catheter management are also addressed.

The recommendations are divided into five distinct interventions:

- education of patients, their carers and healthcare personnel
- assessing the need for catheterisation
- selection of catheter drainage options
- catheter insertion
- catheter maintenance.

Education of patients, their carers and healthcare personnel

UC1. Patients and carers should be educated about and trained in techniques of hand decontamination, insertion of intermittent catheters where applicable, and catheter management before discharge from hospital.

D

UC2. Community and primary healthcare personnel must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance.

D

UC3. Follow-up training and ongoing support of patients and carers should be available for the duration of long-term catheterisation.

D

Assessing the need for catheterisation

UC4. Indwelling urinary catheters should be used only after alternative methods of management have been considered.

D

UC5. The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible. D

UC6. Catheter insertion, changes and care should be documented. D

Catheter drainage options

UC7. 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. C

UC8. Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient. A

UC9. For urethral and suprapubic catheters, the choice of catheter material and gauge will depend on an assessment of the patient's individual characteristics and predisposition to blockage. D

UC10. In general, the catheter balloon should be inflated with 10ml of sterile water in adults and 3-5ml in children. D

UC11. In patients for whom it is appropriate, a catheter valve can be used as an alternative to a drainage bag. A

Catheter insertion

UC12. All catheterisations carried out by healthcare personnel should be aseptic procedures. After training, healthcare personnel should be assessed for their competence to carry out these types of procedures. D

UC13. Intermittent self-catheterisation is a clean procedure. A lubricant for single-patient use is required for non-lubricated catheters. A

UC14. For urethral catheterisation, the meatus should be cleaned before insertion of the catheter, in accordance with local guidelines/policy. D

UC15. An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection. D

Catheter maintenance

UC16. Indwelling catheters should be connected to a sterile closed urinary drainage system or catheter valve. D

UC17. Healthcare personnel should ensure that the connection between the catheter and the urinary drainage system is not broken except for D

good clinical reasons, (for example changing the bag in line with manufacturer's recommendations).

- UC18.** Healthcare personnel must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves. D
- UC19.** Carers and patients managing their own catheters must wash their hands before and after manipulation of the catheter, in accordance with the recommendations in the Standard Principles Section (Section 2). A
- UC20.** Urine samples must be obtained from a sampling port using an aseptic technique. D
- UC21.** Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor. D
- UC22.** A link system should be used to facilitate overnight drainage, to keep the original system intact. D
- UC23.** The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated. D
- UC24.** The meatus should be washed daily with soap and water. A
- UC25.** Each patient should have an individual care regimen designed to minimise the problems of blockage and encrustation. The tendency for catheter blockage should be documented in each newly catheterised patient. D
- UC26.** Bladder instillations or washouts must not be used to prevent catheter-associated infection. A
- UC27.** Catheters should be changed only when clinically necessary, or according to the manufacturer's current recommendations. D
- UC28.** Antibiotic prophylaxis when changing catheters should only be used for patients with a history of catheter-associated urinary tract infection following catheter change, or for patients who have a heart valve lesion, septal defect, patent ductus or prosthetic valve. B
- UC29.** Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. D

Care during enteral feeding

These guidelines apply to adults and children and should be read in conjunction with the guidance on Standard Principles.

The recommendations are divided into four distinct interventions:

- education of patients, their carers and healthcare personnel
- preparation and storage of feeds
- administration of feeds
- care of insertion site and enteral feeding tube.

Education of patients, their carers and healthcare personnel

- | | |
|---|---|
| EF1. Patients and carers should be educated about, and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital. | D |
| EF2. Community staff should be trained in enteral feeding and management of the administration system. | D |
| EF3. Follow-up training and ongoing support of patients and carers should be available for the duration of home enteral tube feeding. | D |

Preparation and storage of feeds

- | | |
|---|---|
| EF4. Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution. | A |
| EF5. The system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube. | B |
| EF6. Effective hand decontamination must be carried out before starting feed preparation. | A |
| EF7. When decanting, reconstituting or diluting feeds, a clean working area should be prepared and equipment dedicated for enteral feed use only should be used. | D |
| EF8. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-touch technique. | D |
| EF9. Feeds should be stored according to manufacturer's instructions and, where applicable, food hygiene legislation. | D |
| EF10. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a refrigerator, and used within 24 hours. | D |

Administration of feeds

- EF11.** Minimal handling and an aseptic no-touch technique should be used to connect the administration system to the enteral feeding tube. C
- EF12.** Ready-to-use feeds may be given for a whole administration session, up to a maximum of 24 hours. Reconstituted feeds should be administered over a maximum 4-hour period. C
- EF13.** Administration sets and feed containers are for single use and must be discarded after each feeding session. B

Care of insertion site and enteral feeding tube

- EF14.** The stoma should be washed daily with water and dried thoroughly. D
- EF15.** To prevent blockage, the enteral feeding tube should be flushed with fresh tap water before and after feeding or administering medications. Enteral feeding tubes for patients who are immunosuppressed should be flushed with either cooled freshly boiled water or sterile water from a freshly opened container. D

Care of patients with central venous catheters

These recommendations apply to the care in the community of all adults and children with central venous catheters (CVCs) that are being used for the administration of fluids, medications, blood components and/or total parenteral nutrition (TPN). They should be used in conjunction with the recommendations on Standard Principles.

These recommendations do not specifically address the more technical aspects of the care of patients receiving haemodialysis, who will generally have their CVCs managed in dialysis centres.

The recommendations are divided into four intervention categories:

- education of patients, their carers and healthcare personnel
- general asepsis
- catheter site care
- standard principles for catheter management.

Education of patients, their carers and healthcare personnel

- CVC1.** Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a central venous catheter. D

CVC2. Community healthcare personnel caring for a patient with a central venous catheter should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline. D

CVC3. Follow-up training and support should be available to patients with central venous catheters and their carers. D

General asepsis

CVC4. An aseptic technique must be used for catheter site care and for accessing the system. B

CVC5. Before accessing or dressing central vascular catheters, hands must be decontaminated either by washing with an antimicrobial liquid soap and water, or by using an alcohol handrub. A

CVC6. Hands that are visibly soiled or contaminated with dirt or organic material must be washed with soap and water before using an alcohol handrub. A

CVC7. Following hand antisepsis, clean gloves and a no-touch technique or sterile gloves should be used when changing the insertion site dressing. D

Catheter site care

CVC8. Preferably, a sterile, transparent, semipermeable polyurethane dressing should be used to cover the catheter site. A

CVC9. If a patient has profuse perspiration, or if the insertion site is bleeding or oozing, a sterile gauze dressing is preferable to a transparent, semi-permeable dressing. D

CVC10. Gauze dressings should be changed when they become damp, loosened or soiled, and the need for a gauze dressing should be assessed daily. A gauze dressing should be replaced by a transparent dressing as soon as possible. D

CVC11. Transparent dressings should be changed every 7 days, or sooner if they are no longer intact or moisture collects under the dressing. A

CVC12. Dressings used on tunnelled or implanted CVC sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner. A

CVC13. An alcoholic chlorhexidine gluconate solution should be used to clean the catheter site during dressing changes, and allowed to air dry. An aqueous solution of chlorhexidine gluconate should be used if the manufacturer's recommendations prohibit the use of alcohol with their product. A

CVC14. Individual sachets of antiseptic solution or individual packages of antiseptic-impregnated swabs or wipes should be used to disinfect the dressing site. D

CVC15. Healthcare personnel should ensure that catheter-site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations. D

General principles for catheter management

CVC16. The injection port or catheter hub should be decontaminated using either alcohol or an alcoholic solution of chlorhexidine gluconate before and after it has been used to access the system. C

CVC17. In-line filters should not be used routinely for infection prevention. D

CVC18. Antibiotic lock solutions should not be used routinely to prevent catheter-related bloodstream infections (CRBSI). A

CVC19. Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter. A

CVC20. Preferably, a single lumen catheter should be used to administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for TPN, and all lumens must be handled with the same meticulous attention to aseptic technique. D

CVC21. Preferably, sterile 0.9 percent sodium chloride injection should be used to flush and lock catheter lumens. D

CVC22. When recommended by the manufacturer, implanted ports or opened-ended catheter lumens should be flushed and locked with heparin sodium flush solutions. D

CVC23. Systemic anticoagulants should not be used routinely to prevent CRBSI. D

CVC24. If needleless devices are used, the manufacturer's recommendations for changing the needleless components should be followed. D

CVC25. When needleless devices are used, healthcare personnel should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system. D

CVC26. When needleless devices are used, the risk of contamination should be minimised by decontaminating the access port with either D

alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system.

CVC27. In general, administration sets in continuous use need not be replaced more frequently than at 72 hour intervals unless they become disconnected or a catheter-related infection is suspected or documented.

A

CVC28. Administration sets for blood and blood components should be changed every 12 hours, or according to the manufacturer's recommendations.

D

CVC29. Administration sets used for total parenteral nutrition (TPN) infusions should generally be changed every 24 hours. If the solution contains only glucose and amino acids, administration sets in continuous use do not need to be replaced more frequently than every 72 hours.

D

Introduction

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

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

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

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

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

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

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

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

Background and context to the Guidelines

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

Incorporating evidence-based infection prevention and control advice into routine clinical care activities is believed to be important in reducing the incidence of preventable healthcare-associated infections.⁽¹⁾ Consequently, guidelines for preventing healthcare-associated infections in caring for patients in primary and community care settings were commissioned.

Scope and Purpose of the Guidelines

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

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

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

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

Each set of guidelines follows an identical format, which consists of:

- a glossary;
- the intervention heading;
- a headline statement describing the key issues being addressed;
- a synthesis of the related evidence and corresponding evidence grade;
- an economic opinion, where appropriate;
- guideline recommendation(s) with the corresponding recommendation grade(s);

- a bibliography listing the cited evidence.

Finally, at the end of each section there is a description of areas for further research, suggested audit criteria, and a bibliography of all evidence reviewed.

Methodology

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

For each set of guidelines, an electronic search was conducted for current national and international guidelines. They were retrieved and subjected to critical appraisal using the AGREE Instrument,⁽³⁾ which provides “a framework for assessing the quality of clinical practice guidelines.”

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

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

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

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

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

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

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

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

The second sift involved a critical review of the full text, and articles relevant to a review question were critically appraised. The SIGN data extraction form⁽⁴⁾ was used to document the results of critical appraisal (Available from the SIGN website <http://www.sign.ac.uk>). A form for descriptive studies was designed by us based on the SIGN methodology.

Following critical appraisal, the evidence was tabulated and reports written for each review question. The evidence was graded using the categories described by Eccles and Mason (2001)⁽⁵⁾ and reproduced below:

Categories of evidence

| | |
|-----|---|
| Ia | Evidence form meta-analysis of randomised controlled trials |
| Ib | Evidence from at least one randomised controlled trial |
| IIa | Evidence from at least one controlled trial without randomisation |
| IIb | Evidence from at least one other type of quasi-experimental study |
| III | Evidence from non-experimental descriptive studies, such as comparative studies, correlation studies and case-control studies |
| IV | Evidence from expert committees reports or opinions and/or clinical experience of respected authorities |

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

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

Factors influencing the guideline recommendations included:

- the nature of the evidence;
- the applicability of the evidence;

- costs and knowledge of healthcare systems.

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

The grading scheme suggested by Eccles and Mason (2001) ⁽⁵⁾ was used to define the strength of recommendation and is reproduced below.

| Recommendation grade | Evidence |
|-----------------------------|---|
| A | Directly based on category 1 evidence |
| B | Directly based on: Category II evidence, or Extrapolated recommendation from category 1 evidence |
| C | Directly based on: Category III evidence, or Extrapolated recommendation from category I or II evidence |
| D | Directly based on: Category IV evidence, or Extrapolated recommendation from category I,II or III evidence |

External consultation

These guidelines have been subject to extensive external consultation with registered stakeholders (see NICE website for consultation process and stakeholders). The guidelines will be reviewed in two years (2005).

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Appendix A Guideline Development Group (GDG)

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Appendix B: Full Scope for the guideline to prevent healthcare associated infection in primary and community care

1. Objective

- 1.1 The National Institute for Clinical Excellence has commissioned a clinical guideline for patients, carers and clinicians on the prevention of healthcare associated infection (HCAI) in primary and community care. The guideline will provide advice on effective and cost-effective care using the best available evidence.
- 1.2 The commission received from the Department of Health and the National Assembly for Wales

We would like NICE to produce a guideline on infection control in primary and community care.

This guideline will be expected to address a standard approach to preventing and controlling healthcare associated infections in primary and community care and additional guidance for selected healthcare interventions with a potential risk for infection.

2. Title

Clinical guideline for the prevention and control of healthcare associated infection in primary and community care.

3. Clinical Need and Practice

- 3.1 As complex care is increasingly performed in primary and community care settings, the risk of infections associated with healthcare interventions increases. This can result in increased morbidity and mortality, greater costs and use of resources and profound consumer dissatisfaction.
- 3.2 This guideline will assist clients and all healthcare providers involved in direct patient care to minimise the risk of infection.
- 3.3 Guideline developers will work closely with service users and carers to ensure that the guidelines are understandable to clients and their carers.

4. Population

This guideline will apply to patients of all ages receiving healthcare interventions in primary and community care.

5. Health care setting

- 5.1 The guideline will cover the care received from primary and community health care professionals who have direct contact with and make decisions concerning the care of patients and will offer 'best practice' advice on preventing healthcare-associated infections. It will describe a standard set of infection prevention measures that anyone giving or receiving care in primary and community care can follow.
- 5.2 The guideline will also be compatible with guidelines for the prevention of hospital-acquired infections, and will influence discharge planning.
- 5.3 This is an NHS guideline. Although it will address the interface with other services, such as those provided by social services, secure settings and the voluntary sector, it will not include services exclusive to these sectors.

6. Interventions and treatment

In addition to standard principles for preventing healthcare associated infections, the guideline will describe measures for preventing infections associated with the use of long-term urinary catheters, central venous catheters and enteral feeding systems.

- 6.1 This guideline will be appropriate for use in preventing infections associated with all direct care activities. It will also assist clients to prevent infections when managing aspects of their own care.
- 6.2 This guideline will focus on using a 'standard approach' for preventing infections and will include issues associated with:
 - hand hygiene;
 - use of personal protective equipment;
 - use and disposal of needles and sharp instruments.
- 6.3 This guideline will not include advice on the diagnosis, treatment and management of specific infections.
- 6.4 This guideline will not include advice on the insertion of central venous catheters or enteral feeding systems as these activities are carried out in acute care facilities.

7. Presentation

The guideline will be available in three forms:

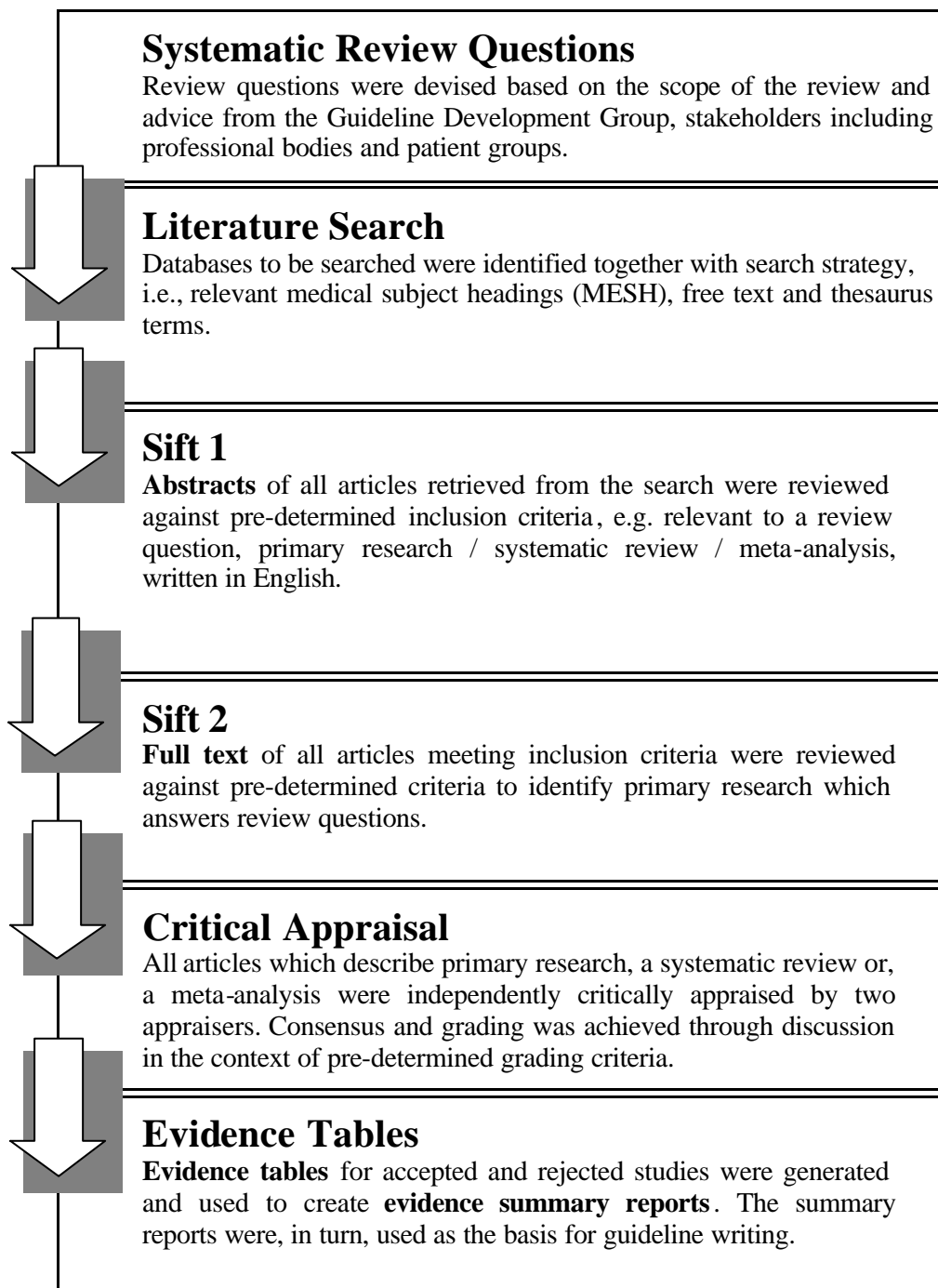
- 7.1 The full guideline containing the evidence base used by the developers.
- 7.2 A short form version, using a standard template, which will form the Institute's guidance to the NHS including a clinical practice algorithm.

- 7.3 The guideline will be accompanied by a version prepared specifically for patients and their carers. This patient/carer version will interpret the recommendations made in the Institute's short form version and will be designed to help patients to make informed choices about their care.

8. Status

- 8.1 This scoping statement has been the subject of a four week period of consultation with stakeholders. The scope has been re-drafted and submitted to the Guidelines Advisory Committee and subsequently the Institute's Guidance Executive, for approval. The development of the guideline will begin in the autumn of 2001.
- 8.2 Information on the guidelines development process, stakeholder involvement and the progress of this guideline is available on the website <http://www.nice.org.uk/>.

Appendix C The Systematic Review Process



SECTION 2 – Standard Principles

Guidelines for preventing healthcare-associated infections using Standard Principles in primary and community care

Glossary

Words included in the glossary are marked with an asterisk (*) the first time they appear in this section.

Alcohol/Alcoholic handrub

In this document alcohol handrub is used as a generic term that included hand rinses and hand gels.

Expert opinion

Opinion derived from seminal works and appraised national and international guidelines.

Hand decontamination

Decontamination refers to the process for the physical removal of blood, body fluids, and transient microorganisms from the hands, i.e., handwashing, and/or the destruction of microorganisms, i.e., hand antisepsis.

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

Nosocomial

Related to hospital or care, e.g., nosocomial infection is a hospital-acquired infection.

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.

Risk assessment

The weighing up of factors associated with a procedure to ascertain the level of protection required.

Sharps

Any sharp instrument that may cause injury. This will include scalpels, needles and lancets.

Transient microorganisms

Microorganisms acquired on the skin through contact with other people, objects or the environment. Often can survive for a few hours before the antibacterial properties of the skin prevent their continuation. Can easily be spread to other people or objects. Majority removed by washing with soap and water.

SECTION 2: Guidelines for preventing healthcare-associated infections using Standard Principles in primary and community care

Introduction

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

1. Hand hygiene;
2. The use of personal protective equipment;
3. The use and disposal of sharps*;
4. Education of patients, their carers and healthcare personnel.

Systematic review process

Five sets of guidelines were identified as a result of the search for national and international guidelines. These were retrieved and appraised using the AGREE instrument.⁽¹⁾ The appraisal for the epic phase 1 guidelines was undertaken by three external independent appraisers.⁽²⁾ These were regarded as sufficiently robust to be used as a basis for these guidelines with additional searches for outstanding questions (SP Appendix 1).

After appraisal, search questions were developed from advice received from focus groups, stakeholders and our specialist advisers (Appendix SP2). The following systematic review questions were used:

Hand hygiene search questions:

1. What is the evidence that contaminated hands are a cause of healthcare-associated infection?
2. Which hand disinfection agents are the most effective at removing / reducing organisms responsible for healthcare-associated infection?
3. When must hands be disinfected in relation to patient care activities?
4. What is the most effective hand washing technique for removing / reducing organisms responsible for healthcare-associated infection?
5. Which hand disinfection agents are least toxic to users?
6. Is there any cost effectiveness evidence relating to the above?
7. What are the training and education implications for staff and patients?

In setting up the search the following MeSH terms were used: infection control; cross infection; universal precautions, equipment contamination; disease transmission; chlorhexidine; disinfectants; soaps; anti-infective agents; surface-active agents; handwashing; hand; skin; epidermis; nails. In addition, the following thesaurus and free text terms were used: antisepsis; sterilisation; decontamination.

These databases were searched from 1998 onwards: Medline, Cumulated Index of Nursing and Allied Health Literature (CINAHL), Embase, The Cochrane Library, National Electronic Library for Health, The NHS Centre for Reviews and Dissemination (CRD), The National Research Register, The Web of Science, The Institute of Health Technology, Health CD Database, Health Management Information, Consortium Database.

Search Results: 21219 articles were identified. These articles were initially sifted to determine if they related to infections associated with hand hygiene, were written in English, were primary research or were a systematic review or a meta-analysis, and appeared to inform one or more of the review questions. Following this first sift, 160 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 24 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, 23 were accepted into the study (1 was rejected).

Protective clothing search questions:

1. Which glove materials are least toxic to healthcare workers (HCWs) for general use?
2. What is the evidence that hands need to be disinfected following the use of gloves?
3. What is the evidence that HCWs use gloves appropriately, as a part of Standard Principles?
4. What is the evidence that the uniforms / clothes of HCWs are a source of healthcare-associated infection?
5. What is the evidence that the use of protective clothing reduces the incidence of healthcare-associated infection?
6. Is there any cost effectiveness evidence relating to the above?
7. What are the training and education implications for staff and patients?

In setting up the search the following MeSH terms were used: infection control; cross infection; universal precautions; equipment contamination; disease transmission; protective clothing; disposable equipment; masks; protective gloves; eye protective devices. In addition the following thesaurus and free text terms were used: antiseptics; disinfection; sterilisation; decontamination; face shield; goggles; apron; uniform; gown; clothing; visor; hood.

The databases were searched as described above.

Search Results: 8611 articles were identified. These articles were initially sifted to determine if they related to infections associated with personal protective equipment, were written in English, were primary research or were a systematic review or a meta-analysis, and appeared to inform one or more of the review questions. Following this first sift, 95 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 7 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, all were accepted into the study.

Sharps search questions:

1. What is the evidence that recommended modes of use and disposal of sharps reduce the incidence of sharps injury in healthcare workers?
2. What is the evidence that education and training interventions improve healthcare workers adherence to recommended modes of practice?
3. What is the evidence that the use of needle-free devices reduce occupational exposure to bloodborne pathogens?
4. Is there any cost effectiveness evidence relating to the above?
5. What are the training and education implications for staff and patients?

In setting up the search the following MeSH terms were used: infection control; cross infection; universal precautions, equipment contamination; disease transmission; needlestick injuries; needles; syringes; occupational exposure; occupational accident; medical waste disposal; blood-borne pathogens. In addition the following thesaurus and free text terms were used: antisepsis; disinfection; sterilisation; decontamination; blood-borne virus; exposure prone procedure; post exposure prophylaxis; sharp; puncture; percutaneous injury; epi pen; vacutainer; resheath.

The databases were searched as described above.

Search Results: 7938 articles were identified. These articles were initially sifted to determine if they related to the safe use and disposal of sharps, were written in English, were primary research or were a systematic review or a meta-analysis, and appeared to inform one or more of the review questions. Following this first sift, 84 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 4 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, all were accepted into the study.

Evidence tables for accepted and rejected studies were generated and used to create summary reports, including evidence grades (Appendix SP3). The summary reports were used as the basis for guideline writing.

Following our reviews, guidelines were drafted which described 26 recommendations within the below 4 intervention categories:

1. Standard Principles for Hand Hygiene;
2. Standard Principles for the Use of Personal Protective Clothing;
3. Standard Principles for the Safe Use and Disposal of Sharps;
4. Education of patients, carers and their healthcare personnel

References

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Intervention 1 Standard Principles for Hand Hygiene

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

The areas discussed include:

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

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

Overviews of epidemiological evidence conclude that hand-mediated transmission is a major contributing factor in the current infection threats to hospital in-patients. These include both methicillin-sensitive and methicillin-resistant *Staphylococcus aureus* (MRSA), and multi-resistant Gram-negative aerobes and enterococci. The transmission of microorganisms from one patient to another via the hands, or from hands that have become contaminated from the environment, can result in adverse outcomes. Primary exogenous infection is a direct clinical threat where microorganisms are introduced into susceptible sites, such as surgical wounds, intravascular cannulation sites, enteral feeding systems or catheter drainage systems. Secondary endogenous infection creates an indirect clinical threat where potential pathogens transmitted by the hands establish themselves as temporary or permanent colonisers of the patient and subsequently causes infection at susceptible sites. Evidence from two previous reviews⁽¹⁾ conclude that in outbreak situations contaminated hands are responsible for transmitting infections and our previous systematic review indicates that effective hand decontamination can significantly reduce infection rates in gastro-intestinal infections and in high-risk areas, such as intensive care units.⁽¹⁾

Our systematic review identified two clinically-based trials^(2,3) and two descriptive studies that confirmed the association between hand decontamination and reductions in infection.^(4,5) In a non-randomised controlled trial (NRCT) a hand washing programme was introduced and in the post intervention period respiratory illness fell by 45%.⁽²⁾ A further NRCT, introducing the use of alcohol hand gel to a long term elderly care facility, demonstrated a reduction of 30% in HAI over a period of 34 months when

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| IIa |
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compared to the control unit.⁽³⁾ One descriptive study demonstrated the risk of cross infection resulting from inadequate hand decontamination in patient's homes.⁽⁴⁾

Expert opinion is consistent in its assertion that effective hand decontamination results in significant reductions in the carriage of potential pathogens on the hands and logically decreases the incidence of preventable HAI leading to a reduction in patient morbidity and mortality.⁽⁶⁻⁸⁾

IV

When must you decontaminate your hands in relation to patient care?

Decontamination refers to the process for the physical removal of blood, body fluids, and transient microorganisms* from the hands, i.e., *handwashing*, and/or the destruction of microorganisms, i.e., *hand antisepsis*.⁽⁶⁾

Guidance suggests that, in deciding when it is necessary to decontaminate hands, **four** key factors need to be considered: ⁽¹⁾

- the level of the anticipated contact with patients or objects;
- the extent of the contamination that may occur with that contact;
- the patient care activities being performed;
- the susceptibility of the patient.

Patients are put at potential risk of developing a healthcare-associated infection when informal carers or healthcare personnel caring for them have contaminated hands. Hands must be decontaminated before every episode of care that involves direct contact with patients' skin, their food, invasive devices or dressings. Current expert opinion consistently recommends that hands need to be decontaminated after completing an episode of patient care and following the removal of gloves to minimise cross contamination of the environment.⁽⁶⁻⁸⁾

IV

Recommendation

SP1. Hands must be decontaminated immediately before each and every episode of direct patient contact or care and after any activity or contact that could potentially result in hands becoming contaminated.

B

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Is any one hand cleaning preparation better than another?

Our previous systematic review⁽¹⁾ identified no compelling evidence to favour the **general** use of antimicrobial handwashing agents over soap, or one antimicrobial agent over another. The current review has identified no new evidence that alters this analysis.

Our systematic review identified seventeen acceptable studies that compared hand hygiene preparations including alcohol based hand rubs and gels, antimicrobial handwashes and liquid soap. Five of the studies were randomised controlled trials (RCT) conducted in clinical settings comparing the use of alcohol-based preparations with other agents.⁽²⁻⁶⁾ Four RCTs demonstrated alcohol to be a more effective hand hygiene agent than non-medicated soap and antimicrobial handwash,⁽²⁻⁵⁾ while a fifth study found no statistical difference between the use of alcohol and antiseptic soap.⁽⁶⁾ These studies underpin a growing trend to adopt the use of alcohol-based hand rinses and gels in clinical practice. Three clinically based, quasi-experimental studies⁽⁷⁻⁹⁾ and seven controlled laboratory experiments⁽¹⁰⁻¹⁶⁾ also demonstrated an association between reductions in microbiological flora and the use of alcohol-based preparations. One clinically-based quasi-experimental study compared the use of two antimicrobial handwash preparations in reducing MRSA.⁽¹⁷⁾ One descriptive study of the use of an antiseptic hand cream by community nurses showed sustained residual effect in reducing microbiological flora.⁽¹⁸⁾

Ib

When deciding which hand decontamination preparation to use, the practitioner must consider the need to remove transient and/or resident hand flora*. Preparations with a residual effect contain antimicrobial agents and are not normally necessary for everyday clinical practice but may be used for some invasive procedures and in outbreak situations. What is important is that healthcare practitioners use an appropriate preparation to decontaminate their hands. National and international guidelines^(1,19) suggest that the acceptability of agents and techniques is an essential criterion for the selection of preparations for hand hygiene. Acceptability of preparations is dependent upon the ease with which the preparation can be used in terms of time and access together with their dermatological effects.^(1,19)

IV

Economic analysis of cost effectiveness is based on the assumption that the rate of infection in primary and community care is 4 percent, i.e., half that in hospital,⁽²⁰⁾ and that alcohol gel reduces infection rate by 30%⁽²¹⁾ or 25%⁽²²⁾ 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⁽²³⁾) 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. of avoiding infection with the associated morbidity and mortality) and hospital attendance, the cost effectiveness of hand hygiene with alcohol rubs would increase.

The cost of a single hospital acquired infection is estimated to be over £3000 ⁽²⁴⁾. The author concludes that even a very low reduction in infections through the use of alcohol handrubs, would be cost saving. It is felt that although the above analysis is in a different setting, it represents a conservative analysis.

Choice of decontamination: is it always necessary to wash hands to achieve decontamination?

In the community and home setting, choosing a method of hand decontamination will be heavily influenced by the assessment of what is practically possible, the available resources in the care setting (particularly patients' own homes), what is appropriate for the episode of care, and, to some degree, personal preferences based on the acceptability of preparations or materials.

- In general, effective handwashing with a non-medicated liquid soap will remove transient microorganisms and render the hands socially clean. This level of decontamination is sufficient for general social contact and most clinical care activities. ⁽¹⁾ IV
- Using an antimicrobial liquid soap preparation will reduce transient microorganisms and resident flora, and result in hand antisepsis. ^(1,19) IV
- Although alcohol does not remove dirt and organic material, the effective use of alcohol-based handrubs on contaminated hands will result in substantial reductions of transient microorganisms, ⁽¹⁹⁾ Alcohol handrubs offer a practical and highly acceptable alternative to handwashing when the hands are not grossly soiled and are recommended for routine use. ^(2-6,19) Ib

Recommendations

SP2. Hands that are visibly soiled, or potentially grossly contaminated with dirt or organic material, must be washed with liquid soap and water. A

SP3. Hands must be decontaminated, preferably with an alcohol-based hand rub unless hands are visibly soiled, between caring for different patients or between different care activities for the same patient. A

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Is hand decontamination technique important?

Investigations into the technique of hand decontamination are limited. Our systematic review identified one RCT comparing different durations of handwashing and handrubbing on bacterial reduction that found no significant differences between the two study groups.⁽¹⁾ One laboratory study investigating methods of hand drying found no statistically significant differences between the four methods studied.⁽²⁾

Ib

Recommendations are therefore based on existing expert opinion that the duration of hand decontamination, the exposure of all aspects of the hands and wrists to the preparation being used, the use of vigorous rubbing to create friction, thorough rinsing in the case of handwashing, and ensuring that hands are completely dry are key factors in effective hand hygiene and the maintenance of skin integrity.⁽³⁻⁴⁾

IV

Recommendations

SP4. Before regular hand decontamination begins, all wrist and ideally hand jewellery should be removed. Cuts and abrasions must be covered with waterproof dressings. Fingernails should be kept short, clean and free from nail polish.

D

SP5. An effective handwashing technique involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under tepid running water before applying liquid soap or an antimicrobial preparation. The handwash solution must come into contact with all of the surfaces of the hand. The hands must be rubbed together vigorously for a minimum of 10-15 seconds, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers. Hands should be rinsed thoroughly before drying with good quality paper towels.

D

SP6. When decontaminating hands using an alcohol handrub, hands should be free of dirt and organic material. The handrub solution must come into contact with all surfaces of the hand. The hands must be rubbed together vigorously, paying particular attention to the tips of the fingers, the thumbs and the areas between the fingers, until the solution has evaporated and the hands are dry.

D

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1: Guidelines for Preventing Hospital-acquired Infections. *Journal of Hospital Infection* 2001;**47**(Supplement):S1-S82.

Does hand decontamination damage skin?

Expert opinion concludes that skin damage is generally associated with the detergent base of the preparation and/or poor handwashing technique.⁽¹⁻²⁾ However, the frequent use of hand preparation agents may cause damage to the skin and normal hand flora is altered which may result in increase carriage of pathogens responsible for healthcare-associated infection.⁽¹⁻²⁾ In addition, the irritant and drying effects of hand preparations have been identified as one of the reasons why healthcare practitioners fail to adhere to hand hygiene guidelines.⁽¹⁻²⁾ A previous systematic review found no consistent evidence to suggest that any product currently in use caused more skin irritation and damage than another.⁽³⁾

IV

Our systematic review identified six studies of which three were RCT conducted in clinical settings.⁽⁴⁻⁶⁾ They compared the use of alcohol-based preparations with soap and the self assessment of skin condition by nurse. In these studies a greater level of irritation was associated with the use of soap. Two further studies, one clinically based quasi experimental study and one descriptive clinical study concluded that alcohol-based handrubs caused less skin irritation.⁽⁷⁻⁸⁾ A laboratory study demonstrated a strong relationship between the frequency of handwashing with a chlorhexidine preparation and dermatitis.⁽⁹⁾

Ib

Expert opinion suggests that hand care is an important factor in maintaining regular hand decontamination practices and assuring the health and safety of healthcare practitioners.⁽¹⁻²⁾

IV

Recommendation

SP7. An emollient hand cream should be applied regularly to protect skin from the drying effects of regular hand decontamination. If a particular soap, antimicrobial hand wash or alcohol product causes skin irritation an occupational health team should be consulted.

D

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Intervention 2 Standard Principles for the Use of Personal Protective Equipment

This section discusses the evidence and associated recommendations for the use of personal protective equipment by healthcare personnel in primary and community care settings and includes the use of aprons, gowns, gloves, eye protection and facemasks. Where appropriate, in addition to the recommendation and evidence grade, there is an indication of a Health and Safety (H&S) requirement.

Infection Control Dress Code – protect your patients and yourself!

Expert opinion suggests that the primary uses of personal protective equipment are to protect staff and patients, and reduce opportunities for the transmission of microorganisms in hospitals.^(1,2) However, as more healthcare is undertaken in the community,⁽³⁻⁵⁾ the same principles apply. A trend to eliminate the unnecessary wearing of aprons, gowns and masks in general care settings has evolved over the past twenty years due to the absence of evidence that they are effective in preventing HAI.⁽¹⁾

IV

The decision to use or wear personal protective equipment must be based upon an assessment of the level of risk associated with a specific patient care activity or intervention and take account of current health and safety legislation.⁽⁶⁻⁹⁾

IV

Recommendation

SP8. Selection of protective equipment must be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare practitioners' clothing and skin by patients' blood, body fluids, secretions or excretions.

D
H&S

References

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Gloves: their uses and abuses

Since the mid-1980s the use of gloves as an element of personal protective equipment has become an everyday part of clinical practice for healthcare practitioners.⁽¹⁻⁶⁾ Expert opinion agrees that there are two main indications for the use of gloves in preventing HAI.^(1,4-6)

IV

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

To glove or not to glove?

Gloves should not be worn unnecessarily as their prolonged and indiscriminate use may cause adverse reactions and skin sensitivity.^(1,7) As with all items of personal protective equipment the need for gloves and the selection of appropriate materials must be subject to careful assessment of the task to be carried out and its related risks to patients and healthcare practitioners.^(1,7) Risk assessment* should include consideration of:

IV

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

Gloves must be discarded after each care activity for which they were worn in order to prevent the transmission of microorganisms to other sites in that individual or to other patients. Washing gloves rather than changing them is not safe and therefore not recommended.^(1,7)

IV

Do gloves leak?

A previous systematic review provided evidence that gloves used for clinical practice leak when apparently undamaged.⁽⁸⁾ In terms of leakage, gloves made from natural rubber latex (NRL) performed better than vinyl gloves in laboratory test conditions. Revised standards (2000) relating to the manufacture of medical gloves for single use have been devised and implemented.⁽⁹⁻¹¹⁾ These require gloves regardless of material to perform to the same standard.

IV

Expert opinion supports the view that the integrity of gloves cannot be taken for granted and additionally, hands may become contaminated during the removal of gloves.^(1,4-7) Our systematic review found evidence that vancomycin resistant enterococcus remained on the hands of healthcare personnel after the removal of gloves.⁽¹²⁾ Therefore, the use of gloves as a method of barrier protection reduces the risk of contamination but does not eliminate it and hands are not necessarily clean because gloves have been worn.

III

Recommendations

- SP9. Gloves must be worn for invasive procedures, contact with sterile sites and non-intact skin or mucous membranes, and all activities that have been assessed as carrying a risk of exposure to blood, body fluids, secretions or excretions, or sharp or contaminated instruments.**

D
H&S

SP10. Gloves must be worn as single-use items. They must be put on immediately before an episode of patient contact or treatment and removed as soon as the activity is completed. Gloves must be changed between caring for different patients, and between different care or treatment activities for the same patient.

D
H&S

SP11. Gloves must be disposed of as clinical waste and hands decontaminated after the gloves have been removed.

D
H&S

References

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Making choices

Expert opinion is quite clear about when gloves **must** be used by healthcare practitioners in general clinical practice.^(1,4,5) Having decided that gloves should be used for a healthcare activity, the practitioner must make a choice between the use of:

IV

- sterile or non-sterile gloves, based on contact with susceptible sites or clinical devices;

- surgical or examination gloves, based on the aspect of care or treatment to be undertaken.

NHS Trusts need to provide gloves that conform to European Community Standard (CE), and which are acceptable to healthcare practitioners.^(1,2) Gloves are available in a variety of materials, the most common being natural rubber latex (NRL) and synthetic materials. NRL remains the material of choice due to its efficacy in protecting against bloodborne viruses and properties that enable the wearer to maintain dexterity.^(1,2) A pilot study of dentists using nitrile gloves in place of NRL found that they compared favourably in terms of puncture resistance.⁽³⁾ The problem of patient or healthcare practitioner sensitivity to NRL proteins must be considered when deciding on glove materials. As a consequence, expert opinion strongly advises that powdered gloves should not be used in healthcare.^(1,2,4,5)

IV

Synthetic materials are generally more expensive than NRL and due to certain properties may not be suitable for all purposes.⁽¹⁾ Nitrile gloves have the same chemical range as NRL and may also lead to sensitivity problems. Vinyl gloves made to European Community standards provide the same level of protection as NRL.⁽²⁾ Polythene gloves are not suitable for clinical use due to their permeability and tendency to damage easily.^(1,2)

IV

The following table highlights the cost comparison of the various gloves materials. Healthcare personnel should be aware of the cost differential in gloves and should select the most appropriate for the activity.

| Product | Pack Size (largest where more than one pack size) | Cost per pack | Cost per individual <u>glove</u> |
|---|--|----------------------|---|
| Lightly powdered protector latex examination gloves | 1000 | £19.97 | £0.02 |
| Lightly powdered vinyl seamless examination gloves | 1000 | £19.95 | £0.02 |
| Nitrile gloves | 1000 | £54.95 | £0.05 |
| Powder free latex examination gloves (non-sterile) | 1000 | £24.97 | £0.02 |
| Powder free sterile latex gloves | 100 | £13.99 | £0.14 |

Web address: <http://www.medisave.co.uk/acatalog/>

Recommendations

- SP12. Gloves that are acceptable to healthcare personnel and that conform to European Community (CE) standards must be available.** H&S
- SP13. Sensitivity to natural rubber latex in patients, carers and healthcare personnel must be documented, and alternatives to natural rubber latex gloves must be available.** H&S
- SP14. Neither powdered gloves nor polythene gloves should be used in healthcare activities.** D
H&S

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Aprons or gowns?

In our systematic review, three studies were identified that highlighted the potential for uniforms to become contaminated.⁽¹⁻³⁾ These studies considered the uniforms of nurses and healthcare assistants in hospital and dentists in an out patient department. All found evidence of contamination of clothing during the shift, though no link was made to any adverse clinical outcome. However, two studies commented on the need for a clean uniform to be worn for each shift and recommended that they should be supplied on the basis of the number of days worked per week rather than hours.^(1,2) IV

Our previous systematic review identified a variety of studies, none of which supported the **routine** use of gowns in general or specialist clinical settings.⁽⁴⁾ However, expert opinion suggests that protective clothing should be worn by all healthcare practitioners when contamination with blood, body fluids, secretions, or excretions (with the exception of sweat), or when close contact with the patient, materials or equipment may lead to contamination of the clothing with microorganisms.^(5,6) IV

Plastic aprons are recommended for general use,^(5,6) but unused aprons need to be stored carefully, i.e., away from potential contamination.⁽¹⁾ Full body gowns need only be used where there is the possibility of extensive splashing of blood, body fluids, secretions or excretions and should be fluid repellent.^(5,6) IV

Recommendations

- SP15. Disposable plastic aprons should be worn when there is a risk that clothing may become exposed to blood, body fluids, secretions or excretions, with the exception of sweat.**
- SP16. Full-body fluid-repellent gowns must be worn where there is a risk of extensive splashing of blood, body fluids, secretions or excretions, with the exception of sweat, onto the skin or clothing of healthcare personnel (for example when assisting with childbirth).**
- SP17. Plastic aprons should be worn as single-use items, for one procedure or episode of patient care, and then discarded and disposed of as clinical waste.**

D
H&S

D
H&S

D
H&S

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

Our previous systematic review failed to reveal any robust experimental studies that suggested any clinical benefit from wearing surgical masks to protect patients during routine ward procedures such as wound dressing or invasive medical procedures.^(1,2)

IV

Personal respiratory protection is required in certain respiratory diseases, e.g., HIV-related or multiple drug-resistant tuberculosis⁽³⁾ and where patients who are severely immunocompromised are at an increased risk of infection. In these instances, surgical masks are not effective protection and specialised respiratory protective equipment should be worn, e.g., a particulate filter mask.^(1,3,4)

IV

Our previous systematic review indicated that different protective eyewear offered protection against physical splashing of infected substances into the eyes (although not on 100% of occasions) but compliance was poor.⁽¹⁾ Expert opinion recommends that face and eye protection reduce the risk of occupational exposure of healthcare practitioners to splashes of blood, body fluids, secretion or excretions.^(2,5,6)

IV

Recommendations

SP18. Face masks and eye protection must be worn where there is a risk of blood, body fluids, secretions or excretions splashing into the face and eyes.

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H&S

SP19. Respiratory protective equipment, for example a particulate filter mask, must be used when clinically indicated.

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H&S

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Intervention 3 Standard Principles for the Safe Use and Disposal of Sharps

This section discusses the evidence and associated recommendations for the safe use and disposal of sharps in community and primary care settings and includes minimising the risks associated with sharps use and disposal and the use of needle protection devices. Where appropriate, in addition to the recommendation and evidence grade, there is an indication of a Health and Safety (H&S) legislation requirement.

Sharps injuries – what’s the problem?

The safe handling and disposal of needles and other sharp instruments should form part of an overall strategy of clinical waste disposal to protect staff, patients and visitors from exposure to blood borne pathogens.⁽¹⁾ The incidence of injuries caused by sharps varies across clinical settings and is difficult to compare due to different denominators for data collection. Audit data suggests that of the occupational injuries that occur in hospitals, 16% are attributable to sharps injuries.⁽²⁾ National surveillance of occupational exposure to bloodborne viruses from 1997-2001 indicates that 68% of percutaneous exposures were caused by sharps. Of the exposures followed up at 6 weeks, 7 percent involved healthcare personnel working in community and primary care settings.⁽³⁾ In the first year of data collection the UK EpiNet sharps injury surveillance project provides data on 888 injuries occurring in 12 NHS Trusts identifying that 80% of injuries involve contaminated sharps, with 43% of injuries sustained by nursing staff and 24% by medical staff.⁽⁴⁾ In general clinical settings, sharps injuries are predominantly caused by needle devices and associated with venepuncture, administration of medication via intravascular lines and recapping of needles during the disassembly of equipment.⁽⁵⁾ All sharps injuries are considered to be potentially preventable.

The average risk of transmission of bloodborne pathogens following a single percutaneous exposure from a positive source has been estimated to be:⁽⁶⁾

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

National and international guidelines, are consistent in their recommendations for the safe use and disposal of sharp instruments and needles.⁽⁷⁻⁹⁾ As with many infection prevention and control policies, the assessment and management of the risks associated with the use of sharps is paramount and safe systems of work and engineering controls must be in place to minimise any identified risks, e.g., positioning the sharps bin as close as possible to the site of the intended clinical procedure.⁽¹⁰⁾ Any healthcare worker experiencing an occupational exposure to blood or body fluids needs to be assessed for the potential risk of infection by a specialist practitioner, e.g., physician, occupational health nurse and offered before testing, immunisation and post-exposure prophylaxis if appropriate.⁽¹¹⁾

Recommendations

SP20. Sharps must not be passed directly from hand to hand, and handling should be kept to a minimum.

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H&S

SP21. Needles must not be recapped, bent, broken or disassembled before use or disposal.

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H&S

SP22. Used sharps must be discarded into a sharps container (conforming to UN3291 and BS 7320 standards) at the point of use by the user. These must not be filled above the mark that indicates that they are full.

D
H&S

SP23. Containers in public areas must be located in a safe position, and must not be placed on the floor. They must be disposed of by the licensed route in accordance with local policy.

D
H&S

References

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Do needle safety devices* reduce avoidable injuries?

Expert advice encourages healthcare providers and their employees to pursue safer methods of working through considering the benefits of new safety devices.⁽¹⁾ The incidence of injuries related to needle devices has led to the development of prevention devices in eleven different product groups.⁽²⁾ They are designed to minimise the risk of operator injury during venepuncture, intravenous therapy and injections, and so-called “downstream” injuries occurring following the disposal of sharps and often involving housekeeping or portering staff responsible for the collection of sharps disposal units. People with insulin dependent diabetes frequently use needle clipping devices.

IV

It would seem to be logical that where needle safety or other protective devices are used, there should be a resulting reduction in sharps injuries. Our systematic review identified four studies that involved the introduction of needle safety devices to reduce reported needlestick injuries.⁽³⁻⁶⁾ All of the studies were descriptive and involved the implementation of other interventions at the same time as the introduction of the needle safety devices. Only two of these studies produced statistically significant reductions in needlestick injuries.^(3,4)

III

A comprehensive report and product review conducted in the US provides background information and guidance on the need for and use of needlestick prevention devices in four clinical applications:⁽²⁾

IV

- delivering intravenous (IV) medications;
- delivering intramuscular and subcutaneous medications;
- introducing IV catheters;
- collecting blood.

The report identifies that none of the devices evaluated is without limitations in relation to cost, applicability and effectiveness. Some of the devices available are more expensive, may not be compatible with existing equipment, and paradoxically, may be associated with an increase in bloodstream infection rates.⁽⁷⁾

National Guidelines and the National Health Service Purchasing and Supply Agency identify that meaningful evaluations are paramount in assessing user acceptability and clinical applicability of needle safety devices.^(8,9) The evaluation should ensure that the safety feature works effectively and reliably, that the device is acceptable to healthcare practitioners and that it does not adversely affect patient care.

IV

Recommendations

- SP24. Needle safety devices must be used where there are clear indications that they will provide safer systems of working for healthcare personnel.**

D
H&S

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Intervention 4 Education of patients, carers and their healthcare personnel

To improve patient outcomes and reduce healthcare costs, it is essential that everyone providing care in the community is educated about hand decontamination, the appropriate use of gloves and protective clothing, and the safe disposal of sharps. Adequate supplies of soap, alcohol rub, towels and sharps bins must be made available wherever care is delivered and this may include providing healthcare personnel undertaking home visits, with their personal supply. Patients and carers should request that healthcare personnel follow these principles.⁽¹⁾

IV

Recommendations

SP25. Everyone involved in providing care in the community should be educated about standard principles and trained in hand decontamination, the use of protective clothing and the safe disposal of sharps.

D

SP26. Adequate supplies of liquid soap, handrub, towels and sharps containers should be made available wherever care is delivered.

D

References

1. Boyce JM, Pittet D. *Guideline for Hand Hygiene in Healthcare Settings. Recommendations of the Healthcare Infection Control Practice Advisory Committee and the HICPAC/SHEA/APIC/ IDSA Hygiene Task Force 2002:58p*

Areas for Further Research

Given the poor data available on community healthcare personnel practice, qualitative and quantitative studies are required to map the current situation. This should include:

- the availability of hand decontamination equipment;
- gloves and protective equipment in community and primary care settings and;
- their use by different healthcare personnel and compliance with current guidance.

Key Audit Criteria

| Aim | Criteria |
|--|--|
| <p>To ensure all healthcare personnel have access to appropriate hand decontamination equipment and protective clothing wherever they deliver care</p> | <p>All healthcare personnel should have an appropriate supply of hand decontamination equipment, gloves, aprons and protective clothing in their care setting.</p> <p>Standard 100%</p> <p>Data collection: self audit</p> |
| <p>Ensure that all healthcare personnel are trained and competent in hand decontamination and risk assessment.</p> | <p>All healthcare personnel involved in care are trained and updated.</p> <p>Standard 100%</p> <p>Data collection: review of staff education records</p> |
| <p>To ensure that all healthcare personnel respond appropriately to any sharps injury</p> | <p>All healthcare personnel should be aware of their local sharps injury policy and how to access appropriate help should they sustain a sharps injury.</p> <p>Standard 100%</p> <p>Data collection: direct questioning</p> |
| <p>To ensure patients and carers are informed and educated about standard principles.</p> | <p>All patients and carers are aware of the need to:</p> <ul style="list-style-type: none"> • Decontaminate their hands; • Use protective clothing; • Dispose of sharps safely. <p>Standard 100%</p> <p>Data collection: direct questioning of patients and carers.</p> |

APPENDIX SP1 – AGREE Scores

AGREE Monitoring Appraisal Form (Guideline for Hand Hygiene in Health-Care Settings Recommendations of the Healthcare Infection Control Practices Advisory Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|----|----|----|-----------|----|---|---|---|-----------|----|----|----|----|----|----|-------|-----------|----|----|----|-------|-----------|----|----|-------|-----------|----|-------|--------------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 3 | 3 | 2 | 8 | 2 | 1 | 2 | 1 | 6 | 4 | 3 | 3 | 4 | 3 | 3 | 1 | 21 | 4 | 3 | 3 | 3 | 13 | 3 | 3 | 4 | 10 | 4 | 1 | 5 |
| Appraiser 2 | 4 | 4 | 4 | 12 | 3 | 1 | 1 | 1 | 6 | 4 | 4 | 4 | 4 | 4 | 2 | 1 | 23 | 4 | 4 | 4 | 4 | 16 | 4 | 3 | 3 | 10 | 1 | 1 | 2 |
| Appraiser 3 | 4 | 4 | 3 | 11 | 4 | 1 | 2 | 1 | 8 | 3 | 3 | 3 | 4 | 4 | 4 | 1 | 22 | 4 | 4 | 4 | 4 | 16 | 4 | 3 | 3 | 10 | 3 | 2 | 5 |
| Appraiser 4 | 4 | 4 | 4 | 12 | 3 | 1 | 3 | 1 | 8 | 2 | 2 | 1 | 4 | 4 | 1 | 1 | 15 | 4 | 4 | 4 | 1 | 13 | 4 | 4 | 4 | 12 | 3 | 1 | 4 |
| Total | 15 | 15 | 13 | 43 | 12 | 4 | 8 | 4 | 28 | 13 | 12 | 11 | 16 | 15 | 10 | 4 | 81 | 16 | 15 | 15 | 12 | 58 | 15 | 13 | 14 | 42 | 11 | 5 | 16 (268) |

Domain Scores

| | |
|--|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (43/48) x 100 = 90%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (58/64) x 100 = 91%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (28/64) x 100 = 44%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (42/48) x 100 = 88%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 4 = 112 Standardised domain score is: (81/112) x 100 = 72%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (16/32) x 100 = 50%</p> |

AGREE Monitoring Appraisal Form (The epic Project. National Evidence-based guidelines for preventing healthcare-associated infections. Jan 2001)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|----------|----------|----------|-----------|----------|----------|----------|----------|-----------|----------|----------|----------|----------|----------|----------|-----------|-----------|----------|----------|----------|-----------|-----------|----------|----------|-----------|-----------|----------|--------------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 4 | 4 | 12 | 4 | 3 | 3 | 1 | 11 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 27 | 3 | 4 | 4 | 2 | 13 | 2 | 3 | 2 | 7 | 4 | 2 | 6 (76) |
| Appraiser 2 | 4 | 4 | 4 | 12 | 4 | 3 | 3 | 1 | 11 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 27 | 3 | 4 | 4 | 2 | 13 | 2 | 3 | 2 | 7 | 4 | 2 | 6 (76) |
| Appraiser 3 | 4 | 4 | 4 | 12 | 4 | 4 | 4 | 2 | 14 | 4 | 4 | 4 | 4 | 4 | 4 | 28 | 4 | 4 | 4 | 2 | 14 | 3 | 4 | 3 | 10 | 3 | 2 | 5(83) | |
| Total | 8 | 8 | 8 | 36 | 8 | 6 | 6 | 2 | 36 | 8 | 8 | 8 | 8 | 8 | 8 | 6 | 82 | 6 | 8 | 8 | 4 | 40 | 4 | 6 | 4 | 24 | 8 | 4 | 17 |

Domain Scores

| | |
|--|---|
| Domain 1 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (36/36) x 100 = 100% | Domain 4 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (40/48) x 100 = 83% |
| Domain 2 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (36/48) x 100 = 75% | Domain 5 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (24/36) x 100 = 67% |
| Domain 3 Maximum possible score = 4 x 7 x 3 = 84 Standardised domain score is: (82/84) x 100 = 98% | Domain 6 Maximum possible score = 4 x 2 x 3 = 24 Standardised domain score is: (17/24) x 100 = 71% |

AGREE Monitoring Appraisal Form (Health Canada - Hands)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|-----------|-----------|----------|-----------|-----------|----------|-----------|----------|-----------|----------|-----------|----------|----------|-----------|----------|----------|-----------|-----------|-----------|-----------|----------|-----------|-----------|----------|----------|-----------|-----------|----------|-----------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 4 | 2 | 10 | 4 | 1 | 4 | 1 | 10 | 4 | 4 | 1 | 3 | 3 | 1 | 1 | 17 | 4 | 3 | 4 | 2 | 13 | 3 | 3 | 3 | 9 | 4 | 1 | 5 (64) |
| Appraiser 2 | 4 | 3 | 3 | 10 | 1 | 1 | 2 | 1 | 5 | 1 | 3 | 1 | 2 | 1 | 1 | 1 | 10 | 2 | 2 | 3 | 2 | 9 | 2 | 1 | 2 | 5 | 1 | 1 | 2 (41) |
| Appraiser 3 | 4 | 4 | 2 | 10 | 4 | 1 | 4 | 1 | 10 | 1 | 3 | 2 | 3 | 4 | 2 | 1 | 16 | 4 | 3 | 4 | 3 | 14 | 4 | 2 | 3 | 9 | 4 | 2 | 6 (65) |
| Appraiser 4 | 1 | 2 | 2 | 5 | 4 | 1 | 2 | 1 | 8 | 1 | 1 | 1 | 1 | 2 | 1 | 1 | 8 | 3 | 2 | 3 | 1 | 9 | 1 | 1 | 1 | 3 | 3 | 1 | 4 (37) |
| Total | 13 | 13 | 9 | 35 | 13 | 4 | 12 | 4 | 33 | 7 | 11 | 5 | 9 | 10 | 5 | 4 | 51 | 13 | 10 | 14 | 8 | 45 | 10 | 7 | 9 | 26 | 12 | 5 | 17 (207) |

Domain Scores

| | |
|---|---|
| Domain 1 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (35/48) x 100 = 73% | Domain 4 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (45/64) x 100 = 70% |
| Domain 2 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (33/64) x 100 = 52% | Domain 5 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (26/48) x 100 = 54% |
| Domain 3 Maximum possible score = 4 x 7 x 4 = 112 Standardised domain score is: (51/112) x 100 = 46% | Domain 6 Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (17/32) x 100 = 53% |

AGREE Monitoring Appraisal Form (ICNA Protective Clothing)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|-----------|-----------|-----------|-----------|----------|----------|-----------|----------|-----------|----------|----------|----------|----------|----------|----------|----------|-----------|-----------|----------|-----------|----------|-----------|----------|----------|----------|-----------|----------|----------|-----------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 3 | 4 | 11 | 2 | 1 | 4 | 1 | 8 | 1 | 3 | 1 | 3 | 2 | 1 | 1 | 12 | 3 | 3 | 4 | 1 | 11 | 2 | 1 | 1 | 4 | 2 | 2 | 4 (50) |
| Appraiser 2 | 3 | 4 | 3 | 10 | 1 | 1 | 4 | 1 | 7 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 3 | 1 | 3 | 1 | 8 | 1 | 1 | 1 | 3 | 1 | 1 | 2 (37) |
| Appraiser 3 | 3 | 2 | 2 | 7 | 2 | 1 | 4 | 1 | 8 | 1 | 1 | 1 | 3 | 1 | 1 | 1 | 9 | 4 | 1 | 4 | 3 | 12 | 1 | 1 | 1 | 3 | 1 | 1 | 2 (41) |
| Appraiser 4 | 3 | 3 | 4 | 10 | 1 | 1 | 4 | 1 | 7 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 8 | 3 | 1 | 3 | 2 | 8 | 2 | 1 | 3 | 6 | 2 | 1 | 3 (43) |
| Total | 13 | 13 | 13 | 38 | 6 | 4 | 16 | 4 | 30 | 4 | 6 | 4 | 9 | 5 | 4 | 4 | 36 | 13 | 6 | 14 | 7 | 39 | 6 | 4 | 6 | 16 | 6 | 5 | 11 (171) |

Domain Scores

| | |
|--|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (38/48) x 100 = 79%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (39/64) x 100 = 61%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (30/64) x 100 = 47%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (16/48) x 100 = 33%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 4 = 112 Standardised domain score is: (36/112) x 100 = 32%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (11/32) x 100 = 34%</p> |

AGREE Monitoring Appraisal Form (ICNA Hand Contamination Guidelines)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|-------------|---|---|---|-----------|---|---|---|---|-----------|---|---|----|----|----|----|-------|-----------|----|----|----|-------|-----------|----|----|-------|----------|----|-------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 1 | 2 | 3 | 6 | 2 | 1 | 2 | 1 | 6 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 8 | 3 | 4 | 4 | 2 | 13 | 2 | 1 | 1 | 4 | 3 | 3 | 6 (43) |
| Appraiser 2 | 3 | 3 | 3 | 9 | 1 | 1 | 3 | 1 | 6 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 3 | 1 | 2 | 1 | 7 | 1 | 1 | 1 | 3 | 1 | 1 | 2 (34) |
| Total | 4 | 5 | 6 | 15 | 3 | 2 | 5 | 2 | 12 | 2 | 2 | 2 | 3 | 2 | 2 | 2 | 15 | 6 | 5 | 6 | 3 | 20 | 3 | 2 | 2 | 7 | 4 | 4 | 8 (77) |

Domain Scores

| | |
|---|---|
| <p>Domain 1 Maximum possible score = $4 \times 3 \times 2 = 24$ Standardised domain score is: $(15/24) \times 100 = 63\%$</p> | <p>Domain 4 Maximum possible score = $4 \times 4 \times 2 = 32$ Standardised domain score is: $(20/32) \times 100 = 63\%$</p> |
| <p>Domain 2 Maximum possible score = $4 \times 4 \times 2 = 32$ Standardised domain score is: $(12/32) \times 100 = 38\%$</p> | <p>Domain 5 Maximum possible score = $4 \times 3 \times 2 = 24$ Standardised domain score is: $(7/24) \times 100 = 29\%$</p> |
| <p>Domain 3 Maximum possible score = $4 \times 7 \times 2 = 56$ Standardised domain score is: $(15/56) \times 100 = 27\%$</p> | <p>Domain 6 Maximum possible score = $4 \times 2 \times 2 = 16$ Standardised domain score is: $(8/16) \times 100 = 50\%$</p> |

APPENDIX SP2 – Standard Principles - Systematic Review Process

Hand Hygiene - Systematic Review Process

Systematic Review Questions

Search questions:

1. What is the evidence that contaminated hands are a cause of healthcare-associated infection?
2. Which hand disinfection agents are the most effective at removing / reducing organisms responsible for healthcare-associated infection?
3. When must hands be disinfected in relation to patient care activities?
4. What is the most effective hand washing technique for removing / reducing organisms responsible for healthcare-associated infection?
5. Which hand disinfection agents are least toxic to users?
6. Is there any cost effectiveness evidence relating to the above?
7. What are the training and education implications for staff and patients?

Databases and Search Terms Used

DATABASES

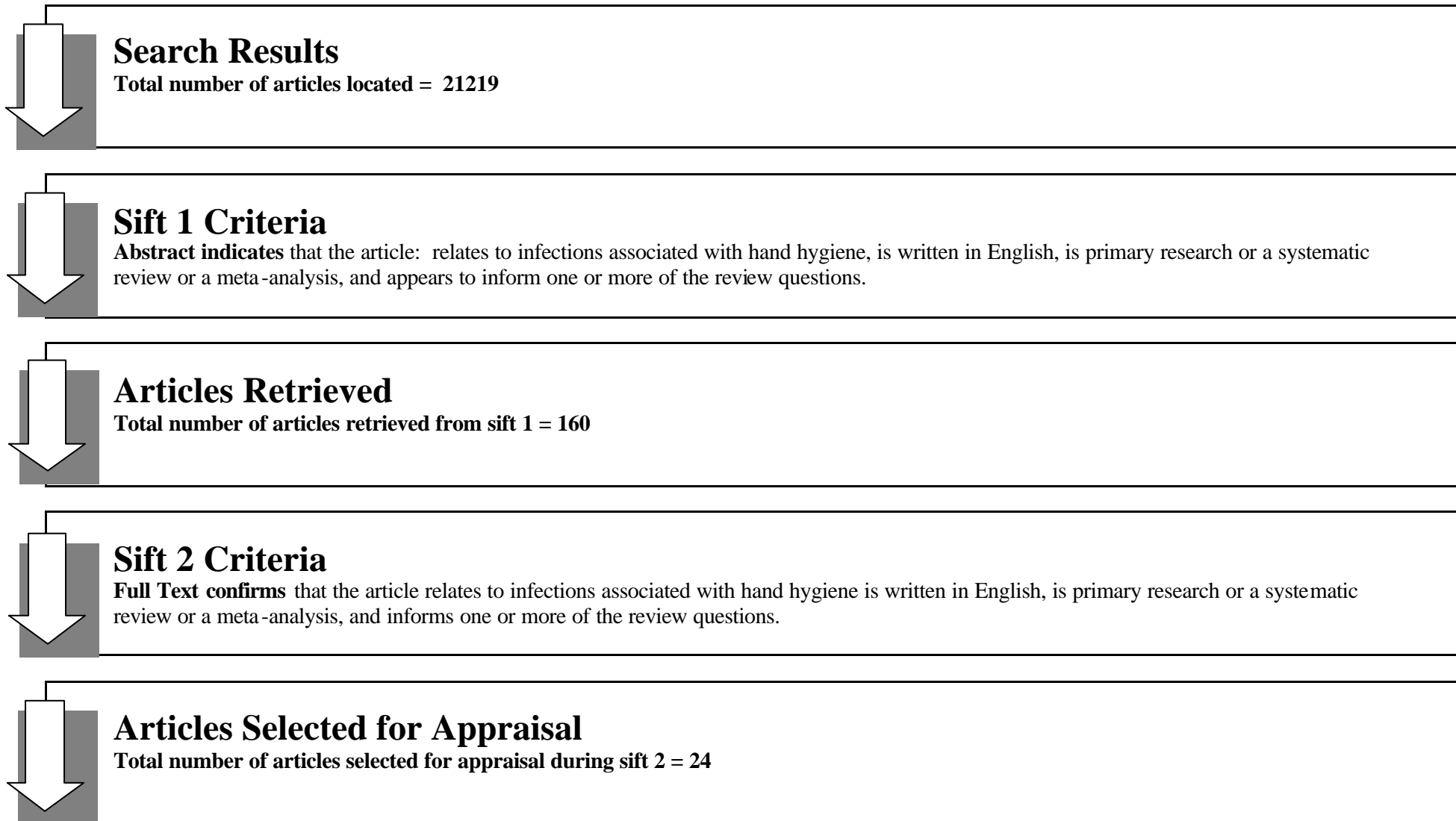
MEDLINE, CUMULATED INDEX OF NURSING AND ALLIED HEALTH LITERATURE (CINAHL), EMBASE, THE COCHRANE LIBRARY, THE NATIONAL ELECTRONIC LIBRARY FOR HEALTH, THE NHS CENTRE FOR REVIEWS AND DISSEMINATION (CRD), THE NATIONAL RESEARCH REGISTER, THE WEB OF SCIENCE, THE INSTITUTE OF HEALTH TECHNOLOGY, HEALTH CD DATABASE, HEALTH MANAGEMENT INFORMATION CONSORTIUM DATABASE.

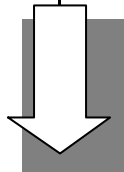
MESH TERMS

infection control; cross infection; universal precautions, equipment contamination; disease transmission; chlorhexidine; disinfectants; soaps; anti-infective agents; surface-active agents; handwashing; hand; skin; epidermis; nails.

THESAURUS AND FREE TEXT TERMS

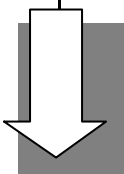
antiseptics; sterilisation; decontamination





Critical Appraisal

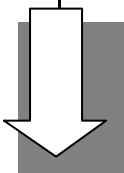
All articles which described primary research, a systematic review or, a meta-analysis and met the sift 2 criteria were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion.



Accepted and Rejected Evidence

Total number of articles accepted after critical appraisal = 23

Total number of articles rejected after critical appraisal = 1



Evidence Tables

Evidence tables for accepted and rejected studies were generated and used to create **evidence summary reports**. The summary reports were, in turn, used as the basis for guideline writing.

Protective Clothing - Systematic Review Process

Systematic Review Questions

Search questions:

1. Which glove materials are least toxic to health care workers (HCWs) for general use?
2. What is the evidence that hands need to be disinfected following the use of gloves?
3. What is the evidence that HCWs use gloves appropriately, as a part of Standard Principles?
4. What is the evidence that the uniforms / clothes of HCWs are a source of healthcare-associated infection?
5. What is the evidence that the use of protective clothing reduces the incidence of healthcare-associated infection?
6. Is there any cost effectiveness evidence relating to the above?
7. What are the training and education implications for staff and patients?

Databases and Search Terms Used

DATABASES

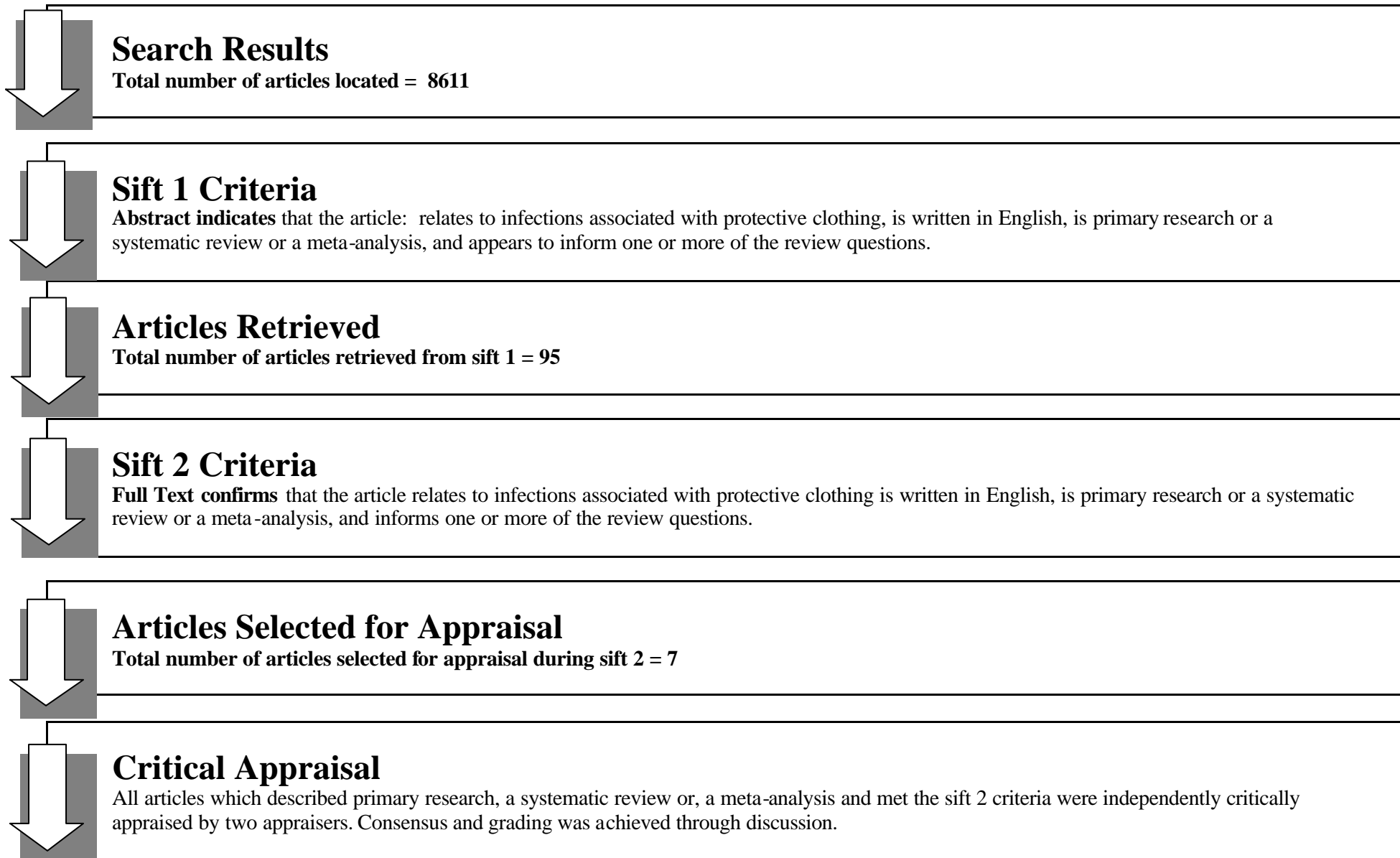
MEDLINE, CUMULATED INDEX OF NURSING AND ALLIED HEALTH LITERATURE (CINAHL), EMBASE, THE COCHRANE LIBRARY, THE NATIONAL ELECTRONIC LIBRARY FOR HEALTH, THE NHS CENTRE FOR REVIEWS AND DISSEMINATION (CRD), THE NATIONAL RESEARCH REGISTER, THE WEB OF SCIENCE, THE INSTITUTE OF HEALTH TECHNOLOGY, HEALTH CD DATABASE, HEALTH MANAGEMENT INFORMATION CONSORTIUM DATABASE.

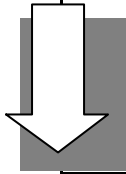
MESH TERMS

infection control; cross infection; universal precautions; equipment contamination; disease transmission; protective clothing; disposable equipment; masks; protective gloves; eye protective devices.

THESAURUS AND FREE TEXT TERMS

antiseptics; disinfection; sterilisation; decontamination; face shield; goggles; apron; uniform; gown; clothing; visor; hood.

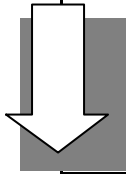




Accepted and Rejected Evidence

Total number of articles accepted after critical appraisal = 7

Total number of articles rejected after critical appraisal = 0



Evidence Tables

Evidence tables for accepted and rejected studies were generated and used to create **evidence summary reports**. The summary reports were, in turn, used as the basis for guideline writing.

Sharps - Systematic Review Process

Systematic Review Questions

Search questions:

1. What is the evidence that recommended modes of use and disposal of sharps reduce the incidence of sharps injury in health care workers?
2. What is the evidence that education and training interventions improve health care workers adherence to recommended modes of practice?
3. What is the evidence that the use of needle-free devices reduce occupational exposure to bloodborne pathogens?
4. Is there any cost effectiveness evidence relating to the above?
5. What are the training and education implications for staff and patients?

Databases and Search Terms Used

DATABASES

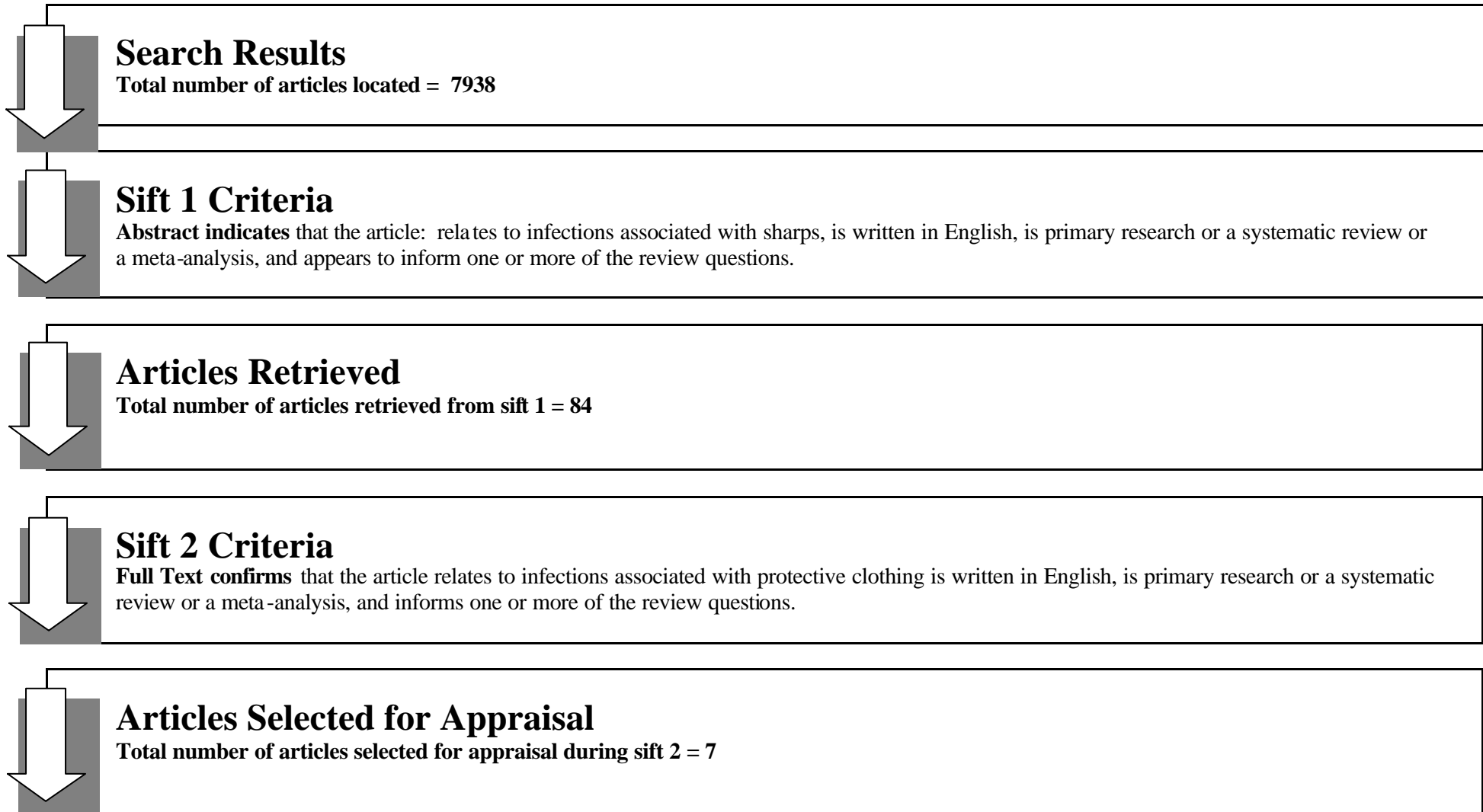
MEDLINE, CUMULATED INDEX OF NURSING AND ALLIED HEALTH LITERATURE (CINAHL), EMBASE, THE COCHRANE LIBRARY, THE NATIONAL ELECTRONIC LIBRARY FOR HEALTH, THE NHS CENTRE FOR REVIEWS AND DISSEMINATION (CRD), THE NATIONAL RESEARCH REGISTER, THE WEB OF SCIENCE, THE INSTITUTE OF HEALTH TECHNOLOGY, HEALTH CD DATABASE, HEALTH MANAGEMENT INFORMATION CONSORTIUM DATABASE.

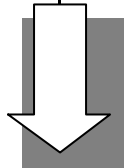
MESH TERMS

infection control; cross infection; universal precautions, equipment contamination; disease transmission; needlestick injuries; needles; syringes; occupational exposure; occupational accident; medical waste disposal; blood-borne pathogens.

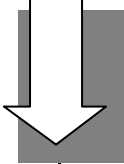
THESAURUS AND FREE TEXT TERMS

antisepsis; disinfection; sterilisation; decontamination; blood-borne virus; exposure prone procedure; post exposure prophylaxis; sharp; puncture; percutaneous injury; epi pen; vacutainer; resheath.

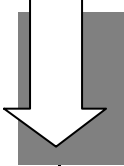




Critical Appraisal
All articles which described primary research, a systematic review or, a meta-analysis and met the sift 2 criteria were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion.



Accepted and Rejected Evidence
Total number of articles accepted after critical appraisal = 4 Total number of articles rejected after critical appraisal = 0



Evidence Tables
Evidence tables for accepted and rejected studies were generated and used to create **evidence summary reports**. The summary reports were, in turn, used as the basis for guideline writing.

APPENDIX SP3 – Standard Principles Evidence Tables

Hands Accepted Studies

| ID | Quest. Number | Author, Date, Country of Origin and Objective | Design, Setting, Sample Size and Population | | Outcomes | Strengths and Limitations |
|----|---------------|--|---|---|---|---|
| H3 | 2 & 4 | <p>Lucet JC, Riguid F, Mentre F, Kassis N, Deblangy C, Andremont A, Bouvet E. 2002. France.</p> <p>To compare the bacterial efficiency of various hand hygiene techniques, including hand rubbing with an alcohol based compound and handwashing with antiseptic agents and with unmedicated soap to assess the factors associated with hand decontamination after care.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>Hospital</p> <p>516 specimens, 258 beforehand hygiene and 258 after.</p> <p>33 Healthcare Workers (HCWs) and Intensive Care Units (ICUs) and 10 from medical wards (14M, 29F)</p> | <p>Q2. Bacterial reduction after hand washing with antiseptic soap or hand rubbing with alcohol-based disinfectant was significantly greater than that obtained after hand washing with the un-medicated soap. There was no significant difference between hand washing with the antiseptic soap and hand rubbing with the alcohol based disinfectant.</p> <p>Q4. No statistically significant difference was found between hand washing with un-medicated soap for 10 or 30 seconds although there was a trend towards greater reduction after hand washing with un-medicated soap for 10's compared with hand washing with un-medicated soap for 30 seconds, 388 specimens cultured positive 241 before and 147 after hand hygiene. There was no significant difference between hand washing with the antiseptic soap (either 10, 30 or 60 seconds) and hand rubbing with the alcohol based disinfectant.</p> | <p>Authors state that the subjects performed the 6 hygiene techniques in a random order immediately after a health care procedure but fail to say how allocation occurred.</p> <p>Presumably depended on where the health care worker worked.</p> <p>Standard times for length of the procedure, the volume of product used, method of drying hands</p> |

| | | | | | |
|-----|---|--|--|---|---|
| H11 | 2 | <p>Herruzo-Cabrera R, Garcia-Caballero J, Martin- Moreno JM, Graciani-Perez-Regadera MA, Perez-Rodriguez J. 2001. Spain.</p> <p>To study the effectiveness of an alcohol solution of N-duopropenide (NDP) in vivo and its effect on the control of a multi-resistant <i>Klebsiella pneumoniae</i> outbreak in NICU that had persisted for 13 months.</p> | <p>Design:</p> <p>1.Randomised Control Trial</p> <p>2.DescriptiveStudy – before and after follow up study</p> <p>Setting:</p> <p>Neonatal Intensive Care Unit (NICU) and Paediatric Intensive Care Unit (PICU)</p> <p>Sample:</p> <p>45 health care workers in NICU and 24 HCW in PICU (gender not stated)</p> <p>Popⁿ:</p> <p>Health care workers.</p> | <p>1.The alcoholic solution of NDP was highly germicidal in vivo, destroying organisms better than classic hand washing on the hands of 69 health care staff in PICU and NICU. Hand washing alone led to a 63% reduction in colonisation. NDP alone led to a 95% reduction in colonisation. Difference $p < 0.01$ average colony forming units after hand washing and NDP use.</p> <p>2. Before NDP use the cumulative incidence of infection of <i>Klebsiella pneumoniae</i> infection 25%. After NDP introduction reduced to 6.5% and then 0% after 5 months ($p < 0.0000001$)</p> | <p>In vivo component demonstrated effect of NDP intervention in non-clinical setting</p> <p>Similar results were obtained for the different study periods</p> <p>Colonisation prevalence was tallied twice.</p> <p>The practice of surveillance and measurement could have led the HCW to modify their practice</p> <p>The results of plate cultures obtained were shown to staff to motivate them to wash their hands.</p> |
| H12 | 2 | <p>Herruzo-Cabrera R, Garcia-Caballero J, Fernandez Acenero MJ. 2001. Spain.</p> <p>Is fast disinfection with an alcohol solution better than hand washing and can it improve compliance?</p> | <p>Design:</p> <p>1.Laboratory Experiment</p> <p>2.Quasi-experiment</p> <p>Setting:</p> <p>1.Laboratory</p> <p>2.Hospital</p> <p>Sample:</p> <p>52 healthy volunteers</p> <p>102 healthcare personnel from burn ICU and 4 other ICU</p> <p>Popⁿ:</p> <p>Healthy volunteers</p> <p>health care personnel</p> | <p>Laboratory component established that: Ethylsulphate and NDP-alcohol produced a 0.9-1.2 \log_{10} reduction in colony forming units.</p> <p>60° alcohol/phenol alcohol 0.4 – 0.6 \log_{10} reduction in colony forming units.</p> <p>Classic hand washing resulted in 0.1-0.3 \log_{10} reduction in colony forming units.</p> <p>In use component demonstrated: NDP alcohol 95% mean reduction in colony forming units ($> 2\log_{10}$) compared to 50% ($0.1 \log_{10}$) in classic hand wash. $P < 0.00001$ reduction for both NDP and hand washing, but always greater with NDP alcohol.</p> | <p>Laboratory study, and an in use component.</p> |

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| H13 | 5 | <p>Pietsch H. 2001. Germany.</p> <p>To compare the dermal tolerance and antimicrobial efficacy of a chlorhexidine antiseptic (Hibiscrub) and a alcohol hand rub (Sterillium).</p> | <p>Design:</p> <p>Laboratory experiment</p> <p>Setting:</p> <p>Laboratory</p> <p>Sample:</p> <p>60 (gender not stated)</p> <p>Popⁿ:</p> <p>Volunteers, no other details.</p> | <p>Alcohol rub was found to cause significantly less skin irritation than a chlorhexidine based antiseptic.</p> | <p>Volunteers not healthcare workers. Author works for a chemical company therefore possible bias.</p> |
| H14 | 2 | <p>Kramer A, Rudolf P, Kampf G, Pittet D. 2002. Switzerland.</p> <p>To investigate antimicrobial efficacy of 10 gels and 4 rinses according to European standards.</p> | <p>Design:</p> <p>Laboratory experiment</p> <p>Setting:</p> <p>Laboratory (Industry)</p> <p>Sample:</p> <p>15 volunteers</p> <p>Popⁿ:</p> <p>Volunteers, details unknown</p> | <p>Most alcohol based hand rinses meet EN1500 requirements within 30s. 30s hand rubs with gel containing a total amount of up to 70% alcohol is significantly less effective than hand rub with 2 propanol 60%.</p> <p>Ethanol content of up to 70% is not as effective as 2 propanol 60%.</p> <p>In terms of bacterial efficacy, 1- propanol can be regarded as the most effective alcohol, followed by 2 propanol and ethanol.</p> <p>Comparison of 2 propanol with ethanol showed that the efficacy of 2 propanol 60% is almost equivalent to ethanol 80%.</p> <p>Therefore ethanol based hand formulations should contain at least 80% ethanol.</p> | <p>Non-clinical study that may not replicate in use conditions.</p> |

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| H15 | 2 | <p>Moadab A, Rupely KF, Wadhams P. 2001. USA.</p> <p>To evaluate the efficacy of a novel surfactant, allantoin and benzalkonium chloride hand sanitiser using the US Food and Drug Administration's method for testing antiseptic handwashes used by health care personnel.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Laboratory experiment</p> <p>College of podiatric medicine</p> <p>40 (gender not stated)</p> <p>Volunteer Students</p> | <p>HandClens (alcohol free product) outperformed Purell (alcohol based product) and met regulatory requirements for a hand sanitizer. Purell failed as an antimicrobial wash and was less effective than a control soap used in the study</p> <p>Both groups met the minimum requirement for the first hand wash, with an average reduction factor of 2.6 for HandClens and 2.6 for Purell. An overall trend of sustained disinfecting power was seen for HandClens as demonstrated by the reduction factor values. This surpassed the minimum persistence values. In contrast Purell's performance diminished over time and values plummeted after only 3 washes. The antimicrobial activity of the alcohol based hand sanitizer was significantly less (wash1, p<0.001, washes 3,7, and 10, p<.001) than that of the alcohol free Han Clens product and hand washes.</p> | <p>Non-clinical study that may not replicate in use conditions.</p> |
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| H16 | 2 & 5 | <p>Winnefeld M, Richard MA, Darncourt, Grob JJ. 2000. France.</p> <p>To assess skin tolerance and antimicrobial effects of two widely accepted hand hygiene measures under in use conditions.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>Hospital</p> <p>52 (2M, 49F)</p> <p>Volunteer nurses in 12 medical and 4 surgical departments</p> | <p>Q2. Alcohol based rinse significantly more effective than liquid soap at removing transient microorganisms p=0.016. 20/50 hand washes with antiseptic soap resulted in residual bacterial contamination of hands.</p> <p>At the end of the study factors influencing the total bacterial count increased with the increasing number of hand washes in the soap group p=0.003 and with the degree of skin damage p=0.005 in the antiseptic group.</p> <p>The rate of successful hand decontamination was low, 20% in hand wash group and 31% in handrub group.</p> <p>Q5. Self assessment of skin condition and grade of skin damage worsened significantly more using soap than in the group using alcoholic disinfectant p=0.004 p=0.01 respectively.</p> | <p>Study conducted under clinical use conditions.</p> <p>Skin assessment on 1st and last day of study using 3 scores 2 determined by the same observer</p> |
| H17 | 1 & 2 | <p>Gould D, Gammon J, Donnelly M, Batiste L, Ball E, De Melo AMSC, Alidad V, Miles R, Halablab M. 2000. UK.</p> <p>To establish whether the potential for cross infection during home visits could be reduced by supplying nurses with an antiseptic cream to be used in addition to their routine hand hygiene precautions</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Community. Clients' homes and clinic settings.</p> <p>17</p> <p>Nurses working in the community delivering various procedures and care.</p> | <p>Q1. Poor conditions in patients' homes compromise nurse's ability to perform adequate hand hygiene effectively and thereby increase risks of cross infection.</p> <p>Q2. Application of an antiseptic cream (chlorhexidine based) exhibited residual effectiveness in reducing bacteria</p> | <p>Complex but comprehensive research in that it uses 3 methods to assess the risk of cross infection.</p> <p>Unclear how many nurses the data relates to.</p> |

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| H18 | 1 | <p>Pittet D, Dharan S, Touveneau S, Sylvie RN, Sauvan V, Perneger TV. 1999. Switzerland.</p> <p>To study the process of bacterial contamination of health care worker's hands during routine patient care in a large teaching hospital.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Hospital</p> <p>266 hospital staff, 417 episodes of care</p> <p>Health care workers</p> | <p>Bacterial contamination increased linearly with time on gloved hands (av 16 colony forming units (CFUs) per minute). Patient care activities significantly associated (p<0.05) with a high contamination level were direct patient contact p<0.001, respiratory care p<0.001, handling body fluids p<0.02. Contamination levels varied with hospital location, Medical rehabilitation ward had higher levels (49 CFU p=0.03).</p> <p>Simple hand washing before patient care without hand antiseptics is associated with a higher colony count 52 CFU p=0.03</p> | <p>Standard definitions of patient care activities were used. There may have been some observational bias.</p> <p>Maximal bacterial colony counts were truncated at 300CFU – longer observational periods would have resulted in a higher proportion of maximal colony counts at later times. Threshold of bacterial contamination associated with an increased risk for sub infection</p> <p>Findings may not be generalisable to non-dominant hand.</p> |
| H20 | 2 | <p>Guilhermetti M, Evandro S, Hernandes D, Fukushigue Y, Garcia LB, Cardoso CL. 2001. Brazil</p> <p>To investigate the effectiveness of hand cleansing agents in removing a hospital strain of Methicillin Resistant Staph. Aureus (MRSA) from artificially contaminated hands of five volunteers.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Laboratory experiment</p> <p>Laboratory (University)</p> <p>5 (2M, 3F)</p> <p>Volunteers</p> | <p>Results suggest that 10% povidine iodine and 70% ethyl alcohol may be the most effective hand cleansing agents for removing MRSA from either lightly or heavily contaminated hands. Plain liquid soap was more effective than chlorhexidine 4% detergent</p> | <p>Non-clinical study that may not replicate in use conditions.</p> |

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| H21 | 2 | Faoagali J, Narelle G, Fong J, Davy J, Dowser M. 1999. Australia. To determine the effect of 4% chlorhexidine gluconate and 1% triclosan on the composition of the hand bacterial flora. | Design: Setting: Sample: Popⁿ: | Longitudinal / comparative study Specialist surgical ward 41 doctors and nurses (gender not stated) Clinical staff | The use of 1% triclosan formulation for a 30 s hand wash effectively removed MRSA from staff hands (p<0.05, in contrast 4% hibiclens was unable to produce or sustain this result p<0.05 although it showed an effective immediate and residual overall anti bacterial effect. Hand colonisation rate with GNB increased pre and post-washing when 1% Triclosan was used. | Clinically based study. |
| H42 | 5 | Boyce JM, Kelliher S, Vallande N. 2000. USA. To compare the frequency of skin irritation and dryness associated with using an alcohol – hand gel regimen for hand antiseptis versus using soap and water for hand washing. | Design: Setting: Sample: Popⁿ: | Prospective Randomised Trial with cross over design Teaching Hospital 32 nurses on 3 wards, 2 ICUs and 1 standard ward. Nurses | Self assessment scores of skin irritation and dryness decreased slightly during the 2 weeks when nurses used the alcoholic – hand-gel regimen (mean baseline score 2, mean final score 2.0 p=0.08) but increased substantially during the 2 weeks when nurses used soap and water (mean baseline score 2.0, mean final score 4.8 p<0.0001). Visual assessment scores by the study nurses did not change significantly when the alcoholic hand gel regimen was used but scores increased substantially when nurses used soap and water (baseline score .59, mean final score 1.21 p=0.05). Epidermal water content of dorsal surface of the nurses' hands changed little when the alcoholic hand gel regimen was used but increased significantly with soap and water hand washing (mean baseline 25.9+/-7.5, mean final reading, 20.5+/- 5.4, p=0.0003. | Small sample size. The cross over nature of the design with a 2 week washout period reduced the likelihood of pre-existing skin problems influencing results. Mean number of hand washes for both groups were the same over the study period. Self-assessment by the study nurses may have been biased as they knew what regimen they were using. 3 methods of assessing skin condition reduced opportunity for bias. |

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| H50 | 4 | <p>Gustavson DR, Ve tter EA and Larson DR, Ilstrup DM, Maker MD, Thompson RL, Cockerill FR. 2000. USA.</p> <p>To evaluate the effects of 4 different drying methods to remove bacteria from washed hands</p> | <p>Design: Laboratory experiment</p> <p>Setting: Laboratory (Healthcare)</p> <p>Sample: 100 (gender not stated)</p> <p>Popⁿ: Volunteers (no break down)</p> | <p>No statistically significant differences were noted in the numbers of colony forming units for each drying method p=0.72</p> | <p>Non-clinical study that may not replicate in use conditions.</p> <p>Glove juice method permits sampling of inter-digital areas and is a more comprehensive measure of sampling skin bacteria</p> |
| H51 | 2 | <p>Paulson DS, Fendler EJ, Dolan MJ, Williams RA. 1999. USA.</p> <p>To evaluate the antimicrobial efficacy and irritation potential of 5 handwash product regimens: a nonantimicrobial lotion soap, an antimicrobial lotion soap, an alcohol gel santizer, a nonantimicrobial lotion soap with an alcohol gel sanitizer and an antimicrobial lotion soap with an alcohol gel sanitizer.</p> | <p>Design: Experimental</p> <p>Setting: Laboratory (industry)</p> <p>Sample: 25 adults between 18-70 years (both sexes, though gender specifics not stated)</p> <p>Popⁿ: Adults</p> | <p>All product configurations were effective in reducing transient microbial levels on hands. The mean log reductions from baseline were greatest for the lotion soaps with alcohol gel sanitizer, less for the alcohol and the antimicrobial soap when used alone, and least for the bland soap. All the products showed a low potential for skin irritation.</p> | <p>Laboratory setting rather than in use.</p> <p>Glove juice sampling procedure was used, the specified method for testing products for use in a health care setting and is known to be accurate and precise.</p> <p>The authors reported that the study was based on small sample sizes and therefore precision may have been compromised.</p> |

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| H52 | 2 & 5 | <p>Larson E, Siberger M, Jakob K, Whittier S, Lena L, Latta PD, Saiman L. 2000. USA.</p> <p>To compare 2 hand care regimens (traditional antiseptic hand wash with chlorhexidine-containing detergent versus mild soap wash with subsequent alcohol-based rinse for degerming as necessary) in a neonatal intensive care unit (NICU).</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Prospective quasi experimental</p> <p>Hospital neonatal intensive care unit</p> <p>16 nurses (gender not stated)</p> <p>Nurses</p> | <p>Q2. The use of mild soap for cleaning and an alcohol-based waterless product provided antimicrobial effectiveness comparable to traditional antiseptic hand washing.</p> <p>Q5. The use of mild soap for cleaning and an alcohol-based waterless product significantly improved skin condition $p < 0.005$.</p> | |
| H53 | 2 & 5 | <p>Larson E, Aiello A, Bastyr J, Lyle C, Stahl J, Cronquist A, Lai L, Della-Latta P. 2001. USA.</p> <p>To compare skin condition and skin microbiology among intensive care unit personnel using one of two randomly assigned hand hygiene regimens: a 2% chlorhexidine gluconate (CHG) containing traditional antiseptic wash and a waterless hand scrub containing 61% ethanol with emollients.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised controlled trial</p> <p>2 critical care units</p> <p>50 (before dropouts, 7 physicians, 36 nurses, 7 other staff) (11M, 39F)</p> <p>Health care workers</p> | <p>Under in-use conditions in two adult critical care units, an alcohol-based hand hygiene product was comparable with a CHG-containing antiseptic detergent in terms of antimicrobial effectiveness, was associated with improved skin condition and took significantly less time to use.</p> | <p>This is a replication of the small study done a year previously (H52) referred to in this study as ‘the pilot’ (p8). This study uses two sites and a larger study population across a number of professional groups (physicians, nurses, housekeepers and respiratory therapists).</p> |

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| H54 | 2 | <p>Girou E, Loyeau S, Legrand P, Oppein F, Brun-Buisson C. 2002. France.</p> <p>To compare the efficacy of hand rubbing with an alcoholic based solution versus conventional handwashing with antiseptic soap in reducing hand contamination during routine patient care.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>94 bedded university hospital</p> <p>23</p> <p>Health care workers.</p> | <p>The median percentage reduction in bacterial contamination for hand rubbing was significantly higher than with hand washing (83% vs. 58% p= 0.012) with a median difference of 26%. The median duration of hand hygiene for each group was 30 seconds.</p> | <p>In use study designed not to interfere with regular clinical activities. The difference in the hand wash group may have been due to the fact that they were less likely to adhere to the duration of 30 seconds recommended, i.e. in only 35% of opportunities did this happen alternatively less than 30s may be enough for the hand rubbing. Bacterial contamination was assessed by agar fingerprints and not the glove juice test which may be more effective in estimating the true burden of bacteria present and therefore underestimating the true estimate of contamination,</p> |
| H55 | 2 | <p>Zaragoza M, Salles M, Gomez J, Bayas JM, Trilla A. 1999. Spain.</p> <p>To compare the effectiveness (reduction of bacterial microflora on hands) of an alcoholic solution compared with the standard hygienic handwashing procedure during regular work in clinical wards and intensive care.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Control Trial</p> <p>Clinic wards and ICU in 1 hospital.</p> <p>50</p> <p>Hospital health care workers</p> | <p>49.6% average reduction for soap and water vs. 88.2% with alcoholic solution p<0.001. alcoholic solution well tolerated by overall acceptance rate classified by 72% of HCW after 2 wk use. There was no difference between medical wards and surgical vs. ICU.</p> | <p>Larger sample needed.</p> <p>One observer monitored healthcare worker activity and may have been some observer bias.</p> |

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| H56 | 1 | <p>Fendler EJ, Ali Y, Hammond BS, Lyons MK Kelley MB, Vowell NA. 2002. USA.</p> <p>To determine the effect of the use of alcohol gel hand sanitizer by caregivers on infection types and rates in an extended care facility.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Controlled Ttudy</p> <p>Hospital</p> <p>265 employees</p> <p>Employees in a 275 bed extended care facility specialising in rehabilitation and subacute care.</p> | <p>One of the primary infection types found was in people with UTI with a Foley catheter. Other primary infections were respiratory tract and wound infections. Comparison of the infection types and rates for the units where hand sanitizers was used compared with those control units where hand sanitizers were not used showed a 30.4% decrease in infection rates for the 34month period in the units where the sanitizer was used.</p> | <p>In use study in normal clinical conditions over an extended period of time.</p> <p>Standardised protocol used for hand hygiene.</p> <p>The study was carried out over 34 months and there may have been differences in infection rates over the time period No measure of compliance with the protocol.</p> |
| H65 | 1 | <p>Ryan MAK, Christian RS, Wohlrabe J. 2001, USA.</p> <p>To implement and evaluate a hand washing program at a large Navy training centre in terms of the programmes effect on the incidence of respiratory disease.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Controlled Trial</p> <p>Navy Training Centre</p> <p>1,089,800 person-weeks reviewed.</p> <p>Navy Trainees. 80% men average age 20 years.</p> | <p>Overall rate of respiratory illness in post intervention period was 45% lower than in the year prior to intervention.</p> | <p>A well designed controlled experiment.</p> |
| H66 | 2 | <p>Cardoso CL, Pereira HH, Zequim JC, Guilhermetti M. 1999. Brazil.</p> <p>To explore the effectiveness of hand-cleansing agents (plain liquid soap, 70% ethyl alcohol, 10% povidone-iodine, 4% chlorhexidine gluconate) for removing a hospital strain Acinetobacter baumannii from artificially contaminated hands of 5 volunteers.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Laboratory experiment</p> <p>Laboratory (University)</p> <p>5 (2M, 3F)</p> <p>5 healthy adults with no skin problems aged 10-47 years.</p> | <p>Results suggest 70% ethyl alcohol and 10% povidone iodine may be the most effective agents for removing A. baumenii strain from heavily contaminated hands.</p> | <p>A well controlled laboratory experiment.</p> |

FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

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| H67 | 2 | Kampf G, Jarosch R, Ruden H. 1998. Germany. To determine the bactericidal efficacy of Chlorhexidine, Hibiscrub (Chlorhexidine and water) and Hibisol (Chlorhexidine and Alcohol) against MRSA and MSSA. | Design: Setting: Sample: Popⁿ: | Laboratory experimental Laboratory (University) 612 tests N/A | Hibisol was significantly more effective $p < 0.05$ against MRSA than Hibiscrub. | A well controlled laboratory experiment. |
| H68 | 5 | Forrester BG, Roth VS. 1998. USA. To investigate the prevalence of hand dermatitis in ICU personnel. | Design: Setting: Sample: Popⁿ: | Descriptive Study Regional Neonatal Intensive Care and Surgical Intensive Care Unit 126 (18M, 108F) All (203) employees in study setting. | There was a strong relationship between frequency of hand washing and dermatitis. Subjects washing hands > 35 times $p < 0.005$ more likely to have occupational hand dermatitis, than those washing hands < 35 times per shift. Authors conclude that most cases were likely to be as a result of hand washing. The solution in use in the study setting was Chlorhexidine. | Sample is predominantly female and no comparative analysis between the two sites used. High prevalence of occupational hand dermatitis may be due to reporting bias. The lack of association of atopy and prevalence of dermatitis may have been due to the phrasing in the questionnaire. |
| H69 | 2 | Dyer DL, Gerenraich KB, Wadhams PS. 1998. USA. To evaluate the immediate and persistent effectiveness of two alcohol- containing hand sanitizers to supplement normal hand washing. | Design: Setting: Sample: Popⁿ: | Laboratory experiment Laboratory (Industry) 56% male and 44% women aged between 18-47. Volunteers. | All 3 hand products were equally effective after a single application. After repeated use the alcohol containing sanitizers did not meet government approved performance standards and the alcohol free sanitizer did. The benzalkonium chloride hand sanitizer was the most favorable of the rinse free formulas for normal hand washing Same results obtained when the rinse was omitted | The company producing one of the products carried out the research study which may have biased the results Subjective assessment of hand condition after completion of tests Carried out under controlled conditions in a laboratory and pathogens artificially introduced The interval between washes was 10 minutes, chosen to model the frequency that may occur in a clinical environment i.e. 10/12 patient contacts per hour, it would be interesting to see whether the agents are effective with 10–15 sec wash as opposed to the 2 minutes given in this study |

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| H193 | ALL | <p>Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.</p> <p>Systematic review of hand hygiene practice and the reduction of HAI.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Systematic Review</p> <p>Laboratory and hospital settings</p> <p>Study Designs: RCT, CCT, Experimental laboratory studies were a major component of retrieved studies</p> <p>N/A</p> | <p>There is a comprehensive description of the methodology used for the review.</p> <p>Search included major databases, Medline, Embase, CINAHL, Cochrane and DARE, references from retrieved studies and existing national and international guidelines.</p> <p>All studies were assessed for clinical utility and study quality.</p> | <p>There may have been a degree of publication bias and the heterogeneity of retrieved studies meant that studies could not be pooled.</p> |
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Hands Rejected Studies

| ID | Quest. Number | Author, Date and Country of Origin | Objective | Design, Setting, Sample Size & Population | | Reasons for Rejection |
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| H19 | 2 | Chudleigh J and Buckingham C. 1999. UK. | To determine whether or not nurses were adhering to existing infection control policies and guidelines. To determine the most appropriate product to use for hand decontamination | Design: | Observational | Number of nurses participating unclear. No quantitative results and p values given 3 variables compared – soap, gloves and alcohol but no documentation as to who used what or how many used which technique or in what combination |
| | | | | Setting: | Hospital – special care baby unit. | |
| | | | | Sample: | 12 nurses (3 unqualified) | |
| | | | | Pop^a: | Nurses | |

Personal Protective Equipment Accepted Studies

| ID | Quest | Author, Date, Country of Origin and Objective | Design, Setting, Sample Size and Population | | Outcomes | Strengths and Limitations |
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| G4 | 4 | <p>Callaghan I. 1998. UK.</p> <p>To examine the levels of contamination on nurses' uniforms and the role if any of plastic aprons.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>2 urban hospitals</p> <p>88 (48 in pilot, 40 in comparative study)</p> <p>Nurses' uniforms.</p> | <p>Uniforms were found to be equally and heavily contaminated at all sites sampled and at all times.</p> <p>Plastic aprons were also heavily contaminated and their use was not associated with significantly less contamination on uniforms. 60 staff (30.6%) did not wear a fresh uniform daily.</p> | <p>Variable not well controlled. Data and statistical analysis missing.</p> |
| G5 | 4 | <p>Perry C, Marshall R, Jones E. 2001. UK.</p> <p>To assess whether MRSA, Clostridium difficile and Vancomycin Resistant Enterococcus (VRE) were present on healthcare worker's uniforms at the beginning and end of a span of uniform.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>City hospital</p> <p>57 (gender not stated)</p> <p>Staff from five different ward areas in one hospital</p> | <p>22 (39%) uniforms contaminated prior to shift. Three had not put on clean uniforms and these had MRSA.</p> <p>By the end of the shift 31 (54%) were positive for one or more organism, VRE on 22.</p> <p>Levels of contamination varied between ward areas, highest medical 92% lowest surgical 7.7%</p> <p>No difference between trained and untrained staff.</p> <p>Uniforms do become contaminated with organisms when carrying out clinical duties. Recommendation that uniforms are supplied on the basis of the number of days rather than hours worked and guidance given on home laundering</p> | <p>Study over one day only</p> <p>No link made with infection prevalence on ward,</p> |

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| G6 | 3 | <p>Godin G, Naccache H, Fortin C. 1998. Canada.</p> <p>To identify factors explaining the intention of physicians to wear gloves when contact with blood or body fluids was possible.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Hospital physicians throughout Canada.</p> <p>667 (504M, 163F)</p> <p>Physicians</p> | <p>Those who supported and considered glove use a norm had 14.61 times greater odds of wearing them compared with those with a moderate or negative perception p<0.001.</p> | <p>Poor response to survey Responses do not necessarily match practice.</p> |
| G34 | 2 | <p>Tenorino AR, Badri SM, Sahgal NB, Hotta B, Matushek M, Hayden MK, Trenholme GM, Weinstein RA. 2001. USA.</p> <p>To assess the effectiveness of routine gloving in the prevention of hand carriage of VRE by health care workers during patient care activities.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study.</p> <p>Urban Hospital</p> <p>60 (50 healthcare workers and the 10 patients with VRE infection in the hospital)</p> <p>HCW hands and gloves before and after contact with a patient with VRE</p> | <p>16 HCW had VRE on hands prior to care Of the 44 who didn't 17 (39%) acquired VRE on gloves and after removal 5 (29%) also had the same strain on their hands VRE acquisition associated with duration of contact, contact with body fluids, diarrhoea, mean VRE colony count on patient's skin.</p> | <p>Study limited by the number of patients infected and no control group, otherwise a thorough study.</p> |

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| G35 | 4 | <p>Huntley DE, Campbell J. 1998. USA.</p> <p>To assess bacterial contamination of uniforms by aerosols during dental procedures.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Dental Clinic</p> <p>26 (1M, 25F)</p> <p>Senior students treating 145 patients.</p> | <p>Aerosol contamination is produced during dental procedures, supporting OSHA's standard that long sleeves be worn to protect exposed skin during exposure prone procedures.</p> <p>Bacterial filters applied to arms and chest before patient appointment and removed after.</p> <p>Control filters 2.67 when clinic in session CFU on dominant arm 31.13, median 29 (p =0.13) Non dominant arm 31.16, median 28 (p = 0.03) Chest 22.43, median 20.5 Ultra sonic scalers and air polishers created most contamination.</p> | <p>Contamination established but not risk to patient.</p> |
| G37 | 3 | <p>Kearns HPO, Burke FJT, Cheung SW. 2001. Eire.</p> <p>To examine the infection control procedures used in general dental practice in the Republic of Ireland.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>National Survey</p> <p>177 (145M, 32F)</p> <p>Data collected on demographics, glove and mask use, sterilising and cleaning procedures and needlestick injuries.</p> | <p>92% (n = 162) used gloves routinely for all patients and procedures 4% (n =7) for selected patients and 5% (n = 8) for selected procedures 80% of routine glove users changed gloves between patients (n =130) and 93% decontaminated hands before donning gloves (n = 151) 14% of non changes felt new gloves not necessary (n = 23) 40% (n =70) had had a needlestick injury and 38% (n=67) reported glove puncture injuries.</p> | <p>Reported use may not reflect practice. High rate of compliance to glove wearing but reported practice does not necessarily reflect actual practice.</p> |

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| G39 | 5 | <p>Murray CA, Burke FJT, Mc Hugh S. 2001. UK.</p> <p>Pilot study to compare the number of glove punctures occurring in latex and nitrile gloves.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Controlled Trial</p> <p>Suggests 5 sites</p> <p>200 used and 200 unused gloves.</p> <p>5 right handed dentists in general practices used 200 of each kind of glove 200 unused gloves of each type also tested.</p> | <p>Following clinical use 1.9% of the latex gloves and 5.3% nitrile (p<0.0001) had punctures, but punctures also found in 2.5% (n=5) latex and 5.5% (n= 11) nitrile unused gloves. No statistical difference between incidence following procedure compared with unused glove.</p> <p>This could be considered to indicate good puncture resistance of the gloves tested in clinical use.</p> | <p>Small number of dentists involved in study though extensive use of the gloves</p> |
| G193 | ALL | <p>Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.</p> <p>Systematic review of the selection and use of personal protective clothing and the reduction of HAI.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Systematic Review</p> <p>Hospital acute settings.</p> <p>Study Designs: RCT, NRCT, Experimental Laboratory studies (Gloves), Descriptive Before and After Studies.</p> <p>N/A</p> | <p>There is a comprehensive description of the methodology used for the review.</p> <p>Search included Medline, Embase, CINAHL, Cochrane and DARE, references from retrieved literature and existing national and international guidelines.</p> <p>All studies were assessed for clinical utility and study quality.</p> | <p>There may have been a degree of publication bias and the heterogeneity of retrieved studies meant that studies could not be pooled.</p> |

Sharps Accepted Studies

| ID | Quest. Number | Author, Date, Country of Origin and Objective | Design, Setting, Sample Size and Population | | Outcomes | Strengths and Limitations |
|----|---------------|---|---|---|--|---|
| S8 | 2 & 3 | <p>Reddy SG, Emery RJ. 2001. USA.</p> <p>Evaluation of the effect of engineering controls (safety syringes and needleless IV systems) in reducing rates of nosocomial sharps injury (NSI).</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Hospital</p> <p>550</p> <p>Staff reporting NSI</p> | <p>Reduction in rate of NSI over 6 year period Drop from 10.6/10.3% in 1994/1995 to 6.45 in 1996 (education programme introduced) Smaller reductions over next 3 years falling 2% between 1997/99. P=<0.0001 χ^2 63.1 df =5</p> | <p>Not conducted in primary care/ community setting, but controls could be applied in setting.</p> <p>The introduction of needle safety devices should logically reduce the incidence of NSI.</p> <p>The introduction of an education programme and the OSHA standard may have had some impact on rates.</p> |
| S9 | 2 & 3 | <p>Gershon RRM, Pearse L, Grimes M, Flanagan PA, Vlahov D. 1999. USA.</p> <p>To determine the impact of a multifocused interventional programme on sharps injury rates.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Community Hospital</p> <p>693</p> <p>Staff reporting sharps injuries.</p> | <p>Significant reduction in NSI over 9 yr period. All NSI 2/3 reduction. All NSI p<.0.0001 from 82 to 24 /1000WFTE (working full time equivalent) Hollow bore NSI p< 0.05 from 196/1000 WTE (6.5 per WFTE) to 53 (1.6 per 1000 WFTE)</p> | <p>Longitudinal study that identifies sustainability, other factors such as changes in staffing levels, shift patterns not clear. Multi-interventional study does not look at the relative impact of the individual interventions. Under-reporting of NSI in general may be a factor. Only relevant to acute care, not certain that the same trend would occur in Community settings.</p> |

FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

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|------|-------|--|--|---|--|---|
| S42 | 2,3,4 | Peate WF. 2001. USA. Evaluation of the introduction of a safety lancet for use with glucometers. | Design: Setting: Sample: Popn: | Descriptive Study Urban fire service 477 (Age range from 20 to 61 years; 81% male, 9% female) Active-duty EMS workers. | Reduction in injuries from 16 per 954 work years to 2 per 477 work years. Significant at 0.05 level z test of proportions z=2.071787 | USA based with OSHA standard in place. Lancets are relatively low risk devices as they are not hollow bore. |
| S43 | 2,3,4 | Zakrzewska JM, Greenwood I, Jackson J. 2001. UK. Change programme to introduce the use of disposable safety syringes into dental practice. | Design: Setting: Sample: Popn: | Descriptive Study Dental hospital/school Qualified clinical staff and students. | Reduction in avoidable NSI in Dental School. Pre change average frequency of avoidable NSI 11.8 per 1000,000 hours worked to 0 per 1000 000 hours worked. Incidence per 100 employees fell from 20.5 pre intervention to 0 post-intervention.. Similar changes were not observed in the clinical unit. | Institutional setting not general dental practice. Comparison between school using safety syringe and a clinical unit continuing to use metal non-disposable syringes may reflect general dental practice. Costs of use may be greater in general practice. No statistical measure of certainty given. Small numbers and statistical significance not demonstrated. |
| S193 | ALL | Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK. Systematic review of the safe use and disposal of sharps and the reduction of HAI and occupational exposure. | Design: Setting: Sample: Popⁿ: | Systematic Review Acute care settings Study Designs: Before and after studies without control groups and descriptive studies were major components of retrieved studies. N/A | There is a comprehensive description of the methodology used for the review. Search included major databases, Medline, Embase, CINAHL, Cochrane and DARE, references from retrieved literature and existing national and international guidelines. All studies were assessed for clinical utility and study quality. | There may have been a degree of publication bias and the heterogeneity of retrieved studies meant that studies could not be pooled. |

APPENDIX SP4 – Reviewed evidence for this section

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Section 3 – Urinary Catheterisation

Guidelines for preventing healthcare-associated infections during long-term urinary catheterisation in primary and community care

Glossary

Words included in the glossary are marked with an asterisk (*) the first time they appear in this section.

| | |
|--|---|
| Aseptic procedure/technique | Method used to prevent microbial contamination of the catheter insertion site. This means that sterile equipment is used and that healthcare personnel wear sterile gloves or employ a no-touch technique during this procedure. |
| Bacteraemia | 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. |
| Bladder instillation | Introducing a 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 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. |
| Carer(s) | A family member or person who regularly looks after a sick, disabled or elderly person. |
| Catheter-associated Urinary Tract Infection | <p>The occurrence of local or distant clinical symptoms or signs attributable to bacteria present either within the urinary tract, or in the bloodstream (with the urinary tract as the source).</p> <p>Infection may arise:</p> <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). NB. The presence of pus cells in the urine (pyuria) of a patient with an indwelling catheter does not , by itself, signify infection. |
| 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. |
| Clean procedure/technique | Hands are decontaminated before and after the procedure. |
| Expert opinion | Opinion derived from seminal works and appraised national and international guidelines. |
| Healthcare personnel | Any person employed by the health service, social service, local authority or agency to provide care for sick, disabled or elderly people. |
| Hydrophilic catheter | 100% silicone intermittent catheter that, with the addition of water, allows virtually friction-free insertion and removal, without lubricating gel. |
| Indwelling (urethral) catheter | A catheter that is inserted into the bladder via the urethra and remains in place for a period of time. |
| Link system | An extension attached to the drainage outlet of the day bag and connected to a larger capacity night drainage bag. |
| Long-term catheter/catheterisation | A catheter left in place for 28 days or more. |
| Night drainage bag | Bags used for overnight urine collection. |
| Self-catheterisation | Urinary catheterisation undertaken by the patient. |
| Single-patient use | Items that can be used several times but are reserved for the use of one patient only. |
| Sterile | Free from any living microorganisms, |

e.g., sterile gloves, sterile catheter.

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 this tunnel.

Urethral

Relating to the tube that conveys urine from the bladder to the external urethral orifice.

Washout(s)

See 'Bladder washout'.

Section 3: Guidelines for preventing healthcare-associated infections during long-term urinary catheterisation* in primary and community care

Introduction

In the community and primary healthcare settings, long-term (>28 days) urinary catheterisation (LTC) is most commonly used in the management of the elderly and patients with neurological conditions. The prevalence of LTC in the United Kingdom (UK) has been estimated as 0.5 percent in those over 75 years old⁽¹⁾ and 4 percent in people undergoing domiciliary care.⁽²⁾ Some patients may require continuous bladder drainage using urethral* or suprapubic catheters*. Alternatively, patients or carers* may insert and remove urethral catheters at regular intervals (intermittent catheterisation).

Catheter care in the community is time consuming and expensive.⁽¹⁻³⁾ LTC should be regarded as a 'method of last resort' in the management of urinary problems as the burden both to the health service and to individual patients is high.⁽⁴⁾ However, there will remain a group of patients for whom LTC is the best option.

The method of catheterisation will depend on each patient's individual requirements, available clinical expertise and services. Infection is a major problem in LTC although there are other non-infectious complications associated with LTC, including physiological/structural damage,⁽⁵⁾ urological cancer⁽⁶⁾ and psycho-social problems.⁽⁷⁾ In selecting particular strategies to manage urinary problems, healthcare practitioners must take account of all of these complications. These guidelines focus on preventing infection. However, because infection has a complex inter-relationship with encrustation and blockage, these aspects of catheter management are also addressed.

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

1. Education of patients, their carers and healthcare personnel*;
2. Assessing the need for catheterisation;
3. Selection of catheter type and system;
4. Catheter insertion;
5. Catheter maintenance.

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Systematic review process

Two sets of guidelines were identified as a result of the search for national and international guidelines. These were retrieved and appraised using the AGREE instrument.⁽¹⁾ The appraisal for the epic phase 1 guidelines was undertaken by two external independent appraisers.⁽²⁾ These were regarded as sufficiently robust to be used as a basis for these guidelines with additional searches for outstanding questions (Appendix UC1).

After appraisal, search questions were developed from advice received from focus groups, stakeholders and our specialist advisers (Appendix UC2). The following systematic review questions were used:

1. If it is necessary to catheterise, which approach – indwelling urethra*/suprapubic /intermittent results in the lowest rates of infection?
2. Is the management or type of drainage system a factor in colonisation/infection?
3. Is the frequency or method of changing catheters (indwelling, suprapubic) a factor in colonisation/infection?
4. Does monitoring urinary pH assist in the prevention of encrustation and blockage of long term indwelling catheters?
5. Which catheters materials cause least irritation / encrustation / blockage?
6. Does the use of bladder irrigation / instillation* / washout*, prevent / reduce encrustation and symptomatic urinary tract infection?
7. Does the use of antibiotic prophylaxis at the time of changing catheters reduce symptomatic infection?
8. Which method of cleaning and storing intermittent catheters result in the lowest rates of colonisation/infection?
9. Is there any cost effectiveness evidence relating to the above?
10. What are the training and education implications for staff and patients?

In setting up the search the following MeSH terms were used: infection control; cross infection; community-acquired infections; disease transmission; urinary tract infections; urinary catheterization; indwelling catheters; antibiotic prophylaxis; irrigation; biofilms; hydrogen ion concentration; urease; proteus; proteus infections; providencia; morganella. In addition the following thesaurus and free text terms were used: intermittent catheterisation; urethral catheterisation; suprapubic catheterisation; bacteriuria*; pyuria; encrustation; blockage; non blocker; bladder irrigation; washout; bladder instillation.

These databases were searched from 1985 onwards: Medline, Cumulated Index of Nursing and Allied Health Literature (CINAHL), Embase, The Cochrane Library, National Electronic Library for Health, The NHS Centre for Reviews and Dissemination (CRD), The National Research Register, The Web of Science, The Institute of Health Technology, Health CD Database, Health Management Information, Consortium Database.

Search Results: 7387 articles were identified. These articles were initially sifted to determine if they related to infections associated with long term urinary catheters, were written in English, were primary research or were a systematic review or a meta-

analysis, and appeared to inform one or more of the review questions. Following this first sift, 978 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 75 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, 34 were accepted into the study (41 were rejected).

Evidence tables for accepted and rejected studies were generated and used to create summary reports, including evidence grades (Appendix UC3). The summary reports were used as the basis for guideline writing.

Following our reviews, guidelines were drafted which described 28 recommendations within the below 5 intervention categories:

1. Education of patients, their carers and healthcare personnel;
2. Assessing the need for catheterisation;
3. Selection of catheter drainage system;
4. Catheter insertion;
5. Catheter maintenance.

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Intervention 1 Education of patients, carers and healthcare personnel

Given the prevalence of LTC and the associated risk of clinical urinary tract infection, it is important that everyone involved in catheter management is educated about infection prevention. As many people, including children, will manage their own catheters, they must be confident and proficient in the procedure, aware of the signs and symptoms of clinical infection and how to access expert help when difficulties arise.⁽¹⁻⁴⁾

IV

Recommendations

UC1. Patients and carers should be educated about and trained in techniques of hand decontamination, insertion of intermittent catheters where applicable, and catheter management before discharge from hospital.

D

UC2. Community and primary healthcare personnel must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance.

D

UC3. Follow-up training and ongoing support of patients and carers should be available for the duration of long-term catheterisation.

D

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Intervention 2 Assessing the need for catheterisation

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

The highest incidence of healthcare-associated infection is associated with indwelling urethral catheterisation.⁽¹⁾ Many of these infections are serious and lead to significant morbidity. In acute care facilities, 20-30% of catheterised patients develop bacteriuria, of whom 2-6 percent develop symptoms of urinary tract infection (UTI).⁽¹⁾ The risk of acquiring bacteriuria is approximately 5 percent for each day of catheterisation,^(2,3) and therefore most patients with LTC are bacteriuric after 20 days of catheterisation.⁽⁴⁾

A study of patients in long-term care facilities demonstrated significantly higher morbidity and mortality in catheterised patients than in matched non-catheterised controls.⁽⁵⁾ Duration of catheterisation is strongly associated with risk of infection, i.e., the longer the catheter is in place, the higher the incidence of UTI.⁽¹⁾

IV

Best practice emphasises that all procedures involving the catheter or drainage system and the related batch codes of these devices are recorded in the patient's records.⁽⁶⁾ Patients should be provided with adequate information in relation to the need, insertion, maintenance and removal of their catheter by the person planning their care.⁽⁶⁾

Recommendations

UC4. Indwelling urinary catheters should be used only after alternative methods of management have been considered.

D

UC5. The patient's clinical need for catheterisation should be reviewed regularly and the urinary catheter removed as soon as possible.

D

UC6. Catheter insertion, changes and care should be documented.

D

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Intervention 3 Catheter drainage options

How to select the right system

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

Our search identified one systematic review⁽¹⁾ concerning the approaches to catheterisation. This reported a higher rate of infection associated with indwelling rather than intermittent catheterisation. This finding is reflected in a recent position paper⁽²⁾ on urinary tract infections in long-term care facilities by the Society for Healthcare Epidemiology of America (SHEA) who recommended that “where clinically appropriate, intermittent catheterisation should be used for urinary drainage rather than a chronic indwelling catheter.”

Ia

Two studies were identified in our search which compared catheter options.^(3,4) The first focussed on the risk of Methicillin-resistant *Staphylococcus aureus* (MRSA) colonisation and infection in nursing home patients.⁽³⁾ This study concluded that indwelling catheters posed a greater risk of infection than intermittent catheters. The second studied men with prostatomegaly and reported a significantly lower rate of infection in those with suprapubic rather than urethral catheters, despite the former being used for two weeks longer.⁽⁴⁾ A non-comparative study of patients with neuropathic bladder demonstrated a low rate of infection (6 percent) associated with the use of long-term suprapubic catheters.⁽⁵⁾ However, 30% of patients in this study reported other catheter-related complaints. Economic opinion suggests that if staff and resource use are the same, suprapubic catheterisation is more cost effective.^(5,6)

III

Eight studies were identified which focussed exclusively on the use of intermittent catheterisation. The study populations encompassed a wide range of patient groups and ages.⁽⁷⁻¹⁴⁾ One theme emerging from these studies was that the prevalence of bacteriuria is equal between men and women^(8,9) though the incidence of clinical UTI appears to be higher in women.^(8,10) There is also some evidence that bacteriuria rates are similar between adults and children.⁽¹⁵⁾

III

Generally, large studies indicated that the rates of infection associated with intermittent catheterisation were low,^(11,12) 1 per 87 months,⁽¹¹⁾ and that hydrophilic catheters* were associated with a further reduction in infection risk.^(7,10)

III

A possible alternative to indwelling and intermittent catheterisation is the penile sheath (condom catheter). Whilst our systematic review did not include a specific question related to the use of penile sheath catheters, there is evidence that this type of device may be preferable in men who are able to empty their bladder and are unlikely to manipulate the system.^(6,15) To date there are no controlled studies comparing penile sheaths with indwelling devices.

IV

Recommendations

UC7. 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.

C

UC8. Intermittent catheterisation should be used in preference to an indwelling catheter if it is clinically appropriate and a practical option for the patient.

A

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Is one catheter better than another?

A systematic review identified three experimental studies that compared the use of coated latex with silicone catheters.⁽¹⁾ No significant difference in the incidence of bacteriuria was found. Our systematic review identified one laboratory study which indicated that bacteria were less likely to adhere to hydrophilic coated catheters than silicone coated catheters.⁽²⁾ However, many practitioners have strong preferences for one type of catheter over another. This preference is often based on clinical experience, patient assessment and which materials induce the least allergic response. There is also some evidence that the balloon material on all silicone Foley catheters has a greater tendency to “cuff” on deflation than latex catheters, particularly when used suprapubically. Cuffing can cause distress and injury to patients when the catheter is removed.⁽³⁾ Our systematic review showed that smaller gauge catheters (12-14 Ch) with a 10 ml balloon minimise urethral trauma, mucosal irritation and residual urine in the bladder, all factors which predispose to catheter-associated infection.^(4,5) A non-systematic review of the literature confirmed this.⁽⁶⁾ For suprapubic catheterisation, a 16 Ch gauge catheter is usually preferable to avoid blockage.⁽⁷⁾ Where there is no difference in the quality of the catheter, the least expensive option should be used.⁽⁸⁾

III

One study⁽⁹⁾ identified by our systematic review compared the use of catheter valves* with a standard drainage system and found no significant difference in urinary tract infection but a patient preference for the catheter valve. The Medical Device Agency suggests patients need to be assessed for their mental acuity, manual dexterity, clothing preferences and use of night drainage bags* when considering using catheter valves.⁽¹⁰⁾

Ib

Recommendations

UC9. For urethral and suprapubic catheters, the choice of catheter material and gauge will depend on an assessment of the patient’s individual characteristics and predisposition to blockage.

D

UC10. In general, the catheter balloon should be inflated with 10 ml of sterile* water in adults and 3-5 ml in children.

D

UC11. In patients for whom it is appropriate, a catheter valve can be used as an alternative to a drainage bag.

A

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Intervention 4 Catheter Insertion

Catheterisation is a skilled procedure

Principles of good practice, clinical guidance^(1,2) and expert opinion*⁽³⁻⁷⁾ agree that urinary catheters must be inserted using sterile equipment and an aseptic technique*. Expert opinion indicates that there is no advantage in using antiseptic preparations for cleansing the urethral meatus prior to catheter insertion.^(1,8) Urethral trauma and discomfort will be minimised by using an appropriate sterile, single-use lubricant or anaesthetic gel. The insertion of urinary catheters by healthcare personnel who are competent in the procedure will minimise trauma, discomfort and the potential for catheter-associated infection.^(1,3,7,9)

IV

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

Ib

Recommendations

UC12. All catheterisations carried out by healthcare personnel should be aseptic procedures. After training, healthcare personnel should be assessed for their competence to carry out these types of procedures.

D

UC13. Intermittent self-catheterisation is a clean procedure*. A lubricant for single-patient use* is required for non-lubricated catheters.

A

UC14. For urethral catheterisation, the meatus should be cleaned before insertion of the catheter, in accordance with local guidelines/policy.

D

UC15. An appropriate lubricant from a single-use container should be used during catheter insertion to minimise urethral trauma and infection.

D

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Intervention 5 Catheter Maintenance

Leave the closed system alone!

Maintaining a sterile, continuously closed urinary drainage system is central to the prevention of catheter-associated infection.⁽¹⁻⁶⁾ The risk of infection reduced from 97% with an open system to 8-15% when a sterile closed system was employed as standard practice.⁽⁷⁻⁹⁾ However, breaches in the closed system such as unnecessary emptying of the urinary drainage bag or taking a urine sample increase the risk of catheter-related infection and should be avoided.^(4,9,10) Hands must be decontaminated and healthcare personnel should wear clean, non-sterile gloves before manipulation.

IV

Reflux of urine is associated with infection and, consequently, best practice suggests catheters are secured to avoid trauma and drainage bags should be positioned in a way that prevents back-flow of urine.^(4,5) Expert opinion also recommends that urinary drainage bags should be supported in such a way that prevents contact with the floor.⁽⁹⁾ For night drainage, a link system* should be used to maintain the original closed system, i.e., a bag attached to the end of the day system.⁽¹¹⁾

IV

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

IV

Recommendations

UC16. Indwelling catheters should be connected to a sterile closed urinary drainage system or catheter valve.

D

UC17. Healthcare personnel should ensure that the connection between the catheter and the urinary drainage system is not broken except for good clinical reasons, (for example changing the bag in line with manufacturer's recommendations).

D

UC18. Healthcare personnel must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves.

D

UC19. Carers and patients managing their own catheters must wash their hands before and after manipulation of the catheter, in accordance with the recommendations in the Standard Principles Section (Section 2).

A

UC20. Urine samples must be obtained from a sampling port using an aseptic technique.

D

UC21. Urinary drainage bags should be positioned below the level of the bladder, and should not be in contact with the floor.

D

UC22. A link system should be used to facilitate overnight drainage, to keep the original system intact.

D

UC23. The urinary drainage bag should be emptied frequently enough to maintain urine flow and prevent reflux, and should be changed when clinically indicated.

D

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Appropriate maintenance minimises infections **Meatal cleansing with antiseptic solutions is unnecessary**

One systematic review considered six acceptable studies that compared meatal cleansing with a variety of antiseptic/antimicrobial agents or soap and water.⁽¹⁾ No reduction in bacteriuria was demonstrated when using any of these preparations for meatal care compared with routine bathing or showering. Expert opinion⁽²⁻⁴⁾ and another systematic review⁽⁵⁾ support the view that vigorous meatal cleansing is not necessary and may increase the risk of infection. Washing the meatus with soap and water during daily routine bathing or showering is all that is needed.

Ia

Recommendation

UC24. The meatus should be washed daily with soap and water.

A

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Instillation and washouts do not prevent infection

Our systematic review suggests that more than 50% of patients with long-term catheters will experience catheter encrustation and blockage.^(1,2) A tendency to encrustation is multifactorial and includes patient factors, catheter materials and bacterial organisms. Several studies identified an association between high urinary pH (alkaline) and encrustation and blocking but there is no evidence that monitoring urinary pH can be used to predict blocking.⁽⁴⁻⁹⁾

IIa

Systematic review⁽¹⁰⁾ evidence and further evidence from one controlled trial⁽¹¹⁾ failed to demonstrate any beneficial effect of bladder instillation or washout with a variety of antiseptic or antimicrobial agents in preventing catheter-associated infection. A laboratory study demonstrated that any effect was only temporary.⁽¹²⁾ Study investigators commented that these agents may prove detrimental to patients with dehydration or low urine output. A study using a model bladder identified that whilst saline had no effect on encrustation. Suby G and mandelic acid washouts both made it more difficult for *P.Mirabilis* to adhere to catheters.⁽¹³⁾

Ia

Ib

Evidence from best practice supports the above and indicates that the introduction of such agents may have local toxic effects and contribute to the development of resistant microorganisms.⁽⁴⁾

IV

Recommendations

UC25. Each patient should have an individual care regimen designed to minimise the problems of blockage and encrustation. The tendency for catheter blockage should be documented in each newly catheterised patient.

D

UC26. Bladder instillations or washouts must not be used to prevent catheter-associated infection.

A

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Changing catheters

There is no definitive evidence as to the optimal interval for changing catheters in patients undergoing long-term urinary drainage via either the urethral or suprapubic route. Our search identified a study which suggested that a higher rate of infection was associated with frequent catheter changes, though evidence is not definitive.⁽¹⁾ Expert opinion suggests changing the catheter according to the clinical needs of the patient or as recommended by the catheter manufacturer (usually every 12 weeks).^(2,3) Our systematic review identified a study that showed if catheter blockage occurs within a shorter interval, catheters should be changed more frequently to avert a future clinical crisis.⁽⁴⁾ An economic analysis suggested that there may be a cost saving in changing a catheter at six weeks when there is an increased likelihood of blockage (>50%).⁽⁵⁾

III

Our systematic review suggests that antibiotic prophylaxis to prevent bacteraemia* at primary catheter insertion for acute retention is of proven value.⁽⁶⁾ In the community setting however, a prospective survey of 120 catheter changes without chemoprophylaxis found zero incidence of clinical complications, despite a 5.6 percent incidence of sub clinical bacteraemia detected by blood culture.⁽⁷⁾ This descriptive finding is matched by the result of an experimental study of residents in a geriatric care centre.⁽⁸⁾ Antibiotic prophylaxis was of no benefit in preventing or delaying bacteriuria following long-term catheter placement. A systematic review⁽⁹⁾ and expert opinion^(10,11) suggest antibiotic prophylaxis at catheter change should be reserved for those with a history of symptomatic UTI following catheter change, for patients catheterised between 3-14 days or to prevent endocarditis in patients with heart valve lesion, septal defect, patent ductus or prosthetic valve.

Ib

Recommendations

UC27. Catheters should be changed only when clinically necessary, or according to the manufacturer's current recommendations.

D

UC28. Antibiotic prophylaxis when changing catheters should only be used for patients with a history of catheter-associated urinary tract infection following catheter change, or for patients who have a heart valve lesion, septal defect, patent ductus or prosthetic valve.

B

References

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Re-use of intermittent catheters

Many people use disposable single-use catheters for intermittent catheterisation. Reusable single patient use catheters need to be cleaned after use. Our systematic review identified two crossover studies of young people with neurogenic bladders indicated that cleaning catheters with soap and water results in acceptably low rates of bacteriuria when compared with the use of sterile catheters.^(1,2) However, manufacturer's recommendations advise against using soap as soap residues may cause urethral irritation. Catheters should be stored in a clean and dry condition, which is least likely to promote the growth of contaminating microorganisms.

Ib

Recommendation

UC29. Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions.

D

References

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Areas for Further Research

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

Intervention 1: Assessing the need for catheterisation

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

Intervention 2: Catheter drainage options

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

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

Intervention 4: Catheter maintenance

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

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

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

Key Audit Criteria

| Aim | Criteria |
|---|--|
| Identify all patients with LTC, their clinical need for catheterisation, assessed and documented. | <p>All patients should have a patient record that documents the reason for catheterisation, type of catheter, catheter insertion, changes and care.</p> <p>Standard 100%</p> <p>Data collection: review of patient notes</p> |
| Ensure that all healthcare personnel are trained and competent in urinary catheterisation. | <p>Healthcare personnel receive training and updates in the management of urinary catheters.</p> <p>Standard 100%</p> <p>Data collection: review of staff education records</p> |
| To prevent catheter-related urinary tract infections (CR-UTI) associated with LTC | <p>All healthcare personnel decontaminate their hands and wear a new pair of non-sterile gloves before manipulating the system.</p> <p>Standard 100%</p> <p>Data collection: observation/ self audit</p> |
| To reduce the incidence of CR-UTI by maintaining a closed system. | <p>All long-term catheters must be connected to a sterile closed drainage system or valve</p> <p>Standard 100%</p> <p>Data collection: observation</p> |
| To reduce the incidence of CR-UTI caused by blocking. | <p>All newly catheterised patients should have a patient record that documents the integrity of the catheter at first change and adjustments made to their change schedule accordingly.</p> <p>Standard 100%</p> <p>Data collection: review of patient notes</p> |
| To ensure patients and carers are informed and educated about catheter management | <p>All patients and carers are aware of the need to:</p> <ul style="list-style-type: none"> • Decontaminate their hands; • Keep the system closed. <p>Standard 100%</p> <p>Data collection: direct patient questioning of patients and carers.</p> |

APPENDIX UC1 – AGREE Scores

AGREE Monitoring Appraisal Form (PHLS Ward Urinary Catheters Guidelines)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|-------------|---|---|---|-----------|----|---|---|---|-----------|---|---|----|----|----|----|-------|-----------|----|----|----|-------|-----------|----|----|-------|-----------|----|-------|-----------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 3 | 2 | 3 | 8 | 4 | 1 | 4 | 1 | 10 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 3 | 3 | 4 | 1 | 11 | 1 | 1 | 1 | 3 | 3 | 2 | 5 (44) |
| Appraiser 2 | 2 | 1 | 2 | 5 | 3 | 1 | 1 | 1 | 6 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 7 | 3 | 3 | 4 | 1 | 11 | 1 | 1 | 3 | 5 | 2 | 1 | 3 (37) |
| Appraiser 3 | 3 | 3 | 3 | 9 | 3 | 1 | 3 | 1 | 8 | 1 | 1 | 2 | 1 | 1 | 1 | 1 | 8 | 3 | 1 | 2 | 1 | 7 | 1 | 1 | 1 | 3 | 3 | 1 | 4 (39) |
| Total | 8 | 6 | 8 | 22 | 10 | 3 | 8 | 3 | 24 | 3 | 3 | 4 | 3 | 3 | 3 | 3 | 22 | 9 | 7 | 10 | 3 | 29 | 3 | 3 | 5 | 11 | 8 | 4 | 12 (120) |

Domain Scores

| | |
|--|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (22/36) x 100 = 61%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (29/48) x 100 = 60%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (24/48) x 100 = 50%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (11/36) x 100 = 31%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 3 = 84 Standardised domain score is: (22/84) x 100 = 26%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 3 = 24 Standardised domain score is: (12/24) x 100 = 50%</p> |

AGREE Monitoring Appraisal Form (The epic Project. National Evidence-based guidelines for preventing healthcare associated infections. Jan 2001)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|----------|----------|----------|-----------|----------|----------|----------|----------|-----------|----------|----------|----------|----------|----------|----------|----------|-----------|----------|----------|----------|----------|-----------|----------|----------|----------|-----------|----------|----------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 4 | 4 | 12 | 4 | 3 | 3 | 1 | 11 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 27 | 3 | 4 | 4 | 2 | 13 | 2 | 3 | 2 | 7 | 4 | 2 | 6 (76) |
| Appraiser 2 | 4 | 4 | 4 | 12 | 4 | 3 | 3 | 1 | 11 | 4 | 4 | 4 | 4 | 4 | 4 | 3 | 27 | 3 | 4 | 4 | 2 | 13 | 2 | 3 | 2 | 7 | 4 | 2 | 6 (76) |
| Appraiser 3 | 4 | 4 | 4 | 12 | 4 | 4 | 4 | 2 | 14 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 28 | 4 | 4 | 4 | 2 | 14 | 3 | 4 | 3 | 10 | 3 | 2 | 5(83) |
| Total | 8 | 8 | 8 | 36 | 8 | 6 | 6 | 2 | 36 | 8 | 8 | 8 | 8 | 8 | 8 | 6 | 82 | 6 | 8 | 8 | 4 | 40 | 4 | 6 | 4 | 24 | 8 | 4 | 17 |

Domain Scores

| | |
|---|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (36/36) x 100 = 100%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (40/48) x 100 = 83%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (36/48) x 100 = 75%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (24/36) x 100 = 67%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 3 = 84 Standardised domain score is: (82/84) x 100 = 98%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 3 = 24 Standardised domain score is: (17/24) x 100 = 71%</p> |

APPENDIX UC2 – Long-term Indwelling Urinary Catheters - Systematic Review Process

Systematic Review Questions

1. If it is necessary to catheterise, which approach – indwelling urethral/ suprapubic /intermittent results in the lowest rates of infection?
2. Is the management or type of drainage system a factor in colonisation/infection?
3. Is the frequency or method of changing catheters (indwelling, suprapubic) a factor in colonisation/infection?
4. Does monitoring urinary pH assist in the prevention of encrustation and blockage of long term indwelling catheters?
5. Which catheters materials cause least irritation / encrustation / blockage
6. Does the use of bladder irrigation / instillation / washout, prevent / reduce encrustation & symptomatic urinary tract infection?
7. Does the use of antibiotic prophylaxis at the time of changing catheters reduce symptomatic infection?
8. Which method of cleaning and storing intermittent catheters result in the lowest rates of colonisation/infection?
9. Is there any cost effectiveness evidence relating to the above?
10. What are the training and education implications for staff and patients?

Databases and Search Terms Used

DATABASES

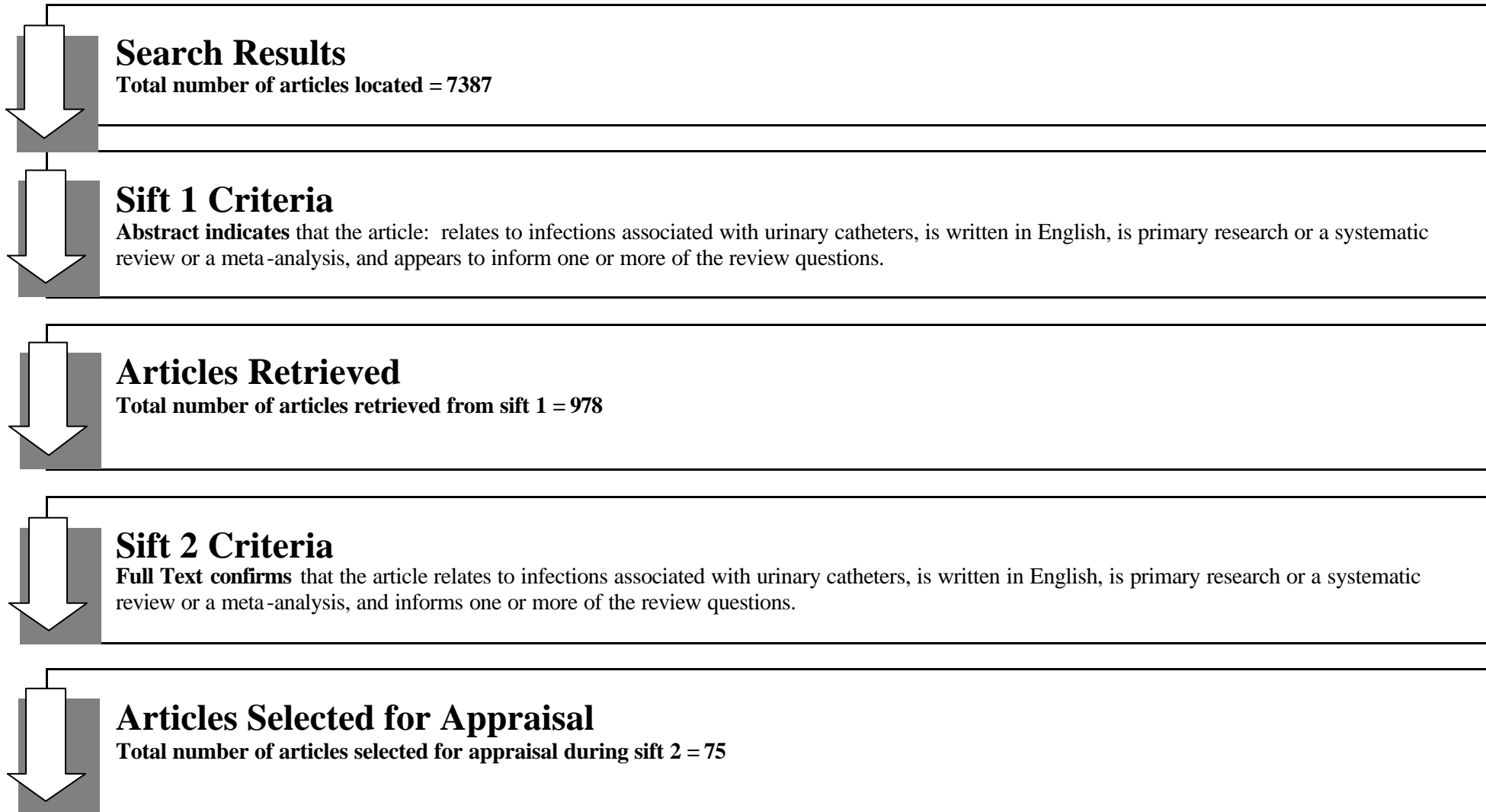
MEDLINE, CUMULATED INDEX OF NURSING AND ALLIED HEALTH LITERATURE (CINAHL), EMBASE, THE COCHRANE LIBRARY, THE NATIONAL ELECTRONIC LIBRARY FOR HEALTH, THE NHS CENTRE FOR REVIEWS AND DISSEMINATION (CRD), THE NATIONAL RESEARCH REGISTER, THE WEB OF SCIENCE, THE INSTITUTE OF HEALTH TECHNOLOGY, HEALTH CD DATABASE , HEALTH MANAGEMENT INFORMATION CONSORTIUM DATABASE.

MESH TERMS

infection control; cross infection; community-acquired infections; disease transmission; urinary tract infections; urinary catheterization; indwelling catheters; antibiotic prophylaxis; irrigation; biofilms; hydrogen ion concentration; urease; proteus; proteus infections; providencia; morganela.

THESAURUS AND FREE TEXT TERMS

intermittent catheterisation; urethral catheterisation; suprapubic catheterisation; bacteriuria; pyuria; encrustation; blockage; non blocker; bladder irrigation; bladder washout; bladder instillation.





Critical Appraisal

All articles which described primary research, a systematic review or, a meta-analysis and met the sift 2 criteria were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion.



Accepted and Rejected Evidence

Total number of articles accepted after critical appraisal = 34

Total number of articles rejected after critical appraisal = 41



Evidence Tables

Evidence tables for accepted and rejected studies were generated and used to create **evidence summary reports**. The summary reports were, in turn, used as the basis for guideline writing.

APPENDIX UC3 – Long-term Indwelling Urinary Catheters Evidence Tables

UC Accepted Tables

| ID | Quest. | Author, Date, Country of Origin and Objective | Design, Setting, Sample Size and Population | | Outcomes | Strengths and Limitations |
|-----|--------|---|---|---|---|--|
| UC6 | 1 | <p>Bakke A, Vollset SE. 1993. Norway.</p> <p>To study factors that may predict the occurrence of bacteriuria and clinical urinary tract infection in patients using clean intermittent catheterisation.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study – 1 year follow-up study</p> <p>Not stated</p> <p>302 (149M, 153F)</p> <p>Residents in Norway carrying out CIC</p> | <p>Bacteriuria equal amongst men and women. The incidence of clinical UTI over twofold higher in women during the 1 year observational period. 25% of patients had no infection at all, while only 1 or 2 lower urinary infections episodes were noted in 23%.</p> <p>More serious infection problems, including upper urinary tract infection, were noted in 17%.</p> <p>In the total male population determinants of high urinary tract infection were: Age of 45 years or less; diseases or injuries of the spinal cord above the conus; affection of the conus and peripheral nerves; high frequency of cleansing the meatus; and catheterisation not performed by patient himself.</p> <p>Determinants of high urinary tract infection in the women were, age and mean catheterisation volume $p < 0.05$. Younger women more at risk than older women.</p> | <p>Complicated descriptive study possibly compromised by the fact that infection rates and severity relied on self reporting. Large sample size.</p> <p>Many of the patients were using prophylactic antibiotics and anti-infective agents which may have had a direct effect on the results. Same cohort as UC35.</p> |

| | | | | | | |
|------|---|--|---|--|--|---|
| UC14 | 6 | <p>Getliffe KA, Hughes SC, Le Claire M. 2000. UK</p> <p>To identify the optimum volume of acidic bladder washout solution (Suby G) to dissolve catheter encrustation and to compare the effectiveness of different bladder washout delivery devices.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>24</p> <p>Pooled urine from 4 volunteers.</p> | <p>Under controlled laboratory conditions, smaller (50 ml) volumes of acidic bladder washout solution are as effective as the 100 ml commonly used, but two sequential washouts with 50 ml are more effective than a single washout.</p> <p>Optiflow as effective as the other devices.</p> | <p>Has not been tried in clinical practice but clinical implications considered. A well conducted study, each experiment repeated 5 times. Washout followed standard procedure.</p> |
| UC32 | 1 | <p>Horgan AF, Prasad B, Waldron DJ et al. 1992. Eire.</p> <p>Three year follow-up of patients who presented to the accident and emergency department with acute urinary retention due to prostatomegaly required catheterisation and were managed either by suprapubic catheters or catheterised urethrally.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study – Prospective Follow-up</p> <p>Urban Hospital Accident and Emergency Unit and Home</p> <p>86 (Males)</p> <p>Men with acute retention due to prostatomegaly.</p> | <p>30 urethral catheter – mean period 3 weeks. 56 suprapubic – mean period 5 weeks. 12 (40%) urethral group had infections. 10 (18%) suprapubic p<0.05. 5 (17%) urethral catheters developed urethral stricture compared with none in suprapubic p<0.001. 13 (23%) suprapubic catheters became dislodged.</p> <p>Prostatic symptoms – mean duration 10 months</p> <p>Makes recommendation that suprapubic catheters be used rather than urethral for the treatment of acute urinary retention.</p> | <p>A well conducted study.</p> <p>Mean duration of catheterisation is misleading due to large range.</p> |

| | | | | | | |
|------|---|---|---|--|---|--|
| UC34 | 6 | <p>Kennedy AP, Brocklehurst JC, Robinson JM. et al. 1992. UK.</p> <p>To compare the use of acidic washout solutions with neutral saline in a group of elderly catheterized females.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>3 urban hospitals</p> <p>25 (Females)</p> <p>All female patients with long-term catheters.</p> | <p>Administration of bladder irrigation using: 100 mls sodium chloride 0.9%, Suby G or Solution R for 20-30 minutes, twice weekly over a 3 week period, followed by a rest week with saline.</p> <p>Catheters changed at the end of each period.</p> <p>More crystals observed during saline washouts ($p < 0.0001$). Struvite appeared significant in saline and rarely seen in Suby G and Solution R ($p < 0.001$).</p> <p>Uric acid identified in Suby G and Solution R. Overall Solution R produced the best results and Suby G the worst.</p> <p>Suggests catheterised patients are potential blockers as they tend to become crystal formers. Acidic washouts do not appear to reduce crystals and may actually damage endothelium.</p> <p>Acidic washouts may be contra-indicated for patients with dehydration or low urine output.</p> | <p>The study addresses an appropriate and clearly focused question. Small study but the fact that it includes total population and crossover trial strengthens its validity. Only 14 completed full trial.</p> |
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|------|---|--|--|--|---|--|
| UC35 | 1 | Bakke A; Vollset SE; Hoisarter PA et al. 1993. Norway. To characterize and quantify the complications related to clean intermittent catheterisation (CIC). | Design: Setting: Sample: Popⁿ: | Descriptive prospective study Out-patients 302 (149M, 153F) Residents in Norway carrying out CIC. | Women had higher infection scores than men 2.5 Vs 1.8 (p<0.01) over 3 month period. Tendency for lower infection scores in men with increasing age (p<0.01). Lower infection score for patients using low friction catheters compared to those using PVC catheters 2.1 vs 3.7 (p<0.05). Results indicate that rates of symptomatic UT infection is lower in those using only low friction catheters compared to those using plain PVC catheters, however only 41 of the patients used plain PVC catheters. | Lack of comparison group makes it difficult to judge if there are any differences in complications with similar groups using other forms of urinary drainage. Same cohort as UC6. |
| UC36 | 5 | Roberts J, Kaak B, Fussell E. 1993. USA To evaluate bacterial adherence of 8 microorganisms to 5 urethral catheters: red rubber polytetrafluoroethylene-coated latex (Teflon), silicone elastomer-coated latex, and hydrophilic-coated latex (Lubricath). | Design: Setting: Sample: Popⁿ: | Descriptive Study Laboratory 120 samples Urine specimen taken from patient with catheter in situ. | No bacteria adhered to the inside or outside of the hydrophilic catheter surfaces regardless of preparation. Infrequent adherence to the outside of catheters except silicone. Adherence variable to the inside of Teflon and elastomer catheters but less than silicone. | No details of origin of specimen. |
| UC38 | 4 | Kunin CM, Chin QF, Chambers S. 1987. USA. To describe the factors associated with the formation of encrustations and blockage of flow of urine, and the microbial flora in the catheter and bladder urine of 50 patients aged 60+years who required a long term catheter. | Design: Setting: Sample: Popⁿ: | Descriptive Study Urban 250-bed skilled nursing home 50 (9M, 41F) Nursing home patients | Blockers tended to tolerate catheter for 7-10 days and excreted more alkaline urine, containing more calcium, protein and mucin than non-blockers. There were significant differences in the composition of 24 hour urine samples between blocked and non-blocked catheters. | The study addresses an appropriate and clearly focused question. All relevant outcomes are measured in standard, valid and reliable way. |

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|------|---|---|---|---|---|---|
| UC41 | 6 | <p>Getliffe K. 1994 (a). UK.</p> <p>To examine the effectiveness of bladder washouts of Suby G, mandelic acid 1% and saline 0.9% in reducing catheter encrustation, in a model bladder.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>15 samples</p> <p>Not relevant as synthetic urine.</p> | <p>Saline washout has no effect.</p> <p>Suggests both Suby G and mandelic acid make it difficult for P mirabilis to adhere to sides and therefore reduce encrustation</p> | <p>Laboratory study – well controlled and thorough.</p> |
| UC43 | 1 | <p>Webb RJ, Lawson AL, Neal DE. 1990. UK.</p> <p>Follow up of 172 patients using Clean Intermittent Self-Catheterisation (CISC).</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive study – Retrospective Follow-up</p> <p>Hospital out-patients at one urban hospital</p> <p>170 (gender not stated)</p> <p>Out-patients using CIC.</p> | <p>145 patients were successfully using CISC at time of writing/ Seven patients were either "unable or unwilling to master the techniques"</p> <p>Symptomatic infection rates were available in 153 patients; 70 (48%) had never had a symptomatic infection (1 total of 1187 infection free patient months) and 22 (14%). Reported only 1 infection (mean time on treatment = 32 months); 32 patients (21%) reported infection rates of less than 1 per year, 9(6%) recorded 2 infections per year, 12 (8%) had 4 infections per year and 8 (5%) complained of 6 or more infections per year. The mean infection rate was 1 per 87 patient months.</p> | <p>General study of CIC that contributes to the evidence.</p> |

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|------|---------|--|---|---|---|--|
| UC52 | 1,2,6,7 | <p>Saint S and Lipsky BS. 1999. USA.</p> <p>To provide 'an evidence based synthesis of the literature on preventing catheter-associated urinary tract infections to develop recommendations for clinicians'.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Systematic synthesis of literature</p> <p>Various (mainly hospital)</p> <p>N/A</p> <p>Adults</p> | <p>Catheterisation should be avoided when not required, and when needed terminated as soon as possible. Use of suprapubics and condom catheters may be associated with a lower risk of UTI.</p> <p>Aseptic catheter insertion and a properly maintained closed drainage system are critical to reducing risk of bacteriuria.</p> <p>Instillation of antimicrobial agents into the bladder and urinary drainage bags are crucial to reducing the risk of bacteriuria. Instillation of antimicrobial agents into the bladder or urinary drainage bag and rigorous meatal cleaning seem to be of little benefit.</p> <p>Systemic antibiotic drug therapy seems to prevent UTIs but primarily in patients catheterised for 3-14 days.</p> | <p>Only 1 database (Medline used).</p> <p>Other references identified by expert consideration and review of references in retrieved articles.</p> <p>Preference given to RCT, data on prevention summarised qualitatively. Therefore no formal metaanalysis.</p> |
| UC55 | 3 | <p>Bregenzer T, Frei R, Widmer A et al. 1997. Switzerland.</p> <p>To determine the incidence and clinical relevance of bacteraemia induced by urinary catheter replacements.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive</p> <p>2 Long-term care hospital facilities</p> <p>39 (26M, 13F). 120 routine catheter replacements.</p> <p>Geriatric patients in long-term care facilities.</p> | <p>Minimal increase in bacteraemia (27/480, 5.6%) and bacteriuria (5/120, 4.2%). 0/120 had clinical symptoms or signs of infection.</p> <p>Catheter replacement does not necessarily increase the chance of colonisation.</p> | <p>Study carried out within routine clinical practice. All subjects included underwent the same treatment. Criteria for inclusion and exclusion clearly stated. Study was restricted to elderly (over 65yrs).</p> <p>However there was no comparison group to test this.</p> |

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|------|---|--|---|--|--|--|
| UC61 | 1 | <p>Bakke A Digranes A. 1991, Norway.</p> <p>To assess the occurrence of bacteriuria in all patients using CIC in a defined population over a period of one year.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study-Prospective.</p> <p>Hospital Out Patients</p> <p>407 (206M, 201F)</p> <p>Adult out-patients using CIC Feb-Aug 1988.</p> | <p>1413 urine samples cultured. Bacteriuria in 51% of samples, no difference between male and female. Frequency of bacteriuria significantly lower in patients using antibiotics and methenamine hippurate cpw those not using anti-infectives (p<0.05). Gram -ve species higher (p<0.001) among patients using antibiotics or methenamine hippurate compared with those not using anti-infectives. Majority of patients with bacteriuria were asymptomatic.</p> | <p>1 year follow-up of a total CIC population. Epidemiological study.</p> |
| UC66 | 2 | <p>Hardyck C, Petrinovich L. 1998. USA.</p> <p>To compare the effectiveness of two drainage systems in controlling urinary tract infections and the total costs of drainable bags (DB) versus non-drainable bags (NDB).</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Patient's Homes</p> <p>82 (36M, 27F)</p> <p>Home care patients</p> | <p>UTI rate in the DB group was 1395 with 27 admissions. The NDB rate was 71 with 2 admissions. The reduction in UTIs resulted in cost savings that outweighed the higher cost of the NDB units.</p> | <p>Selection of sample unclear. Data collection based on retrospective reports from multiple informants.</p> |
| UC72 | 6 | <p>Stickler DJ, Clayton CL, Chawla JC, 1987, UK.</p> <p>To test the efficacy of povidone iodine 2% w/v, phenoxyethanol 2.4v/v, chlorhexidine 200ug/ml +/- Tris and EDTA against E. coli, Pv starti, Pr mirabili, K pneumoniae, Ps aeruginosa and S. faecalis</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>48 samples</p> <p>Sterile pooled urine.</p> | <p>With the exception of phenoxy ethanol against Pv Stuartii and possibly Ps aeruginosa, all washouts only temporarily reduced bacterial growth.</p> <p>Phenoxyethanol is the only effective antiseptic against Pv Stuartii and, if given twice against Ps aeruginosa, daily washouts of other antiseptics merely reduce microorganisms that recover within 24 hours. It is the cells in the biofilm that are the most difficult to treat.</p> | <p>A well reported laboratory study.</p> |

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|------|-------|--|---|--|--|---|
| UC74 | 4 & 5 | <p>Getliffe KA. 1994 (b). UK.</p> <p>A prospective long-term study of 47 community patients with long-term catheters, identifying them as blockers and non-blockers.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Community</p> <p>42 (18M, 24F).</p> <p>Community patients living at home or in warden controlled community settings across three health authorities.</p> | <p>Q4: Blocker status was significantly associated with high urinary pH and high urinary ammonia.</p> <p>Q5: At least 76% of all patients experienced one or more recurrent problems associated with catheterisation, with almost half (47%) complaining of urinary leakage, and nearly a third (37%) suffering from retention. A prevailing tendency towards 'crisis care' existed for patients classed as blockers. Blockers had a significantly shorter time between recatheterisations than non blockers. P<0.0001.</p> <p>Blocker status associated with females, poor mobility and with high urinary pH and ammonium, and catheters needed replacing <6 weeks.</p> <p>Q5: Blockers were significantly less mobile than non-blockers.</p> <p>Q5: There was no relationship between blocking and fluid intake.</p> | <p>The study addresses an appropriate and clearly focused question. All relevant outcomes are measured in standard, valid and reliable way.</p> |
| UC75 | 5 | <p>Roe BH, Brocklehurst J. 1987. UK.</p> <p>A preliminary investigation of patients' understanding and knowledge of their catheter's location and function, its acceptance, problems associated with its use, social implications and its subsequent management.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Qualitative Study</p> <p>A community study in one health authority</p> <p>36 (20M, 16F)</p> <p>Patients over 50 years with long-term catheter.</p> | <p>Patients with a catheter of at least 18 Charriere were more likely to experience pain 32 (89%) experienced leakage at least once a week 23 (64%) blocked with a median occurrence of between 1 and 3 months.</p> | <p>Data collected from medical/nursing records and carers as well as patients though results not clearly linked to source.</p> |

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|------|---|--|--|--|---|--|
| UC87 | 1 | Duffy LM, Cleary J, Ahern SA et al. 1995. USA. To compare the safety and cost of clean versus sterile intermittent bladder catheterization in male nursing home patients. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial 3 long term facilities 80 (Males) Veterans aged 36-96 years. | No significant differences found between clean and sterile groups with regard to: treatment episodes, time to first infection, types of organism cultured or cost of antibiotic treatment. | Randomised by research site. Previous history of UTI identified by authors as possible confounding factor. |
| UC88 | 7 | Romanelli G, Guistina A, Cravarrezza P. 1990. Italy. To evaluate the bacteriological and clinical efficacy of aztreonam in the prevention of UTI in elderly hospitalised patients who needed indwelling urethral catheterisation. | Design: Setting: Sample: Popⁿ: | Randomised controlled trial Hospital medical ward 162 (96M, 66F) Elderly hospitalised patients needing urethral catheterisation. Age range: 60-91 years. | A single dose 2g im. of aztreonam is effective in preventing UTI in elderly patients needing indwelling urethral catheters. 89% of the aztreonam group had negative urine cultures compared with 46% of the placebo p<0.001. For the diabetics, 29 received aztreonam and 30 placebo 14% and 63% respectively had UTI p<0.001. All patients were followed up for 7 days. | Not double blind. Well matched experimental group and controls. Prophylactic use of antibiotic was before first catheterisation. |
| UC91 | 5 | Getliffe K. 1990. UK. To examine a number of issues related to catheter blockage in patients at home. | Design: Setting: Sample: Popⁿ: | Descriptive Study Community settings (patients homes in one district authority). 81 (47M, 34F) Patients with indwelling urinary catheters for more than four weeks. | Despite all catheters being susceptible to encrustation and blockage, the length of time a catheter remains functional can vary and requires individual care regimens. Over 50% of patients suffer from recurrent encrustation and blockage. | All relevant outcomes are measured in a standard, valid and reliable way. However it relies on the nurses completing the questionnaire accurately and fully. |

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|------|---|--|---|--|---|--|
| UC96 | 2 | <p>Wilson C, Sandhu SS, Kaisary AV. 1997. UK</p> <p>To compare the use of a catheter-valve with the standard drainage system in terms of morbidity and patient preference.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>Hospital (one follow up at home)</p> <p>100 (84M, 16F)</p> <p>Patients undergoing long term catheterisation.</p> | <p>17 involved in crossover study, all preferred valve system.</p> <p>No significance in UTI rate between groups. Patient satisfaction significantly higher in valve group, 92% compared with those in the standard drainage group.</p> <p>Use of valve was more cost effective.</p> | <p>Lacking detail as to underlying conditions or how patient preference collected.</p> |
| UC99 | 4 | <p>Burr RG, Nuseibeh I. 1995. UK.</p> <p>To relate blockage of the urinary catheter to urine chemistry.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Spinal Injuries Unit</p> <p>44 (46M, 18F)</p> <p>Patients with spinal cord lesions with indwelling urinary catheters.</p> | <p>Catheter blockage was significantly related to the duration of cord lesion, patient age, urinary pH and calcium concentration. The only significant prediction of catheter blockage were urine pH and calcium concentration.</p> <p>Patients troubled by frequent blockage (n=21) and those who experienced no blockage (n=23) were compared. Maximum pH and calcium concentrations correctly discriminated between 91% of the patients (95% CI 78-97%).</p> <p>Urinary pH and calcium levels were higher in patients who had a more recent spinal injury.</p> | <p>Convenience sample.</p> |

| | | | | | | |
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| UC100 | 1 | Charbonneau-Smith R. 1993. Canada. To assess the effectiveness of the O'Neil Sterile Field™ urinary catheter in reducing number and length of infections in a group of spinal cord injured patients (requiring intermittent catheterisation). | Design: Setting: Sample: Popⁿ: | Descriptive Study Long-term care facility 110 (gender not stated) Traumatic spinal cord injuries. | The use of the O'Neil catheter (UK equivalent Instant Cath Protect) results in a reduction in number of infections (from 3 to 1 per person – medians) and reduction in length of infection (from 39.5 to 12.5 days – medians). Comparison was between retrospective control data and prospective experimental data. | No discussion of other changes that may have taken place in the unit between the control-experimental times that could potentially reduce number and length of infections was recorded. |
| UC113 | 1 | Terpenning MS; Bradley SF; Wan JY et al. 1994. USA. To assess colonization and infection with methicillin-resistant Staphylococcus aureus (MRSA), high-level gentamicin-resistant enterococci (R-ENT) and gentamicin and/or ceftriaxone-resistant Gram-negative bacilli (R-GNB) and the factors that are associated with colonization and infection with these organisms. | Design: Setting: Sample: Popⁿ: | Descriptive Study – Prospective Before and After Nursing home care unit 551 (542M, 9F) Patients admitted to unit June 1989 – May 1991. | Catheterisation is a significant risk factor. Infection rates tend to be lower with intermittent catheterisation than with indwelling. Statistically significant catheterisation associated with recurrent UTI (p=0.007) indwelling catheters (p=0.001). | Catheterisation only one of many risk factors studied. No details given regarding the number of patients within this sample who were catheterised. |
| UC116 | 8 | Moore KN. 1990. Canada. To compare the effectiveness of 2 solutions for cleaning plastic urethral catheters used for clear intermittent catheterisation: sunlight liquid detergent and cetrimide 1:30 (Savlon). | Design: Setting: Sample: Popⁿ: | Cross over study Home 30 (16M, 14F) Patients aged 1-18 years with neurogenic bladder using CIC for 2 months. | 60 catheters examined from each group. No difference between the two groups in terms of the contaminated catheters or type of organisms cultured 4/8 hours after cleaning. Very low colony count on contaminated catheters. | Plastic catheters were used only once, when normally they are re-used for 1-3 weeks. Therefore limited generalisability. |

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| UC122 | 8 | <p>Griffith D, Nacey J, Robinson R, et al. 1993. New Zealand.</p> <p>To determine whether microwaves were an effective means of sterilising polyethylene catheters and to provide a simple sterilisation protocol which patients using this technique could follow.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>2 groups of catheters in batches of 6 tested at 5 different times periodically. Total number not specified.</p> <p>Not stated.</p> | <p>Colony count reducing with increased duration of microwaving. After 6 mins, complete sterilisation was achieved. Suggests that this is a reliable cost-effective method for sterilising polyethylene catheters for ISC that could be carried out easily by patients. Suggests infection may be as low as 1 in 8 patient months using this technique.</p> | <p>Proteus sp bacteria were used and the authors report that their sensitivity to microwaves is similar to other species eg. E coli, Klebsiella, Pseudomonas and Enterobacter but these were not tested in this study.</p> |
| UC124 | 4 | <p>Kunin C. 1989. USA.</p> <p>To study the blocker/non blocker 'phenomenon':</p> <ol style="list-style-type: none"> 1. How consistently do patients remain as blockers or non blockers? 2. Do blockers have more febrile episodes? 3. Is there a relationship between formation of encrustations and: urinary microbial sp.; production of urease; pH and constituents of urine? 4. Do some organisms protect against encrustations? 5 Does antimicrobial therapy alter formation of encrustations? | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>260 bed nursing home.</p> <p>65 (Females)</p> <p>Nursing home patients with indwelling catheters.</p> | <p>Urine of blockers was significantly more alkaline and contained less Mg PO₄ and urea than non blockers.</p> | <p>No comment on the advisability of monitoring urinary pH.</p> |

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| UC125 | 7 | Firestein M, Mendelson D, Gronich E et al. 2001. Israel. To investigate whether prophylactic antibiotics given during catheter replacement can prevent or delay the development of subsequent bacteriuria | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Geriatric Centre 70 (21M, 49F) Residents with long-term urinary catheters. | Treatment group 1gm of IV meropenem 30 minutes before catheterisation. Use of prophylactic antibiotic did not prevent or delay development of bacteriuria after long term urinary catheter replacement. No significant difference in urine cultures between treatment and control groups at 3, 7, 14 or 28 days. | Patients recruited had no antibiotics for previous 2 weeks. Random allocation to treatment. Treatment and control groups similar. Regular follow-up over 28 days. |
| UC128 | 4 | Choong S, Wood S, Fry C et al. 2001. UK. To determine the relationship between urinary pH, UTI and encrustation in patients with long term catheters. | Design: Setting: Sample: Popⁿ: | Descriptive Study Setting not stated 64 (gender not stated) Patients with long-term indwelling urinary catheters. | Non-blockers had a significantly more acidic voided urine pH (6.26) with a wide safety margin between voided and crystallization pH (7.66) and no infection. | No patient details included. Not clear how many specimens taken or over what time frame. |
| UC137 | 1 | Perrouin-Verbe B, Labat JJ, Richard I et al. 1995. France. 1. To evaluate the overall rate of complications of CIC. 2. To record reasons for acceptance of CIC, frequency of UTI and rates of urethral strictures. | Design: Setting: Sample: Popⁿ: | Retrospective period prevalence survey Rehabilitation hospital Aim 1: 159 (113M, 46F) Aim 2: 21 Spinal cord injury patients. | Aim 1: 60% had asymptomatic cytobacteriological infection (39.7% females; 66% males); 28% symptomatic infection (17.3 females; 32.7% males) P<0.05 in both groups. Aim 2: Symptomatic infections <1 every 2 yrs in 11pts; <1 a year in 1 pt; 1-2 episodes in 5; 2-4 times a year in 4pts. Asymptomatic cytobacteriological infections: <1 infection every 2 yrs in 15; <1 per year in 2; 1-2 times per yr in 2; 2 pts had permanent antimicrobial prophylaxis. | Non-random sample from total population. Outcomes well defined. Authors suggest a comparative study should be undertaken. |

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| UC138 | 1 & 8 | <p>Moore KN, Kelm M, Sinclair O et al. 1993. Canada.</p> <p>To test the hypothesis that bacteriuria would be reduced in subjects who used single-use rather than clean reused catheters for intermittent self catheterisation.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Crossover Study (Randomised Controlled Trial)</p> <p>Clinic at children's hospital</p> <p>2 samples. 30 in crossover (15M, 15F). 23 comparisons.</p> <p>Spina bifida children age range: 3-16 years.</p> | <p>Q1: 6 months crossover using sterile single-use catheters or clean reused. A comparable group used sterile catheters only. 38% +ve cultures in crossover groups regardless of whether sterile single use or clean reused catheters were employed. Compared with 36% +ve cultures in the group using only sterile catheters. No differences between males and females, those performing self or parental catheterisation.</p> <p>Q8: Soapy water and rinsing can be used as method of cleaning a catheter for re-use.</p> | <p>Crossover design adds to internal validity.</p> <p>Only conducted amongst subjects with spinabifida and therefore generalisability may be limited.</p> |
| UC140 | 1 | <p>Sheriff MK, Foley S, Mc Farlane J et al. 1998. UK.</p> <p>To identify the current place of long-term suprapubic catheterisation in the management of neuropathic bladder, how should these be best managed and what do patients think about this form of bladder management.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Neurological unit</p> <p>157 (80M, 77F)</p> <p>Patients referred to neurological unit.</p> | <p>9 (6%) developed recurrent UTI. 28 (18%) experienced blockages. 12 (8%) leakage.</p> <p>Overall 30% of patients had catheter related complaints.</p> <p>Suggests suprapubic catheterisation is an effective and well tolerated method for patients with neuropathic bladder for whom surgery is the only option.</p> | <p>Well designed study conducted in a standard, valid and reliable way.</p> |

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| UC143 | 3 | <p>White MC, Ragland KE. 1995. USA.</p> <p>To determine in home care patients on long term urinary catheterisation:</p> <ol style="list-style-type: none"> 1. the urinary catheter infection rate, 2. the characteristics of patients who get UTI's compared with those who do not, 3. the influence of catheter change interval on the length of time patients remain infection free. | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Historical Cohort Study</p> <p>Patient's Home</p> <p>106 (gender not stated)</p> <p>Home care patients</p> | <p>Only patients who were free of infection at the start of home care period were included in analysis: n=81. Incidence = 20.9 infections/10,000 catheter days.</p> <p>Of those whose catheters were changed at intervals of 2 weeks or less – 15.4% remained free of infection after 4 weeks. Those whose catheters were changed at 4 to 6 week intervals – 80% remained free of infection after 6 weeks. The number of different nurses changing the catheter was also significant, with a relative hazard of 1.38 (CI 1.22 – 1.55). Relative hazard rate for infection = 11.94 (CI 5.46-26.22) for catheter change \leq 4 weeks versus catheter change $>$4 weeks. This analysis controlled for age, sex, severity of illness and number of nurses changing catheter.</p> | <p>Limitations: retrospective chart review; data on other risk factors for infection e.g. co-morbidities not collected/not available.</p> |
| UC145 | 4 | <p>Burr RG, Nuseibeh IM. 1997. UK</p> <p>To study the relationship between urine pH and calcium to catheter blockage and suggest how to reduce encrustation.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Spinal Injuries Centre</p> <p>60 (42M, 18F)</p> <p>Spinal injuries patients</p> | <p>Mean and maximum circadian pH and Ca was higher in blockers than non-blockers. pH and calcium urine measurement in laboratory correctly diagnosed 56-58 (96.6%) as blockers or non-blockers.</p> | <p>Included newly injured patients whose calcium levels may have been higher than normal.</p> <p>No information on patient selection.</p> |

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| UC149 | 1 | <p>Shekelle PG, Morton SC, Clark KA, Pathak M, Vickrey BG. 1999. USA.</p> <p>To identify controlled clinical trials, cohort and cross sectional studies that assessed risk factors for UTI and included bacteriuria or UTI as an outcome.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Systematic Review</p> <p>Not reported</p> <p>Multiple studies</p> <p>Adults and adolescents over the age of 13 years with neurogenic bladder due to spinal cord dysfunction.</p> | <p>Eight studies were reviewed using different populations and were consistent in their findings: persons using intermittent catheterisation had fewer infections than those with indwelling catheters and those voiding without catheters.</p> | <p>Well-conducted systematic review but the many of studies are quite old.</p> <p>Databases searched and selection criteria clearly stated.</p> |
| UC193 | All | <p>Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.</p> <p>To develop national evidence-based guidelines for preventing hospital acquired infections associated with the use of short-term indwelling urethral catheters.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Systematic Review</p> <p>Acute care settings</p> <p>Study Designs: Mainly controlled trials, some experimental and descriptive.</p> <p>N/A</p> | <p>Comprehensive description included in technical report.</p> <p>All databases included, 7 in total. No hand searching.</p> <p>All articles subjected to clinical review and critical appraisal.</p> | <p>For some areas only low grade evidence available</p> |

UC Rejected Studies

| ID | Quest. Number | Author, Date and Country of Origin | Objective | Design, Setting, Sample Size and Population | | Reasons for Rejection |
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| UC5 | 6 | Pearman JW, Bailey M, Harper WE. 1987. Australia. | To compare the efficacy of Trisdine and Kanamycin-colistin in reducing bacteriuria in new spinal injuries patients. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Spinal Injuries Unit 18 (15M, 3F) Spinal cord injury patients. | The sample size is not appropriate. |
| UC9 | 1 | Eika B, Frøkipper J. 1989. Denmark. | The aim of this study was to analyse a group of women using CISC. | Design: Setting: Sample: Popⁿ: | Descriptive Study - Retrospective Review Not reported 80 (Females) Women with neurogenic and non neurogenic voiding problems. | Unreliable data source. |
| UC10 | 6 | King JB, Stickler DJ, 1992. UK. | To examine the activity of repeated installations of chlorhexidine 0.02%w/v, chlorhexidine/EDTA/TRIS and mandelic acid 1.0%w/v against established infections of Pseudomonas aeruginosa, Proteus mirabilis, Providencia stuartii and Escherichia coli. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory Not available. Not available. | Laboratory study using bladder model. |

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| UC12 | 4 | Mobley HLT, Warren JW. 1987. USA. | To observe the incidence of urease production and blockage in women 65 years with silicone- latex coated catheters in place for 100 days. | Design: Setting: Sample: Popⁿ: | Descriptive Study Setting not stated 32F > 65 years Long-term catheterised | Study question unclear. No details of recruitment or sample. |
| UC23 | 6 | Robertson MH, Norton MS, 1990, UK. | To test the effect of 1% mandelic acid bladder washouts on 40 patients with indwelling urethral catheters. | Design: Setting: Sample: Popⁿ: | Experimental Study Hospital In-Patients (assumed as no detail). 40 Patients with indwelling catheters harbouring Proteus or Pseudomonas sp. but asymptomatic. | Too many items missing, e.g., setting, characteristics of study population. |
| UC24 | 6 | Muncie HL, Hoopes JM, Damron DJ et al. 1989. USA. | To ascertain whether once daily irrigations of long-term catheters with normal saline has an effect on the formation of encrustation and blockage and the development of infection. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Urban hospital 44 (gender not stated) Patients with long-term indwelling catheters. | High dropout rate (21/41). |
| UC27 (now UC147) | 6 | Maizels M, Schaeffer AJ. 1980. USA. | To determine whether the incidence of bacteriuria can be reduced in catheterised patients by instilling hydrogen peroxide into the drainage bag. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Spinal cord injury unit. 31 (24M, 7F) Acute spinal injuries. | Sample too small for study design. |

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| UC28 | 4 | Hedelin H, Larsson L, Eddeland A et al. 1985. Sweden. | To observe which factors affected the frequency of catheter blockage and change within a 6-week schedule. | Design: Setting: Sample: Popⁿ: | Descriptive Study Department of long-term care and rehabilitation 19 (5M, 14F) No information | Sample underpowered. |
| UC30 | 1 | Mitsui T, Minami K, Furuno T et al. 2000. Japan. | Long-term outcome of spinal cord injury (SCI) patients was compared between those managed by suprapubic cystomy (SPC) and clean intermittent catheterisation (CIC). | Design: Setting: Sample: Popⁿ: | Descriptive Study - Long term Follow-up Outpatients 61 (57M, 4F) Spinal cord injury patients. | Method and criteria for determining infection and other complications not stated. Methodology not clear. Follow-up time different. Groups comparable in terms of age, sex and sample number but Group A were high cervical lesions and Group B low cervical lesions preventing meaningful comparison. |
| UC44 | 1 | Hellstrom P, Tammela, T, Lukkarinen O et al. 1991. Finland. | To investigate the efficacy, safety and complications of clean intermittent catheterisation | Design: Setting: Sample: Popⁿ: | Descriptive Study Hospital Outpatients 41 (26M, 15F) Patients attending urology department | Sample too small given variables such as: age range, the wide range of underlying / pre-existing aetiologies, different frequency of CIC, and no monitoring of catheterisation techniques, e.g., hand washing. No stats given. |

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| UC45 | 4 | Hedelin H, Bratt CG, Eckerdal G et al., 1991, Sweden. | To correlate urinary pH with the precipitation of catheter encrustation and detect any unusual urea-splitting bacteria in catheter urine samples with a raised pH but without growth of urease-producing bacteria. | Design: Setting: Sample: Popⁿ: | Descriptive Study Hospital with 500 beds for long-term care and rehabilitation 11 (8M, 3F) No information | Sample underpowered. No baseline measures. |
| UC47 | 6 | Elliott TSJ, Reid L, Gopal Rao G et al. 1989. UK. | To test the effect of bladder washouts on the urothelium. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Not stated 50 (30M, 20F) Control – normal adult men. Women had long-term indwelling urinary catheters. | Small study – only females in intervention group. |
| UC54 | 4 | Kohler-Ockmore J. 1991. UK. | To identify factors which may cause catheter blockage and how they may be overcome. | Design: Setting: Sample: Popⁿ: | Descriptive Study Community; own home and nursing homes 54 3 health districts residents with catheters for >3 months. | <i>No information on gender, confounding conditions or catheter types.</i> Analysis poor and incomplete. |

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| UC58 | 7 | Wiseman O. 1997. UK. | To determine the management of long-term urinary catheter in asymptomatic patient in the Accident and Emergency department. | Design: Setting: Sample: Popⁿ: | Descriptive Study (Retrospective) Accident and Emergency department 40 patients with 80 presentations (68M, 12F) A&E | <i>Audit though described as research. Flawed urine collection method.</i> |
| UC71 | 8 | Kurtz MJ, Van Zandt K, Burns JL. 1995. USA. | To identify a single effective and inexpensive cleaning method that could be recommended to clients using intermittent catheterisation. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory 16 Children re-using non-latex catheters for IC. | Small sample. |
| UC73 | 2 | Roe BH. 1990. UK. | To test the effects of an education programme (including an information booklet and demonstration) on the management of urine drainage systems by patients and carers. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Community (Home and Home Care) 45 (gender not stated) 2 district health authority, patients >18 years of age. | Small sample inadequate for statistical tests. Method of randomisation not stated. Drop out rate unacceptable. |

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| UC78 | 8 | Mervine J, Temple R. 1997. USA. | <p>To determine the effect on:</p> <ol style="list-style-type: none"> 1. the concentration of bacteria of washing (with soap and water) red rubber and clear plastic intermittent-use catheters, 2. the amount of time in a microwave oven required to eliminate stock bacteria from red rubber and clear plastic catheters, 3. the effect of repeated use of a microwave oven on the patency and pliability of red rubber and clear plastic catheters. | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Pop^a:</p> | <p>Experimental</p> <p>Laboratory</p> <p>Urine from patients was used but it is not stated how many specimens were obtained.</p> <p>Patients in urban hospital giving urine for routine culture or on CIC.</p> | <p>No detail on sample size or patient details.</p> <p>No statistical analysis.</p> |
| UC79 | 1 & 7 | Prieto-Fingerhut T, Banovac K, Lynne CM. 1997. USA. | <p>To determined the effect of sterile and nonsterile intermittent catheterisation on the incidence of urinary tract infection (UTI) in patients after spinal cord injury.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Pop^a:</p> | <p>Randomised Controlled Trial</p> <p>Medical Rehabilitation Centre</p> <p>29 (16M, 13F)</p> <p>Spinal cord injury patients</p> | <p>Numbers are small. Method of randomisation not stated.</p> <p>No details of reliability of catheterisation techniques.</p> <p>No baseline measurements.</p> |

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| UC80 | 1 | Terpenning MS, Allada R, Kauffman CA. 1989. USA. | A prospective study of elderly patients receiving IC for development of bacteriuria and/or urinary tract infection. | <p>Design: Descriptive Study (Prospective Follow-up study)</p> <p>Setting: Veteran Administration Hospital and nursing home</p> <p>Sample: 35 (34M, 1F)</p> <p>Popⁿ: Patients aged 60 years and over with long-term catheter.</p> | Total population not given and no idea of refusals/drop outs. Sample size too small given two sites. No standardisation of catheter used. Descriptive statistics only. |
| UC81 | 1 | Ouslander JG, Greengold B, Chen S. 1987. USA. | To examine the relative frequency of urinary tract infection (UTI) and bacteriuria among male nursing home patients managed with and without catheters. | <p>Design: Descriptive Study – Comparative Follow-up</p> <p>Setting: Nursing Home</p> <p>Sample: 92 (Males)</p> <p>Popⁿ: Male nursing home residents.</p> | Comparison group preferentially included patients with a past history of a GU diagnosis. Significant differences among the groups that could have affected their susceptibility to infection. Observation uncontrolled but long follow up period. No baseline measurements of UTI. Many confounding variables. Small sample, two groups which do not meet power requirements. |
| UC83 | 1 | Johnson DE, Muncie HL, O'Reilly JL et al. 1990. USA. | To assess the safety and efficacy of a new external urine collection system for women. | <p>Design: Descriptive Study - Observational</p> <p>Setting: Hospital and a medical centre</p> <p>Sample: 26 (Females)</p> <p>Popⁿ: All women over 65 years old not receiving antibiotics.</p> | Insufficient description of methodology. |

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| UC86 | 1 | Quigley PA, Riggin OZ. 1993. USA. | To determine whether there was a difference in the incidence of urinary tract infection that occurred following use of two types of catheterization (intermittent) techniques: open catheterization and closed catheterisation. | <p>Design: Randomised Controlled Trial</p> <p>Setting: Hospital rehabilitation</p> <p>Sample: 30 (gender not stated)</p> <p>Popⁿ: Rehabilitation patients, spinal cord injuries and stroke patients.</p> | Small sample - 14 in the control group and 16 experimental groups. Groups not treated equally. No stats. Multiple factors affecting reliability of data collection. |
| UC89 | 1 & 6 | Pearman JW, Bailey M, Riley LP. 1991. Australia. | To compare the incidence of "significant bacteriuria" following two different methods of intermittent catheterisation, a) nelaton catheter with Trisidine instillation and b) O'Neal catheter (Nelaton with introducer) in patients with acute spinal chord trauma. | <p>Design: Uncontrolled randomised trial</p> <p>Setting: Urban hospital spinal department</p> <p>Sample: 37 (30M, 7F)</p> <p>Popⁿ: Patients with acute spinal cord trauma.</p> | The sample size is not appropriate. Groups not homogenous. No baseline measurements. Unreliable in terms of standardisation and monitoring of catheterisation technique. No identification of confounding variable. |
| UC92 | 1 | Wyndale JJ, Maes D. 1990. Belgium. | To study the long term effects and complications resulting in patients using intermittent self catheterisation. | <p>Design: Descriptive Study - Retrospective Follow-up</p> <p>Setting: Hospital Outpatients/rehabilitation</p> <p>Sample: 75 (33M, 42F)</p> <p>Popⁿ: Patients using CISC.</p> | Method used to select patients or source of patients unclear. Insufficient information on demographics of sample. No baseline measures. Patients monitored over varying lengths of time. |

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| UC94 | 8 | Silbar EC, Cicmanec JF, Burke BM et al. 1989. USA. | To see whether microwaving would make aseptic intermittent self-catheterisation a practical possibility. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory No details given about patients. Patients with UTI | No details are given about the population and sample. Greater concentration of bacteriuria used than would have been found on a patient. |
| UC95 | 1 | Taylor CED, Hunt GM, Matthews IG. 1986. UK. | A comparison was made between two groups of children using CIC. | Design: Setting: Sample: Popⁿ: | Descriptive Study Assume hospital outpatients at Addenbrookes, Cambridge 24 (1M, 23F) Myelomeningocele and spina bifida patients. | Small sample. No attempt to control acknowledged extraneous variables. No baseline measurements. |
| UC97 | 2 | Bennett CJ; Young MN; Razi SS et al. 1997. USA. | To determine whether an introducer tip catheter reduces urinary tract infection in spinal cord injured patients on intermittent catheterisation. | Design: Setting: Sample: Popⁿ: | Descriptive Study Hospital 19 (gender not stated) Spinal cord injuries unit. | Small sample. Variability in number of catheterisations was high. Sampling method unclear. |
| UC98 | 1 | Perkash I, Giroux J. 1993. USA. | To evaluate long-term clean intermittent catheterisation for genito-urinary complications ' in non-hospitalised spinal cord injury patients and to ' institute and evaluate prompt management. | Design: Setting: Sample: Popⁿ: | Descriptive Study – Observational/follow-up Community setting/Outpatients 50 (Males) Spinal cord injuries. | Small sample. 66% discontinued. |

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| UC109 | 2 | Joseph C, Jacobsen C, Strausbaugh L et al. 1991. USA. | A pilot study of intermittent urinary catheterisation in elderly nursing home patients utilizing a new modification of clean technique and conventional sterile technique. | <p>Design: Randomised Controlled Trial</p> <p>Setting: Elderly Nursing Home Care Unit.</p> <p>Sample: 14 (Males)</p> <p>Popⁿ: Residents >50 years of age.</p> | Pilot study which states sample inadequate. Study protocol not adhered to. |
| UC114 | 1 & 2 | Oie S, Kamiya A, Seto T et al. 2000. Japan. | To evaluate the microbial contamination of a widely used in-use lubricant for non-touch urethral catheters. | <p>Design: Descriptive Study</p> <p>Setting: Out patients department</p> <p>Sample: 46</p> <p>Popⁿ: Attendees at hospital outpatient department.</p> | This system is not used in the UK. Potential sample bias. |
| UC117 | 1 | Maynard FM and Glass J. 1987. USA. | To report on 5 year urological outcomes in a population of new spinal cord injury patients who were all managed initially by clean technique of intermittent catheterisation. | <p>Design: Descriptive Study – Observational</p> <p>Setting: Outpatients</p> <p>Sample: 40 (33M, 7F)</p> <p>Popⁿ: Out-patients</p> | Self reports of estimated frequency over the last year of UTI, not necessarily confirmed by lab reports and lab reports not available to researcher. Relies on long term memory. Unclear when follow up occurred and this may have been variable between patients. No stats available, may have been that sample size was too small. |

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| UC118 | 7 | Orrett FA & Permanand N. 1993. Trinidad. | Presumed objective to identify the prevalence and incidence of bacteriuria developing in chronically catheterised out-patients who have been prescribed prophylactically systematic antibiotic therapy at each out-patients clinic visit. | Design: Setting: Sample: Popⁿ: | Descriptive Study Hospital outpatient clinic 120 (119M, 1F) Urology out-patients | States this is a RCT but methodology unclear, no control group. No statistics provided. Timing of microbiological assessment unclear. Also unclear whether the results of this study are directly applicable to the patient group targeted by the study. |
| UC121 | 6 | Nesbit SA, Katz LE, McClain BW et al. 1999. USA. | To compare the efficacy of amphotericin B 10mg vs. 50mg per litre of sterile water as a continuous irrigation for 72 hours to eradicate funguria. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Urban hospital, medical floor or intensive care 28 (8M, 20F) All hospitalised patients whose physicians ordered amphotericin B continuous bladder irrigation. | Small study that failed to recruit adequate numbers. |
| UC127 | 6 | Linsenmeyer TA, Jain A, Thompson BW. 1999. USA | To determine the effectiveness of neomycin/polymyxin bladder irrigations in asymptomatic spinal cord injury patients with resistant organisms. | Design: Setting: Sample: Popⁿ: | Descriptive study Rehabilitation Unit 10 (7M, 3F) Spinal cord injury patients who had undergone bladder irrigation. | Small study, two people had two sets of irrigation. Use of statistics inappropriate in this sample. |

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| UC130 | 8 | Sims L, Ballard N. 1993. USA. | To review the records of spinal cord injured subjects and compare two CIC catheter cleaning and storage procedures (wet and dry). | Design: Setting: Sample: Popⁿ: | Descriptive Study (Retrospective) Neurological rehabilitation unit 48 (37M, 11F) Spinal cord injury patients. | The findings may have been influenced by the between group differences in length of time of catheterisation intervals. Potential lack of sensitivity in detecting a type 2 error. Generalisability limited due to convenience sampling. Sampling bias due to unequal distribution of subjects and small sub groups. Limited reliability of retrospective data collection. |
| UC131 | 3 & 7 | Polastris F, Auckenthaler R, Loew F et al. 1990. Switzerland. | To quantify the micro-organisms present in blood at urinary catheter removal and reinsertion. To identify whether: Q3: there was an increased risk of bacteriuria during UC removal and insertion, Q7: prophylactic antibiotics would be useful before this manipulation. | Design: Setting: Sample: Popⁿ: | Descriptive Study Geriatric Medical Centre 33 (15M, 18F) Patient's chronic indwelling catheter positive urine cultures. | Lack of clarity on sampling technique, e.g. 33 patients specified – 46 cases in group 2. |

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|-------|---|---|---|--|--|---|
| UC133 | 1 | Kuhn W, Rist M, Zaech G. 1991. Switzerland. | Presumed aim is to record long term outcomes (bacteriological 'evolution', acceptance, continence and complications) of IUSC. | Design: Setting: Sample: Popⁿ: | Descriptive Study Paraplegic centre 46 (27M, 19F) Patients using ISC. | The study does not address an appropriate and clearly focused question. The selection of subjects to the study may have induced bias. |
| UC134 | 1 | Wyndaele JJ, de Taeye N. 1990. Belgium. | To evaluate intermittent self catheterisation with intermittent catheterisation performed by a catheter team. | Design: Setting: Sample: Popⁿ: | Descriptive Study Spinal injury unit 25 (22M, 3F) Paraplegics | Outcomes difficult to measure given that some patients (unspecified) had pre-existing UTI. Unspecified number of patients received antibiotics during the study. |
| UC135 | 1 | Yadav A, Vaidyanaathan S, Panigrahi D. 1993. India. | Presumed aim was to record the frequency of infective episodes' in two groups of patients with neuropathic bladders who used clean intermittent catheterisation. | Design: Setting: Sample: Popⁿ: | Descriptive Study Spinal injury unit 48 (gender not stated) Patients with neuropathic bladders. | The study does not address an appropriate and clearly focused question. The selection of subjects to the study has induced bias. Measurements not standardised. |
| UC139 | 1 | Sadowski A, Duffy L, 1988, USA. | To investigate the current usage, procedural differences, incidence of documented urinary tract infections and staff satisfaction with CIC in a long term care setting. | Design: Setting: Sample: Popⁿ: | Descriptive Study (Survey) Long term care facilities 103 facilities Patients in long term care using urinary catheters. | Questionnaire study with poor response (48%) and reporting bias. |

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| UC141 | 2 | Giannantoni A, Du Stasi SM. Scivoletto G et al. 2001. Italy. | To compare patients' acceptance and safety related to the use of the conventional Nelaton catheter and the prelubricatd nonhydrophilic catheter in spinal cord injured patients on intermittent catheterization. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Hospital in-patients 18 (16M, 2F) Spinal cord injury patients. | Sample too small for RCT. |
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APPENDIX UC4 - Reviewed evidence for this section

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SECTION 4 – Enteral Feeding

Guidelines for preventing healthcare-associated infections during enteral feeding in primary and community care

Glossary

Words included in the glossary are marked with an asterisk (*) the first time they appear in this section.

| | |
|---|---|
| Buried bumper syndrome | A complication of PEG tubes where the internal disc becomes buried in the stomach lining. |
| Closed System | Sterile, pre-filled ready-to-use feeds that do not expose the feed to the air during assembly. |
| Enteral feeding | Feeding via a tube that can include any method of providing nutrition via the gastrointestinal tract. |
| Expert opinion | Opinion derived from seminal works and appraised national and international guidelines. |
| HACCP (Hazard analysis and critical control point) | Hazard analysis and critical control point. A system to identify potential hazards in food preparation. |
| 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. |
| No touch technique | Avoiding direct contact of the hand with feed ingredients. |
| 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. |
| Ready-to-use | Feeds prepared and supplied by the manufacturer, that only require attaching to the feeding tube. |
| Single use | For use on one occasion only. |

SECTION 4: Guidelines for preventing healthcare-associated infections during enteral feeding* in primary and community care

Introduction

Once enteral feeding (EF) in hospital became common practice in the late 1980s, it was inevitable that those requiring prolonged feeding would continue this treatment at home. Enteral feeding is usually prescribed for patients in hospital requiring artificial nutrition support (ANS) for 7-10 days and long term feeding / home enteral tube feeding (HETF) may be considered for patients needing ANS for more than 30 days.⁽¹⁾ HETF has expanded rapidly and by the end of 2000, 11,817 adult patients receiving HETF were registered with the British Artificial Nutrition Survey (BANS).⁽²⁾ Of these, 46.5% were over 70 years of age. Over 60% of the patients were receiving tube feeds because of disorders of the central nervous system, of which cerebral vascular accident accounted for 34%. It was reported that over half the adult patients and virtually all children starting home enteral feeding lived in their own home and 40% of adults lived in nursing homes.

Nutrition Support Teams (NST) are recommended to support patients receiving artificial nutrition.⁽²⁾ However, only 22% of NST stated that they were responsible for HETF and 47% stated that they were never responsible.⁽²⁾ In addition, only one third felt that they had sufficient time to train patients on HETF prior to discharge from hospital. It is therefore not surprising that enteral feeding places a growing workload on community healthcare personnel⁽³⁾ and an audit of patients on HETF highlighted a need for continuing support.⁽⁴⁾ Contamination of feeds is a key concern in HETF as it has been found that more than 30% of feeds in hospital and home are contaminated with a variety of microorganisms, largely due to the preparation or administration of feeds,⁽⁵⁾ and this has been linked to serious clinical infection.⁽⁶⁾ The rates of contamination are highest in home settings and reinforces the need for infection prevention guidelines.⁽⁵⁾

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

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

1. Education of patients, their carers and healthcare personnel;
2. Preparation and storage of feeds;
3. Administration of feeds;
4. Care of insertion site and enteral feeding tube.

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Systematic review process

Three sets of guidelines were identified as a result of the search for national and international guidelines. These were retrieved and appraised using the AGREE instrument.¹ As all were written prior to 1995, they did not score highly in some areas and their contribution has been used as expert opinion* only. (See Appendix EF1)

After appraisal, search questions were developed from advice received from focus groups, stakeholders and our specialist advisers (See Appendix EF2). The following systematic review questions were used:

1. Was one type of feeding system superior to others in terms of infection rates?
2. Did the administration of the feed contribute to infection?
3. Was it safe to reuse equipment used in the administration of feeds?
4. Were there any storage issues that contribute to infection?
5. Was the stoma site a source of infection?
6. Was there any cost effectiveness evidence relating to the above?
7. What were the training and education implications for staff and patients?

In setting up the search the following MeSH terms were used: cross infection; community acquired infection; infection control; food contamination; equipment contamination; enteral nutrition, nutritional support, gastrostomy, gastroenterostomy, jejunostomy. In addition the following thesaurus and free text terms were used: home nutrition; home artificial nutrition; PEG feed; tube feed; tube nutrition; gastric feed; gastric nutrition; enteral feed; enteric feed; nasoenteric; intragastric; post-pyloric; percutaneous; transpyloric; gastrojejunostomy; gastroduodenostomy; duodenostomy.

These databases were searched from 1990: Medline, Cumulated Index of Nursing and Allied Health Literature (CINAHL), Embase, The Cochrane Library, National Electronic Library for Health, The NHS Centre for Reviews and Dissemination (CRD), The National Research Register, The Web of Science, The Institute of Health Technology, Health CD Database, Health Management Information, Consortium Database.

Search Results: 19369 articles were identified. These articles were initially sifted to determine if they related to infections associated with enteral feeding, were written in English, were primary research or were a systematic review or a meta-analysis, and appeared to inform one or more of the review questions. Following this first sift, 301 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 42 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, 30 were accepted into the study (12 were rejected).

Evidence tables for accepted and rejected studies were generated and used to create summary reports, including evidence grades (Appendix EF3). The summary reports were used as the basis for guideline writing.

Guidelines were then drafted which described 15 recommendations within the below 4 intervention categories:

1. Education of patients, their carers and healthcare personnel;
2. Preparation and storage of feeds;
3. Administration of feeds;
4. Care of insertion site and enteral feeding tube.

References

1. The AGREE Collaboration (June 2001) *Appraisal of Guidelines for Research and Evaluation (AGREE) Instrument*. London, St. George's Hospital Medical School.

Intervention 1 Education of patients, carers and healthcare personnel

Although not a specific question for our systematic review, it has become evident from our research that the responsibility for preparing and administering HETF lies usually with the patient, their carers and in some cases, community healthcare personnel. An audit of the nursing knowledge of percutaneous endoscopic gastrostomy (PEG)⁽¹⁾ of hospital nurses in a district general hospital identified gaps in their knowledge and management of enteral feeding systems and a similar situation was noted in the community.⁽²⁾ The BANS survey noted the less than optimum support people on HETF receive⁽³⁾ despite expert opinion stressing the need for education and training.^(4,5) Given that nutrition is a key Department of Health patient-focused benchmark for healthcare practitioners,⁽⁶⁾ it is of concern that this does not include those receiving artificial nutrition and consequently support and preparation for these patients is not widely available.

IV

A system known as Hazard Analysis and Critical Control Point (HACCP)* is employed widely in the food industry to highlight areas where food safety may be at risk. The Parenteral & Enteral Nutrition Group of the British Dietetic Association supports the use of HACCP in enteral feeding to increase safety and as an educational tool.⁽⁷⁾

Recommendations

- | | |
|---|---|
| EF1. Patients and carers should be educated about, and trained in the techniques of hand decontamination, enteral feeding and the management of the administration system before being discharged from hospital. | D |
| EF2. Community staff should be trained in enteral feeding and management of the administration system. | D |
| EF3. Follow-up training and ongoing support of patients and carers should be available for the duration of home enteral tube feeding. | D |

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Penlines 2000;**16**:3-8.

Intervention 2 Preparation and storage of feeds

Select the right system

Our systematic review identified two randomised controlled trials, which demonstrated that closed systems* (i.e., sterile prefilled ready-to-use* feeds that do not expose feed to the air during assembly) as available from all major manufacturers, have lower contamination rates than open systems*.^(1,2)

Ia

The design of the system is also important in order to minimise handling.⁽³⁻⁵⁾

IIa

Recommendations

EF4. Wherever possible pre-packaged, ready-to-use feeds should be used in preference to feeds requiring decanting, reconstitution or dilution.

A

EF5. The system selected should require minimal handling to assemble, and be compatible with the patient's enteral feeding tube.

B

References

1. Wagner DR, Elmore MF, Knoll DM. Evaluation of "Closed" Vs "Open" Systems for the Delivery of Peptide-Based Enteral Diets. *Journal of Parenteral and Enteral Nutrition* 1994; **18**(5):453-457.
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Hygienic preparation of feeds is essential

Hand hygiene is critical and hand decontamination is discussed more fully in Standard Principles (SP1-6 pages 31 - 36). The International Scientific Forum on Home Hygiene has also published comprehensive guidance on food preparation and cleanliness in the home.⁽¹⁾ Our systematic review identified three studies⁽²⁻⁴⁾ concerned with feed preparation. The evidence on the use of gloves is contradictory. Two studies^(2,3) suggested that gloves were preferable and one suggested bare hands if properly decontaminated were acceptable.⁽⁴⁾ However all three studies linked contamination to the amount of manipulation a system required and reinforces the guidance above.

IIb

Standard principles stress the importance of hand decontamination and expert opinion⁽⁵⁻⁷⁾ stresses the need to prepare the work surface and, where necessary the equipment for reconstituting or diluting the feed. Equipment used for either opening sterile feeds or preparing feeds should be dedicated for enteral feeding use only. It should be cleaned in a

IV

dishwasher or washed with hot soapy water, rinsed and then dried and stored covered until required. Cooled boiled water or freshly opened sterile water should be used to prepare feeds in the home.^(5,8)

Recommendations

- | | |
|---|---|
| EF6. Effective hand decontamination must be carried out before starting feed preparation. | A |
| EF7. When decanting, reconstituting or diluting feeds, a clean working area should be prepared and equipment dedicated for enteral feed use only should be used. | D |
| EF8. Feeds should be mixed using cooled boiled water or freshly opened sterile water and a no-touch technique*. | D |

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8. Whittingham S. *Pocket guide to clinical nutrition. Supplement 12: Microbiological Control*, London BDA. 2001:16p.

Store feeds safely

Expert opinion⁽¹⁾ and manufacturers^(2,3) advise that ready-to-use, prepackaged feeds should be stored in a clean environment, protected from extremes of temperature. Stock should be rotated to avoid feeds exceeding their best before date.

IV

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

IV

Recommendations

- | | |
|--|---|
| EF9. Feeds should be stored according to manufacturer's instructions and, where applicable, food hygiene legislation. | D |
| EF10. Where ready-to-use feeds are not available, feeds may be prepared in advance, stored in a refrigerator, and used within 24 hours. | D |

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3. Abbott nutrition. *Home feeding solutions: Your guide to how the Abbott Hospital to Home Service works*. Abbott Laboratories Ltd. 2001:10p.

Intervention 3 Administration of feeds

Minimal handling reduces risk

Four reports,⁽¹⁻⁴⁾ which studied enteral feeds delivered in a variety of settings, demonstrated that the risk of contamination is related to the manipulation of the system and the system design. This reinforces earlier guidance about selecting a system that requires minimal handling.

Ib

When assembling the system, first assess the condition of the connection. A no-touch technique should be used to connect the feed container to the administration set using the minimum number of connectors possible. Contact with the patient's clothes should be avoided when attaching the administration set to the enteral feeding tube.⁽⁵⁾

IV

Administering feeds for the maximum time possible reduces handling to a minimum. Sterile ready-to-hang feeds can be left for a maximum time 24 hours and non-sterile (reconstituted) feeds for 4 hours.^(5,6) However even closed systems can become contaminated if hands are not adequately decontaminated.⁽³⁾

III

Bacterial contamination has been associated with the re-use of feed bags and administration sets.⁽⁷⁾ One study in a long term care facility⁽²⁾ suggested that administration set changes could be left up to 72 hours but other studies^(6,8-10) suggested that 24 hours is the maximum time acceptable. Three experimental, in vitro studies⁽¹¹⁻¹³⁾ considered the re-use of equipment but none identified a satisfactory system for disinfecting equipment that might be acceptable in practice. As evidence suggests re-use is not advisable, the administration system should be considered single use* only and discarded after each session.

IIb

Currently there appears to be a debate on the re-use of single use syringes used to flush enteral feeding tubes. Our systematic review found no evidence to either support or refute the reuse of syringes. The Medical Device Agency's current guidance is that items labelled single use must not be reused under any circumstances and the reuse of such items has legal implications.⁽¹⁴⁾

Recommendations

EF11. Minimal handling and an aseptic no-touch technique should be used to connect the administration system to the enteral feeding tube.

C

EF12. Ready-to-use feeds can be given for a whole administration session, up to a maximum of 24 hours. Reconstituted feeds should be administered over a maximum 4-hour period.

C

EF13. Administration sets and feed container are for single use and must be discarded after each feeding session.

B

References

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Intervention 4 Care of insertion site and enteral feeding tube

Keep the tube clear

Our systematic review searched for evidence regarding the stoma site as a source of infection. Although some evidence related to infection immediately after insertion of the first tube, we have found no evidence relating to infections in a healed stoma.^(1,2) However, after the stoma site has healed, usually 10-12 days after placement, no dressings are necessary. Instead the site should be inspected and cleaned daily, and dried thoroughly. The tube should be rotated 360 degrees regularly to avoid infections related to ‘buried bumper syndrome’*.⁽³⁾

IV

To help minimise the potential risk of microbial colonisation of the internal and external surfaces of enteral feeding tubes, expert opinion suggests that the tube should be flushed with either cooled boiled water or freshly opened sterile water before and after each change of feed, aspiration or drug administration.⁽⁴⁻⁵⁾ However, expert advice from specialist members of the Guideline Development Group suggests that fresh tap water may be safely used for flushing enteral feeding tubes in immunocompetent patients.^(6,7)

IV

Recommendations

EF14. The stoma should be washed daily with water and dried thoroughly.

D

EF15. To prevent blockage, the enteral feeding tube should be flushed with fresh tap water before and after feeding or administering medications. Enteral feeding tubes for patients who are immunosuppressed should be flushed with either cooled freshly boiled water or sterile water from a freshly opened container.

D

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Areas for Further Research

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

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

Descriptive studies of enteral feeding practices in a range of primary care trusts.

This should include healthcare personnel, patients and carers, their preparation to undertake enteral feeding and ongoing support, availability and use of equipment. Data should also be collected on the incidence of stoma site infections.

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

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

Intervention 2: Preparation and storage of feeds

Epidemiological studies of the incidence of clinical infection associated with reconstituting enteral feeds for different populations and in different care settings.

These should at least encompass the predominant populations - older people and those with neurological deficits in both institutional and domiciliary settings and children. There needs to be clear definition of the 'cases' and the populations from which they are drawn.

Intervention 3: Administration of feeds

Randomised controlled trials of single use, single patient use and reusable syringes.

Outcome measures need to include rates of clinical infection, patient/carer satisfaction and cost effectiveness.

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

Key Audit Criteria

| Aim | Criteria |
|---|--|
| Identify all patients undergoing HETF are linked to a Nutrition Support Team or community specialist for ongoing support. | <p>All patients should have a patient record that documents their contact person for ongoing support.</p> <p>Standard 100%</p> <p>Data collection: Review of patient notes</p> |
| Ensure that all healthcare personnel are trained and competent in administration of HETF. | <p>All healthcare personnel involved in the care of people receiving enteral feeding are trained and updated</p> <p>Standard 100%</p> <p>Data collection: Review of staff education records</p> |
| To prevent infections associated with the administration of HETF. | <p>All healthcare personnel decontaminate their hands before starting feed preparation and manipulating the system.</p> <p>Standard 100%</p> <p>Data collection: Observation/ self audit, incidence of HETF related infection.</p> |
| To prevent infections associated with the administration of HETF by maintaining a closed system. | <p>Ready-to-hang feeds are used wherever possible, and hung for no longer than the maximum recommended time.</p> <p>Standard 100%</p> <p>Data collection: Observation/ patient records, incidence of HETF related infection.</p> |
| To prevent infections associated with the administration of HETF caused by blocking. | <p>All patients should have a patient record that documents the care of their enteral tube, including flushing regimen</p> <p>Standard 100%</p> <p>Data collection: Review of patient notes, incidence of HETF related infection.</p> |
| To ensure patients and carers are informed and educated about HETF. | <p>All patients and carers are aware of the need to:</p> <ul style="list-style-type: none"> • Decontaminate their hands; • Keep the system closed. <p>Standard 100%</p> <p>Data collection: direct patient questioning of patients and carers.</p> |

APPENDIX EF1 – AGREE SCORES

AGREE Monitoring Appraisal Form (Enteral and Parenteral Nutrition in the Community – British Association for Parenteral and Enteral Nutrition. Nov 1994)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|----------|----------|----------|-----------|----------|----------|----------|----------|-----------|----------|----------|----------|----------|----------|----------|----------|-----------|----------|----------|----------|----------|-----------|----------|----------|----------|-----------|----------|----------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 4 | 4 | 12 | 4 | 1 | 2 | 1 | 8 | 1 | 1 | 1 | 4 | 1 | 1 | 1 | 10 | 2 | 2 | 4 | 2 | 10 | 4 | 1 | 1 | 6 | 4 | 1 | 5 (50) |
| Appraiser 2 | 3 | 3 | 4 | 10 | 4 | 2 | 3 | 1 | 10 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 8 | 4 | 2 | 3 | 2 | 11 | 3 | 2 | 1 | 6 | 2 | 1 | 3 (48) |
| Total | 7 | 7 | 8 | 22 | 8 | 3 | 5 | 2 | 18 | 2 | 2 | 2 | 6 | 2 | 2 | 2 | 18 | 6 | 4 | 7 | 4 | 21 | 7 | 3 | 2 | 12 | 6 | 2 | 8 |

Domain Scores

| | |
|--|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (22/24) x 100 = 92%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (21/32) x 100 = 65%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (18/32) x 100 = 56%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (12/24) x 100 = 50%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 2 = 56 Standardised domain score is: (18/56) x 100 = 32%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 2 = 16 Standardised domain score is: (8/16) x 100 = 50%</p> |

AGREE Monitoring Appraisal Form (Guidelines for the use of parenteral and enteral nutrition in adult and pediatric patients. ASPEN 1993)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|-------------|---|---|---|-----------|---|---|---|---|----------|---|---|----|----|----|----|-------|-----------|----|----|----|-------|-----------|----|----|-------|----------|----|-------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 3 | 3 | 4 | 10 | 3 | 1 | 3 | 1 | 8 | 1 | 1 | 1 | 1 | 3 | 3 | 4 | 14 | 4 | 3 | 4 | 1 | 12 | 1 | 1 | 1 | 3 | 2 | 1 | 3 (50) |
| Total | 3 | 3 | 4 | 10 | 3 | 1 | 3 | 1 | 8 | 1 | 1 | 1 | 1 | 3 | 3 | 4 | 14 | 4 | 3 | 4 | 1 | 12 | 1 | 1 | 1 | 3 | 2 | 1 | 3 |

Domain Scores

| | |
|--|--|
| <p>Domain 1 Maximum possible score = 4 x 3 x 1 = 12 Standardised domain score is: (10/12) x 100 = 83%</p> | <p>Domain 4 Maximum possible score = 4 x 4 x 1 = 16 Standardised domain score is: (12/16) x 100 = 75%</p> |
| <p>Domain 2 Maximum possible score = 4 x 4 x 1 = 16 Standardised domain score is: (8/16) x 100 = 50%</p> | <p>Domain 5 Maximum possible score = 4 x 3 x 1 = 12 Standardised domain score is: (3/12) x 100 = 25%</p> |
| <p>Domain 3 Maximum possible score = 4 x 7 x 1 = 28 Standardised domain score is: (14/28) x 100 = 50%</p> | <p>Domain 6 Maximum possible score = 4 x 2 x 1 = 8 Standardised domain score is: (3/8) x 100 = 38%</p> |

AGREE Monitoring Appraisal Form (American Gastroenterological Association – Guidelines for the use of enteral nutrition. Nov 1994)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|-------------|---|---|---|-----------|---|---|---|---|----------|---|---|----|----|----|----|-------|-----------|----|----|----|-------|-----------|----|----|-------|----------|----|-------|---------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 1 | 2 | 2 | 5 | 1 | 1 | 2 | 1 | 5 | 1 | 1 | 1 | 2 | 2 | 1 | 1 | 9 | 1 | 3 | 3 | 2 | 9 | 1 | 1 | 1 | 3 | 1 | 1 | 2 (33) |
| Appraiser 2 | 3 | 1 | 2 | 6 | 1 | 1 | 1 | 1 | 4 | 1 | 1 | 1 | 2 | 1 | 1 | 1 | 8 | 3 | 3 | 3 | 2 | 11 | 1 | 1 | 1 | 3 | 1 | 1 | 2 (34) |
| Total | 4 | 3 | 4 | 11 | 2 | 2 | 3 | 2 | 9 | 2 | 2 | 2 | 4 | 3 | 2 | 2 | 17 | 4 | 6 | 6 | 4 | 20 | 2 | 2 | 2 | 6 | 2 | 2 | 4 |

Domain Scores

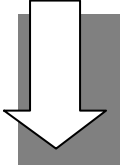
| | |
|--|--|
| <p>Domain 1 Maximum possible score = $4 \times 3 \times 2 = 24$ Standardised domain score is: $(11/24) \times 100 = \mathbf{46\%}$</p> | <p>Domain 4 Maximum possible score = $4 \times 4 \times 2 = 32$ Standardised domain score is: $(20/32) \times 100 = \mathbf{63\%}$</p> |
| <p>Domain 2 Maximum possible score = $4 \times 4 \times 2 = 32$ Standardised domain score is: $(9/32) \times 100 = \mathbf{28\%}$</p> | <p>Domain 5 Maximum possible score = $4 \times 3 \times 2 = 24$ Standardised domain score is: $(6/24) \times 100 = \mathbf{25\%}$</p> |
| <p>Domain 3 Maximum possible score = $4 \times 7 \times 2 = 56$ Standardised domain score is: $(17/56) \times 100 = \mathbf{30\%}$</p> | <p>Domain 6 Maximum possible score = $4 \times 2 \times 2 = 16$ Standardised domain score is: $(4/16) \times 100 = \mathbf{25\%}$</p> |

APPENDIX EF2: Enteral feeding - Systematic Review Process

The Systematic Review Process

Systematic Review Questions

Review questions are devised based on the scope of the review and advice from the Guideline Development Group, stakeholders and professional bodies.

- 
1. Was one type of feeding system superior to others in terms of infection rates?
 2. Did the administration of the feed contribute to infection?
 3. Was it safe to reuse equipment used in the administration of feeds?
 4. Were there any storage issues that contribute to infection?
 5. Was the stoma site a source of infection?
 6. Was there any cost effectiveness evidence relating to the above?
 7. What were the training and education implications for staff and patients?

Literature Search

Databases to be searched are determined together with search strategy, i.e., relevant medical subject headings (MESH), free text and thesaurus terms.

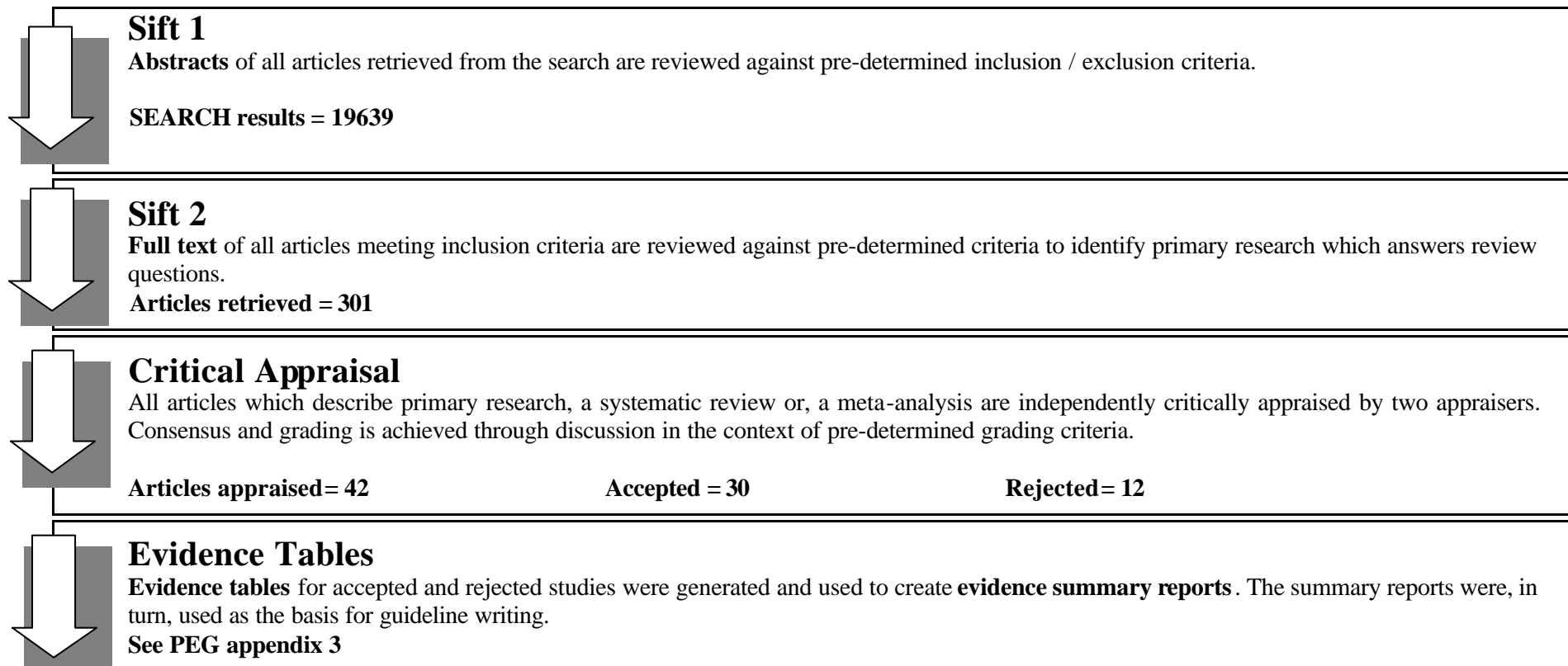
MESH TERMS

infection control; cross infection; community-acquired infections; food contamination; equipment contamination; enteral nutrition, nutritional support, gastrostomy, gastroenterostomy, jejunostomy.

THESAURUS & FREE TEXT TERMS

PEG feed; tube feed; tube nutrition; gastric feed; gastric nutrition; enteral feed; enteric feed; naso enteric feed or nutrition; intra gastric feed or nutrition; post pyloric feed or nutrition; percutaneous feed or nutrition; transpyloric feed or nutrition; gastrojejunostomy; gastroduodenostomy; duodenostomy.

Exclusions : letters



APPENDIX EF3 – Enteral feeding Evidence Tables

EF Accepted Studies

| ID | Quest. Number | Author, Date, Country of Origin and Objective | <i>Design, Setting, Sample Size and Population</i> | | Outcomes | Strengths and Limitations |
|----|---------------|--|--|-------------------------------|---|---|
| P1 | 1 | Dentinger B, Faucher KJ, Ostrom SM et al. 1995. USA. Assess the contamination in a closed system of enteral feeding over 36 hours. | Design: | Experimental Laboratory Study | Of the 211 samples, 18 had one cfu and one had 137 colony forming unit (CFU). That is 19 (9%) had some contamination. No feeding bottles had separation or coagulation (not defined) immediately or one week after the study indicating they had no contamination. It appears from the data presented here that microbiological contamination does not enter from the formula, closed system or administration set. | Patients were not actually fed; the level of contamination is extremely likely to be an underestimate of the level observed when patients are fed. A higher protocol standard than normal regarding handling was used. Study supported by industry. |
| | | Setting: | Care Centre | | | |
| | | Sample: | 211 containers were used to simulate continuous enteral feeding for 36 hours. | | | |
| | | | Popⁿ: | In-patients of care facility. | | |
| P2 | 1 | Beattie TK and Anderton A. 1998. UK. To compare the risks of introducing microbial contamination when assembling and running two commonly used, ready-to-hang, enteral feeding systems with a newly introduced feeding system. Nutrition glass bottles and steriflo vs nutrition pack. | Design: | Experimental | Results indicate sterilisation of a sealed system (steriflo), prior to assembly or during further manipulation, reduces microbiological contamination. Disinfection of a non-sealed system of nutrition glass bottles does not prevent contamination when faulty handling occurs. | Lack of standardisation between the 7 protocols in terms of interventions and numbers of samples makes comparison difficult. No details of control. |
| | | Setting: | Laboratory | | | |
| | | Sample: | 7 experimental protocols reported 5 times per protocol. NB sampling variable for each protocol. Total samples=90 (5x11) + baseline:-7x5. | | | |
| | | | Popⁿ: | Laboratory Study | | |

| | | | | | | |
|----|---|--|---|--|---|--|
| P6 | 1 | <p>Weenk GH, Kemen M and Werner HP. 1993. Germany.</p> <p>To compare four enteral feeding systems in terms of their ability to limit the chance of introducing microbial contamination during the set up of the systems: nutriset bag, nutriset container, nutriset crown cork bottle and nutriset steriflo.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>2 hospital intensive care units (ICUs) and 2 simulated ward conditions</p> <p>48 cultures</p> <p>Not stated</p> | <p>NB ">" indicates the system(s) on the left of the sign had higher levels of counts – which is worse - than the system(s) to the right of the sign.</p> <p>1: samples with cfus just after setting up time (0 hrs), no significant diff between systems (although there were difference observed in cfus: Bag>all other methods)</p> <p>2: a) samples with different levels of counts after 6 hrs (crown cork) 12 hrs (all other systems): no significant differences between systems at 100cfu/ml level b) looking at the systems with ANY cfus (vs. NO cfus): Bag> crown cork, container>Steriflo significant at 5%</p> <p>3: number of bags with no counts after incubation for 72hrs: Bag>Crown cork, container, Steriflo significant at 5%</p> <p>Steriflo system emerged as safest in this study.</p> <p>BUT NOTE:</p> <p>1: no feed samples reached 100cfu/ml during the times they were recommended for ward use (6hr for crown cork; 12 hrs for all others) 2: the significant differences between systems were measuring absence of counts, NOT the British Dietetic Standards of 100cfu/ml</p> | <p>The main issue in the interpretation of this paper is whether total absence of cfus is important (in which case Steriflo is the best) or whether the BDA standard should be used, in which case, there is no significant difference between systems. Patients do not appear to have been involved.</p> |
|----|---|--|---|--|---|--|

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|----|---|--|---|--|--|--|
| P7 | 1 | <p>Wagner DR, Elmore MF, Knoll DM. 1994. USA.</p> <p>To quantify: factors associated with the use of three different feeding-delivery systems for peptide-based diets, sterile closed, open system-can, open system powder:</p> <ul style="list-style-type: none"> • preparation time • total formula waste • bacterial contamination | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Random Controlled Trial</p> <p>Two critical care units in a community hospital</p> <p>Samples: 87 closed system (CS), 72 open system can (OS-Can), 60 open system powder (OS-powder).</p> <p>Critical care patients requiring enteral feeding</p> | <p>1: initial contamination: No contamination in any CS, compared with 22 (30%) of OS-Can and (60) 100% of OS powder, with ANY growth (differences between OS-Can and OS-Powder significant) $p<0.001$.</p> <p>2: initial contamination: No high contamination (defined as $>10,000\text{cfu/ml}$) in any CS, compared with 4(5%) in OS-Can and 24(40%) in OS Powder (differences between OS-Can and OS-Powder significant) $p<0.001$.</p> <p>3: final contamination: 5 (6%) of CS, 58 (80%) of OS-Can and 60 (100%) of OS powder had any growth at the end of delivery (difference between CS and other two systems significant) $p<0.001$.</p> <p>4: final contamination (high) 2 (2%) CS had high contamination compared with (60%) OS-Can and 50 (83%) OS Powder (all differences significant) 43 ($p<0.001$).</p> | <p>The BDA standard of 100 cfu/ml is not used or reported so it is not possible to compare the results with other similar studies. Inadequate information given about potentially confounding factors.</p> |
| P8 | 1 | <p>Herlick SJ, Vogt C, Pangman et al. 2000. Canada.</p> <p>Compare open and closed systems in two long-term care facilities (each with two units) on the following:</p> <p>a) Bacterial contamination</p> <p>b) Diarrhoea</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Crossover Experiment</p> <p>4 chronic care units in two long-term care facilities</p> <p>36. Facility A-13, B-23</p> <p>People with brain injury</p> | <p>Bacterial contamination:</p> <p>Overall, with the 72 samples: no growth at all in 20 (56%) of closed systems compared with only 1 (3%) of open systems no significant level reported).</p> <p>High contamination (greater than 10,000 cfu/ml) found in 78% open samples compared with 39% from closed system ($p<0.05$)</p> <p>Coliform found in 5.6% of closed system compared with 28% open system (significant at $p<0.05$)</p> <p>BUT: there were no significant differences in facility A compared with very highly significant differences in facility B between the two systems.</p> | <p>It would appear that differences between sites can be larger than differences between systems.</p> <p>Several study measures were affected by different prescribing practices. Also, some of the nurses at A had previous experience of a closed system, whereas none at B had this. Finally, the system at B required a more difficult connection to a foley catheter.</p> <p>The study is, perhaps, a little small in size, but appears well-conducted with major sources of confounding identified or removed.</p> |

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|-----|-------|---|---|--|---|--|
| P9 | 1 | <p>Vanek VW. 2000. USA.</p> <p>To review the compliance rate with maximum enteral feeding hang-time policy for open vs. closed systems and to determine the incidence of tube feeding contamination.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive</p> <p>One hospital site many different units</p> <p>138 (69M, 69F)</p> <p>In-patients requiring enteral feeding</p> | <p>67% compliance for open delivery system. 10 closed systems hung for 20.8 – 45.8 hours sterile. 8 open systems hung for 6.8 – 26.6 hours. Compliance with hang times 67% open 88% closed. 2 contaminated. Recommend closed systems whenever possible.</p> | <p>Many different sites within the hospital but all patients included.</p> |
| P12 | 1 & 2 | <p>Lee CH, Hodgkiss IJ. 1999. Hong Kong.</p> <p>To compare two commercially available enteral feeding systems IsoSource Closed system (Novartis), and Compat Pumpset (Novartis) and the effect on the level of contamination when subjected to different handling procedures.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>2 experimental protocol repeated 3 times per protocol. Total sample = 24 (3x6) + (baseline x 6)</p> <p>Laboratory Study</p> | <p>Suggests a complete ready assembled system is best to reduce risk of contamination and wearing of gloves.</p> <p>No bacterial contamination with sterile gloves even when manipulation faulty</p> <p>Bare hand contamination noted at 4 hours and rising</p> <p>Contaminated hands contamination noted at 4 hours at a higher level than bare hands</p> <p>No differences between the 2 systems “to resist bacterial challenge”.</p> <p>No contamination was detected when clean non-sterile gloves were used but study showed it was possible to deliver a sterile feed even when using bare hands. Conclusion is that the level of contamination is related to the degree of manipulation of the system.</p> | <p>No details of control.</p> |

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|-----|---|--|---|---|--|
| P13 | 2 | <p>Graham S, McIntyre M, Chicoine J et al. 1993. Canada.</p> <p>To determine whether more prolonged intervals between bag and tubing changes adversely affected patient health.</p> | <p>Design: Randomised Trial</p> <p>Setting: 417 bed long-term care facility</p> <p>Sample: 11 patients for the first study period and 12 for the second.</p> <p>Popⁿ: Elderly, clinically stable and suffering neurological disease.</p> | <p>No significant differences in morbidity when 24 hour tube changes compared with 72 hours.</p> <p>The results indicate that it may not be necessary to change tubing and bags every 24 hours and that they could be left for 72 hours without increased infection.</p> | <p>A range of feeding access was used, including nasogastric which may have had some bearing on the result.</p> <p>2 study periods, data collection and definition. Consistent sampling frame known. Randomisation method satisfactory and explicit.</p> |
| P15 | 2 | <p>McKinlay J, Anderton A, Wood W et al. 1995. UK.</p> <p>To compare the levels and types of micro-organisms present in residual feed in nutritional containers and giving sets when either 500mls or 1000 mls pre-filled, ready-to-hang nutritional containers were used to administer 1-2 litre quantities of feed to patients on hospital wards over 24 hours using a single giving set over this period.</p> | <p>Design: Randomised Controlled Trials</p> <p>Setting: Urban hospital</p> <p>Sample: 42 (gender not stated)</p> <p>Popⁿ: In-patients requiring enteral feeds.</p> | <p>Number of days feeds contaminated: 3/30 (10%) 500ml 2/30 (7%) 1000ml Most frequently and heavily contaminated from distal end.</p> <p>The results indicate that the more frequently the bags are changed the more likely it is that the feed will become infected.</p> | <p>No information on patients' underlying conditions.</p> |

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| P16 | 2 | <p>Patchell CJ, Anderton A, Holden C et al. 1998. UK.</p> <p>To examine the effects of improvements in the enteral feeding protocol, coupled with an intensive staff training programme on bacterial contamination.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Urban Hospital/Some patients' homes</p> <p>21 children (gender not stated)</p> <p>All patients receiving Nutrison paediatric standard as an enteral feed.</p> | <p>In patients: using the new protocol only 3/77 (4 %) of samples were contaminated at the end of the administration period as compared with 28 (45%) using the old protocol. p<0.001</p> <p>Home patients: 2/36 (6%) samples contaminated compared with 8 (28%) at the start and 18 (62%) at the end under previous protocol. p<0.001.</p> <p>New protocol involved priming the feeding on an alcohol treated metal tray, spraying the bottle opener and top with 70% alcohol wearing sterile non-disposable gloves and filling the feeding reservoir with feed for up to 24 hours use rather than 4 hours.</p> | <p>No patient details given. Small sample. Cannot identify which changes to the protocol are the most important.</p> |
| P17 | 2 | <p>Rupp MM, Weseman R, Nedra M et al. 1999. USA.</p> <p>To determine whether prolonged infusion of a sterile, closed system, non-air dependent enteral feeding solution was associated with bacterial contamination or nosocomial infection.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive study</p> <p>Urban hospital</p> <p>15(7M, 8F)</p> <p>Patients who underwent liver transplantation</p> | <p>5 patients had 8 nosocomial infections, none associated with feeds. Mean infusion time 22.7 hours. None contaminated. Concludes that when properly handled, non-air dependent, sterile, closed system enteral feeds can be safely administered with hang times of 24 hours.</p> | <p>The patients were particularly ill in this study and sample small. Met power calculation.</p> |

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| P19 | 2 | <p>Patchell CJ, Anderton A, MacDonald A, George I et al. 1994. UK.</p> <p>To define further the mechanisms producing feed contamination and the setting in which it occurs' comparing the contamination of a modified feed with a ready-to-use feed in hospital and at home.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Trial</p> <p>One Urban Hospital in-patients compared with home patients</p> <p>35 children (21M, 14F)</p> <p>Children 1-5 years or weighing 8-20 Kg receiving at least 50% energy needs via enteral feeding.</p> | <p>Inpatients: Although no contamination of the modular feeds was detected immediately after mixing 14% had evidence of contamination by the start of administration, which had increased to nearly 50% by the end (p<0.001). Despite less contamination at the start (2%) the ready-to-use feeds were equally contaminated as the modular feed at the end of the administration.</p> <p>Home patients: As in hospital the modular feeds were significantly more contaminated at the start of administration with over 75% of feeds contaminated compared with 28% of ready to use feeds. This significant difference was maintained by the end of administration when all modular feeds were contaminated compared with nearly two thirds of ready-to-use feeds (p<0.01).</p> <p>The study highlights the importance of hygiene training for parents and the desirability of a ready-to-use formula.</p> | <p>Research on home patients using PEGs however, no information is given about the diseases the children are suffering from.</p> |
| P20 | 2 | <p>Anderton A and Aidoo KE. 1991. UK.</p> <p>The effect of handling procedures on microbial contamination of enteral feeds – a comparison of the use of sterile vs non-sterile gloves.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>40 (gender not stated)</p> <p>Volunteers with uninfected and undamaged skin.</p> | <p>No feed contamination from subjects wearing sterile gloves, and only <1 cfu per plate when the volunteers wore non-sterile gloves, compared with 54 cfu/ml when no gloves used.</p> | <p>Needs to be repeated in a clinical setting.</p> |

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| P22 | 2 | Beattie TK, Anderton A. 1999. UK. To investigate the levels of contamination in four currently used 1000mL, 'ready-to-hang' enteral feeding systems Osmolite (Ross Ready-to-Hang), Steriflo, Dripac-flex and Easybag when faulty procedures were used during assembly of the systems. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory 65 samples (5x4x3) + 5 catheters. Laboratory Study | Contamination. 87% Osmolite. 27% Dripac. 80% Steriflo. 13% Easybag (p<0.05). 13% had >10 ⁴ cfu/ml. 'Closed' systems do become contaminated, especially when manufacturers instructions are not followed. | Experimental study. |
| P23 | 3 | Anderton A, Nwoghu CE. 1991. UK. To evaluate the effectiveness of a representative range of currently used cleaning procedures in removing bacteria from the lumina of the tubes. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory In vitro study (3 systems, 5 cleaning methods, each duplicated) Laboratory Study | The only effective cleaning method was a complicated procedure involving hypochlorite, unlikely to be followed completely in practice. Reuse is not advised. | Not explicitly stated whether all 3 types of catheter were subjected to all 5 cleaning regimens. |
| P24 | 3 | Smarszcz RM, Proicu GC, Dugle JE. 2000. USA. To assess the microbiological colonization of the Ross Hide-A-Port extension tubes challenged with 4 separate organisms S. epidermis, Entereobacter aerogenes, Candida Albicans and Acinetobacter. | Design: Setting: Sample: Popⁿ: | Experimental Laboratory 132 tubes Laboratory Study | At 18 days:- Water alone ineffective in eliminating organisms. Soap and water did not prevent adherence of bacteria and yeast though better than water alone and reduced Candida to <10 ⁵ . Use of ammonia sanitizer significantly reduced organisms. | Lab study, use of sanitizer needs to be demonstrated in clinical practice. |

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| P25 | 2 | <p>Kohn CL. 1991. USA.</p> <p>To determine whether formula contamination increased when delivery sets were used for 24 hours in the clinical settings and for an additional 48 hours in the laboratory.</p> | <p>Design:</p> <p>Descriptive study</p> <p>Setting:</p> <p>Urban hospital and Laboratory</p> <p>Sample:</p> <p>21 (10M, 11F)</p> <p>Popⁿ:</p> <p>Patients requiring continuous, full strength Osmolite feeds in a pump.</p> | <p>Of 21 delivery sets 23.8% unacceptably contaminated at 24 hours and by 48 hours 42.9% unacceptable.</p> <p>Suggests if use 10⁵cfu/ml, giving sets should not be used for more than 24 hours, due to the amount of contamination. Therefore the cost effective advantage of prolonged use is not met.</p> | <p>No universal definition of unacceptable contamination.</p> <p>This study used 10⁵ cfu/ml.</p> |
| P30 | 5 | <p>Sturgis TM. Yancy W, Cole JC et al. 1996. USA.</p> <p>To determine whether prophylactic antibiotic treatment with Cefazolin reduces the incidence of peristomal infection after percutaneous gastrostomy.</p> | <p>Design:</p> <p>Randomised Controlled Trials</p> <p>Setting:</p> <p>Hospital and follow-up nursing home</p> <p>Sample:</p> <p>115patients, 30 Cefazolin, 31 placebo and 54 already on antibiotics.</p> <p>Popⁿ:</p> <p>Patients referred for PEG.</p> | <p>Wound infections:- 4/30 (13%) cefazolin Placebo 6/31 (19%) 2/54 (3%) on antibiotics</p> <p>58% infections occurred 72 hours after insertion.</p> <p>A single dose of Cefazolin does not reduce the overall peristomal wound infection in percutaneous endoscopic infection. Patients receiving prior extended antibiotic therapy have fewer peristomal wound infections.</p> | <p>Wound evaluation on patients discharged were by telephone though seen by an investigator if an infection was thought to be developing.</p> |
| P32 | 5 | <p>Kozarek RA, Payne M, Barkin J et al. 1995. USA.</p> <p>A prospective multicentre trial to establish the use, ease of insertion and short and long term safety profile of the One-step button gastrostomy</p> | <p>Design:</p> <p>Descriptive Study</p> <p>Setting:</p> <p>5 urban hospitals</p> <p>Sample:</p> <p>86 (gender not stated)</p> <p>Popⁿ:</p> <p>Patients with CVA, neurological problems, Cancer, including head and neck</p> | <p>Peristomal infection before 1 week: 7, after 4 weeks: 4.</p> <p>Suggests the theoretical advantages on one-step gastrostomies are outweighed by placement problems and subsequent complications and suggests further work is needed</p> <p>Follow up longer than usually reported, mean 1.5 months range 2-180 days</p> | <p>Study largely about insertion but contains important infection data.</p> |

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| P74 | 1 | <p>Duncan HD, Bray MJ, Kapadia SA et al. 1996. UK.</p> <p>To determine if UK size is important in affecting the complications of percutaneous endoscopic gastrostomy (PEGs), i.e infection and leakage.</p> | <p>Design:</p> <p>Randomised Uncontrolled Trial</p> <p>Setting:</p> <p>Urban district general hospital</p> <p>Sample:</p> <p>52 (18M, 34F)</p> <p>Popⁿ:</p> <p>Patients referred for PEGs.</p> | <p>No significant differences in the number of PEG site infections between the 12 and 20 FG groups, suggesting that the larger 20 FG offers no advantage over the 12 FG tube apart from its ease of insertion.</p> <p>12 FG–Minor peristomal infection 5, serious 3.</p> <p>20 FG–Minor peristomal infection 6, serious 6.</p> | <p>21 deaths during follow-up though no significant difference between tubes.</p> |
| P75 | 1 | <p>Van den Hazel S, Mulder C and Den Hartog G et al. 2000. Netherlands.</p> <p>A randomized controlled trial to compare two PEG catheters which were similar in design, but one was made of polyurethane and the other of silicone. These catheters were compared with regard to PEG-related complications and PEG survival.</p> | <p>Design:</p> <p>Randomised Trial</p> <p>Setting:</p> <p>Hospital</p> <p>Sample:</p> <p>106 (gender not stated)</p> <p>Popⁿ:</p> <p>All patients requiring PEG catheters.</p> | <p>During the first four weeks of follow-up, major complications occurred twice with both polyurethane and silicone PEGs (relative risk 3.8. 95% confidence interval: 1.37-10.5).</p> <p>Long-term follow-up was available in 96 patients. Seven polyurethane PEGs and 10 silicone PEGs were removed because of PEG malfunctioning, the remainder functioned well until death or the reinstatement of oral feeding. The median complication-free survival was 916 days for the polyurethane PEG and 354 days for the silicone PEG (Log rank test: P=0.24).</p> | <p>No analysis is done about whether the different surgeons have different rates of infection.</p> <p>The mean period for PEG placement was considerably less for the polyurethane PEG than for the silicone PEG.</p> |

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| P77 | 2 | <p>Anderton A and Aidoo KE. 1990. UK.</p> <p>To examine the procedures used in the opening and decanting of a range of different types of pre-packed liquid feeds and to determine the resultant levels of contamination</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Laboratory</p> <p>160 (80 feed containers disinfected, 80 not disinfected)</p> <p>Laboratory Study</p> | <p>When using non-disinfected containers and the feed decanted wearing sterile gloves and using disinfected bottle openers or scissors no contamination was detected in samples from crown cap or screw cap bottles, but the feed from the cans (3/12 – 4 hours, 12/20 – 2 hours) and the tetrapaks (6/20 – 24 hours) were contaminated by organisms from their surfaces. More samples from cans were contaminated.</p> <p>The main source of contamination seemed to come from the experimenter’s hands and counts up to 10² cfu/ml were recorded for feeds that had been decanted from screw-cap bottles, tetrapaks and cans by experimenters with either unprotected bare hands or experimentally contaminated hands.</p> | <p>An experimental setting.</p> |
| P78 | 2 & 4 | <p>Fagerman KE. 1992. USA.</p> <p>To describe the effect of enteral quality control (QC) programs on bacterial levels within the enteral nutrition service in two institutional settings</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Hospital A – 500 bed tertiary care facility. Hospital B – 100 primary care referring hospital.</p> <p>Incomplete information. Hosp A – 6000 feeds.</p> <p>No details given.</p> | <p>ENS samples were either contamination free or within acceptable limits after modifications to protocols in both hospitals. Improved sanitation in preparation has greatest improvement in reducing bacterial levels.</p> <p>Q4: Use of Potassium Sorbate as a preservative was effective in maintaining feeds sterile at 12 hours in room temperature.</p> | <p>This is really 2 studies reported in one paper.</p> |

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| P80 | 1 | <p>McKinlay J, Wildgoose A, Wood W et al.. 2001. UK.</p> <p>To investigate the effect that recent changes in system design may have in reducing the risk of contamination when administering Nutricia, Ross and Abbott feeds</p> | <p>Design:</p> <p>Randomised Trial</p> <p>Setting:</p> <p>Urban Hospital</p> <p>Sample:</p> <p>85 (gender not stated)</p> <p>Popⁿ:</p> <p>In-patients requiring enteral feeds.</p> | <p>Contamination found in 14/120 (12%) Nutrison packs compared with 25/120 (21%) Ross (p<0.05).</p> <p>On 19 occasions similar organisms were isolated from both the feed and patient specimens.</p> <p>Most frequently and heavily contaminated specimens were collected from the distal end of giving set.</p> <p>Retrograde spread of the patient's own flora is a source of contamination and samples from a distal end may reflect endogenous rather than exogenous contamination.</p> <p>System design is important re contamination.</p> | <p>A useful clinical study</p> <p>Randomisation not blinded</p> |
| P82 | 1&2 | <p>Bott L, Husson MO, Guimber D et al. 2001. France.</p> <p>To evaluate the risk of contamination of enteral feeding systems in children fed at home via gastrostomy</p> | <p>Design:</p> <p>Descriptive Study</p> <p>Setting:</p> <p>Homes</p> <p>Sample:</p> <p>20 children (12M, 8F)</p> <p>Popⁿ:</p> <p>Children with a gastrostomy and fed at home</p> | <p>45% distal giving sets showed overgrowth and 30% were contaminated.</p> <p>Manipulation error observed in 40% cases though this was not associated with contamination of feeds.</p> <p>No difference in contamination between gastrostomy button or tube.</p> <p>Gastric bacterial over growth was not associated with retrograde colonization.</p> <p>Demonstrates that to avoid /minimise contamination, closed systems should be used in preference to open systems for feeding at home.</p> | <p>All observations and samples taken by one person during a normal procedure.</p> <p>Defined overgrowth as 10⁴ cfu/ml.</p> <p>Observation by study operator may have influenced outcome.</p> <p>Small sample but a limited population.</p> |

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| P86 | 3 | <p>Grunow JE, Christenson JC, Doris Moutous D. 1989. USA.</p> <p>To determine the incidence of contamination in a delivery system reused in vitro simulating nocturnal supplemental enteral feeding.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Laboratory Experiment</p> <p>'Vacant room' in a children's hospital</p> <p>Flexiflo Top Fill Enteral Nutrition Systems (Ross Laboratories)</p> <p>Not Applicable</p> | <p>Clean enteral nutrition systems can be reused after short infusion periods and used up to 7 days in vitro without significant contamination. Bacteria cannot be eradicated from heavily contaminated bags by rinsing.</p> | <p>Well conducted laboratory study.</p> |
| P89 | 2 | <p>Freedland CP, Roller RD, Wolfe BM et al. 1989. USA.</p> <p>Evaluation of an open, continuous enteral tube feeding system in clinical use, i.e., Biosearch Top Fill 500cc enteral feeding bag, extension tubing and a Dobhoff enteral pump or an Imed Volumetric Infusion pump.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Urban hospital</p> <p>33 patients (gender not specified) 82 enteral feeding cultures.</p> <p>All hospital patients (except neonates) undergoing continuous enteral pump feeding for a minimum of 3 days without interruption >24 hours.</p> | <p>Contaminated enteral feeds may constitute reservoirs for contamination of other body sites. Contamination of feeds with <i>Serratia marcescens</i> correlated with cultures for the same organisms in patient's other body sites (p<0.01).</p> <p>Undiluted canned feeds were significantly less contaminated at 24hrs than those requiring mixing of powder (p<0.0001).</p> | <p>Well conducted study.</p> |

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| P92 | 2 | <p>Skiest DJ, Khan N, Feld R et al. 1996. USA.</p> <p>To determine whether administering enteral feeding intermittently (IEF) as opposed to continuously (CEF) results in decreased rates of gastric colonisation in mechanically ventilated patients.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>2 urban hospitals</p> <p>16 CEF (4M, 3F), IEF (5M, 4F)]</p> <p>ICU patients about to begin enteral feeding</p> | <p>IEF resulted in lower gastric pH and gastric colonisation. Mean am gastric pH in IEF significantly lower than CEF (p=0.0008). No significant difference in pm pH – (p>0.05).</p> | <p>This is a hospital based critical care study and it is difficult to extrapolate to community setting Very small sample size to generalise (Pilot Study)</p> |
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| P94 | 2 | <p>Schroeder P, Fisher D, Volz M et al. 1983. USA.</p> <p>To estimate the type and amount of contamination that occur in nutrient feeding solutions in a community hospital using normal procedures.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Descriptive Study</p> <p>Community hospital</p> <p>9 in study 5. The others were Laboratory and simulated clinical studies.</p> <p>Not reported</p> | <p>Enteral feeding systems can support considerable microbial contamination that varies in type and amount. Awareness of study and education did not reduce contamination.</p> <p>Study 1 looked at the sterility of unrefrigerated NFS using 5 cans and samples taken at 4 hr intervals (laboratory)</p> <p>Study 2 contamination due to decanting(laboratory)</p> <p>Study 3 contamination due to decanting and nurses unaware they were being monitored (simulated clinical)</p> <p>Study 4 duplicated study 3(different systems)</p> <p>Study 5 contamination in gavage feeding bags without nurses being aware of the study (clinical)</p> <p>Study 6 contamination in gavage feeding bags with nurses aware of the study (clinical)</p> <p>Study 7 contamination as a result of organisms travelling from a colonised nasogastric tube into gavage tubing (laboratory).</p> <p>Study 1 Ensure did not reveal growth over 24 hours.</p> <p>Study 2 No bacterial growth over 48 hours regardless of delivery systems.</p> <p>Study 3 Contamination in all systems by 24 hours</p> <p>Study 4 Less growth than study 3 even at 36 hours.</p> <p>Study 5 All but one system contaminated at 24 hours</p> <p>Study 6 Considerable growth at 24 hours</p> <p>Study 7 No bacterial growth in any tube samples</p> | <p>Effect of enteral contamination on patients not measured</p> <p>Samples small</p> |
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| P97 | 2 | <p>Elston-Hurdle BJ, Grey C, Roy I et al. 1989. USA.</p> <p>To evaluate the extent of bacteriological contamination following low-level contamination of enteral feed preparation with <i>Pseudomonas aeruginosa</i>, <i>Klebsiella pneumoniae</i> or <i>Enterobacter cloacae</i>.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Experimental</p> <p>Acute setting, possibly ICU</p> <p>58 infusion sets, patient details missing</p> <p>Not stated</p> | <p>Suggests feeds may be hung for 24 hours without reservoir bag change with no major risk of reservoir contamination.</p> <p>Little risk to patient and reduction in costs if reservoir bags and connection tubes are hung with good technique.</p> <p>In vivo: No growth at 12 hours in bag or reservoir end of tubing. At 24 hours 2/58 had growth</p> <p>In vivo: no growth in bag or reservoir end tubing at 24 hours. Patient end of tubing all contaminated with challenge bacteria</p> | <p>Several details missing, numbers small.</p> |
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EF Rejected Studies

| ID | Quest. Number | Author, Date and Country of Origin | Objective | Design, Setting, Sample Size & Population | Reasons for Rejection |
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| P3 | 1 | Iber, FI, Livak AL and Patel M. 1996. USA. | To describe 111 PEG tubes with a view to learning more about the reasons for PEG failure | Design: Descriptive study Setting: Hospital Department of Gastroenterology Sample: 111 PEGs removed, replaced or dislodged at the hospital during an 11 month period Pop^p: In-patients receiving PEG feedings. | Lack of control of possible confounders. |
| P4 | 1 | Payne-James, J; Rana SK, Bray MJ et al. 1992. UK. | To compare contamination of enteral diet containers using three different giving sets. | Design: Descriptive study Setting: Urban DGH Sample: 55 (gender not specified) Pop^p: In patients receiving continuous 24 hour infusion. Phase I (18 patients) Phase II (17 patients) Phase III (18 patients) | Small sample in each phase. |
| P11 | 1 | Gottlieb K, Leya J, Kruss D et al. 1993. USA. | To investigate the prevalence of fungal colonization in a variety of PEG types. | Design: Descriptive Study Setting: Veterans Administration Hospital Sample: 10 (Males) Pop^p: Patients from 2 wards with functioning PEGs in-situ. | The sample size is not appropriate |

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| P21 | 2 | Thurn J, Crossley K, Gerdt A et al. 1990. USA. | A prospective study to determine the relationship between contamination of enteral feeds and nosocomial infection. | <p>Design: Descriptive Study</p> <p>Setting: One hospital but 3 different intensive care areas</p> <p>Sample: 24 patients (20M, 4F)</p> <p>Popⁿ: Patients requiring enteral feeds between Sept 1986 - April 1987.</p> | The sample size is not appropriate |
| P27 | 2 & 3 | Donius MA. 1996. USA. | To compare contamination of formula collected from the distal end of the tubing set of a refillable bag with contamination of a commercially prepared 1000ml pre-filled ready-to-hang enteral feeding system. | <p>Design: Descriptive study</p> <p>Setting: Long-term care facility</p> <p>Sample: 4 patients (gender not stated)</p> <p>Popⁿ: Stable patients requiring enteral feeds.</p> | Very small study, underpowered, though it confirms findings in another study |
| P31 | 5 | Nunley D, Berk SL. 1992. USA. | A retrospective study to evaluate the gastrostomy site as source of MRSA colonization. | <p>Design: Descriptive Study</p> <p>Setting: Urban hospital</p> <p>Sample: 26 reports of Gastrostomy site cultures.</p> <p>Popⁿ: Patients with gastrostomy</p> | A retrospective study of notes 1985-1987 but reported in 1992, therefore old data and dependant on accurate record keeping. |
| P76 | 2 | Weenk G, van Unen E, van Ess I et al. 1995. Netherlands. | To assess the risks of using a ready-to-use 1 litre enteral feeding system in a centre for burns patients. | <p>Design: Descriptive Study</p> <p>Setting: Burns unit</p> <p>Sample: 5 patients (gender not specified)</p> <p>Popⁿ: Patients with severe burns requiring enteral feeding.</p> | The sample size is not appropriate |

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| P81 | 2 | Anderton A, Nwogh CE, McKune I et al. 1993. UK. | To investigate and compare the levels and types of bacterial contamination in enteral feeds prepared and administered in hospital and the home | <p>Design: Descriptive Study</p> <p>Setting: Patients' homes and hospital</p> <p>Sample: 95 feeds sampled from 6 children (gender not stated)</p> <p>Pop^p: Children being fed at home and in hospital over a 3 month period.</p> | <p>Patients and parents collected home samples which may have altered contamination levels.</p> <p>Parents and patients were responsible for collection and storage of home samples. Children received multiple doses of antibiotics for their cystic fibrosis</p> |
| P83 | 2 | Perez SK, Brandt K. 1989. USA. | To explore the differences in bacterial growth in continuous enteral feeding when using tap water versus sterile water over 24 and 48 hours. | <p>Design: Quasi experimental</p> <p>Setting: Hospital</p> <p>Sample: Unclear – 32 surgical bedded but data only given for 10 people</p> <p>Pop^p:</p> | <p>Small study no controls. Findings inconclusive. No data on patients.</p> |
| P87 | 3 | Oie S, Kamiya A, Hironaga K, Koshiro A. 1992. Japan. | To examine the contamination of enteral feeding solution immediately after administration, after 30 mins and 2hrs and the effectiveness of decontaminating administration containers for reuse. | <p>Design: Controlled Experiment</p> <p>Setting: One hospital and two unspecified 'affiliated institutions'</p> <p>Sample: 22 samples from 22 patients</p> <p>Pop^p: No patient details given</p> | <p>Sample inadequate.</p> |
| P90 | 1 | Heyland DK. 1998. Canada. | Examine the relationship between nutritional support and infectious morbidity and mortality in the critically ill patient | <p>Design: Systematic Review and Meta-analysis</p> <p>Setting:</p> <p>Sample:</p> <p>Pop^p: Adult patients undergoing major surgery, suffering major trauma.</p> | <p>This review offers little evidence of use for the guideline development.</p> |

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| P91 | 1 | Eddy VA, Snell JE, Morris JA. 1996. USA. | Determine short and long term complications associated with needle catheter jejunostomy | <p>Design: Descriptive Study</p> <p>Setting: University medical centre</p> <p>Sample: 122 (95M, 27F)</p> <p>Pop^a: Patients who had received needle catheter jejunostomies included in study over 6 year period.</p> | NEJ relevant but conduct of study means results are unreliable. |
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APPENDIX EF4 – Reviewed evidence for this section

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- (4) Anderton A. Microbial aspects of home enteral nutrition - a discussion. *Journal of Human Nutrition and Dietetics* 1990; 3:403-412.
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- (15) Beattie TK, Anderton A. Bacterial contamination of enteral feeding systems due to faulty handling procedures - a comparison of a new system with two established systems. *Journal of Human Nutrition and Dietetics* 1998; 11:313-321.
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SECTION 5 Central Venous Catheterisation

Guidelines for preventing healthcare-associated infections in caring for patients with central venous catheters in primary and community care

Glossary

Words included in the glossary are marked with an asterisk (*) the first time they appear in this section.

Expert opinion

Opinion derived from seminal works and appraised national and international guidelines.

Localised Catheter Colonisation

Significant growth of a microorganism (> 15 CFU) from the catheter tip, subcutaneous segment of the catheter, or catheter hub.

CRBSI (Catheter-related Bloodstream Infection)

Bacteraemia/fungaemia in a patient with an intravascular catheter with at least one positive blood culture obtained from a peripheral vein, clinical manifestations of infections (i.e., fever, chills, and /or hypotension), and no apparent source for the BSI except the catheter. One of the following should be present: a positive semiquantitative (>15 CFU/catheter segment) or quantitative (>10³ CFU/catheter segment) culture whereby the same organism (species and antibiogram) is isolated from the catheter segment and peripheral blood; simultaneous quantitative blood cultures with a ≥5:1 ratio of CVC versus peripheral; differential period of CVC culture versus peripheral blood culture positivity of >2 hours.

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.

Catheter thrombus

Clot adherent to or occluding the catheter or a fibrin sleeve in the vessel around the catheter.

Healthcare personnel

Any person employed by the health service, social service, local authority or agency to provide care for sick, disabled or elderly people.

SECTION 5: Guidelines for preventing healthcare-associated infections in caring for patients with central venous catheters in primary and community care

Introduction

Patients in the community with chronic health conditions may require long-term central vascular access as a necessary component of their treatment. Shorter-term central vascular access may also occasionally be needed, e.g., for completion of intravenous antimicrobial therapy. Bloodstream infections (BSI) related* to the use of central venous catheters (CVCs) are associated with substantially increased costs, morbidity and mortality. Although the use of CVCs accounts for the vast majority of hospital-acquired BSI, the rates of catheter-related BSI (CRBSI)* in patients in community and primary healthcare settings in England are unknown.

Expert review of evidence

These guidelines are primarily based upon an expert review of evidence-based guidelines for preventing intravascular device-related infections developed at the Centers for Disease Control and Prevention (CDC) in the United States of America by the Healthcare Infection Control Practices Advisory Committee (HICPAC).^(1,2) Using a validated guideline appraisal instrument developed by the AGREE collaboration,⁽³⁾ three experienced appraisers independently reviewed these guidelines, taking into consideration supplementary information provided by HICPAC at our request (see CVC Appendix 1). We concluded that the development processes were valid and that the guidelines were: evidence-based; categorised to the strength of the evidence examined; reflective of current concepts of best practice; and acknowledged as the most authoritative reference guidelines currently available. They were subsequently recommended as the principal source of evidence for developing the guidance below.

Systematic review process

After this appraisal, we systematically searched, retrieved and appraised additional supporting evidence published since the HICPAC guidelines were developed (CVC Appendix 2). This search was confined to elements of infection prevention where expert members of the Guideline Development Group indicated new developments or changes in technology had occurred, or where pertinent new experimental trials or systematic reviews had been published.

The following systematic review questions were used:

- Should the catheter insertion site be protected by a dressing and, if so, which type of dressing should be used and how frequently should it be changed?
- Which antiseptic/disinfectant was best for: preparation of the skin site (cutaneous antisepsis) prior to central venous catheter insertion; cleansing of the entry site once the catheter was in place (if any such evidence exists that routine cleansing prevents infections); cleaning the catheter hub and/or injection ports prior to accessing the system?
- Should the catheter be routinely flushed before or after accessing. If so, which solution, e.g., heparin or normal saline, should be used.?
- Would low-dose systemic anticoagulation reduce the risk of bloodstream infections?
- Was the maintenance of a closed system, e.g., Vygon Bionector 2 Connection Accessory, practicable, effective in reducing infection complications, and cost-effective?
- Did stopcocks and three-way taps increase the risk of catheter colonisation* and/or bloodstream infections?
- Did the use of inline filters (in-line filtration of microbes/endotoxins) prevent bloodstream infections?
- How frequently should the intravenous catheter administration set be changed?

In setting up the search the following MeSH terms were used: Infection control; cross infection; universal precautions; equipment contamination; disease transmission; bacteremia; chlorhexidine; povidone-iodine; anticoagulants; sepsis; central venous catheterisation; indwelling catheters; parenteral nutrition. In addition the following free text terms were used: PICC; TPN; catheter hub; catheter port; dressings; flushing solutions.

These databases were searched from 1998: Medline, Cumulated Index of Nursing and Allied Health Literature (CINAHL), Embase, The Cochrane Library, National Electronic Library for Health, The NHS Centre for Reviews and Dissemination (CRD), The National Research Register, The Web of Science, The Institute of Health Technology, Health CD Database, Health Management Information, Consortium Database.

Search Results: 4650 articles were located. They were initially sifted to determine if they related to infections associated with central venous catheters, were written in English, were primary research or were a systematic review or a meta-analysis, and appeared to inform one or more of the review questions. Following this first sift, 153 full text articles were retrieved. Using the same criteria as in the first sift, retrieved full-text articles were then re-sifted to select those for critical appraisal. A total of 18 full text articles were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion. Following critical appraisal, 11 were accepted into the study (7 were rejected).

Evidence tables for accepted and rejected studies were generated and used to create evidence summary reports (see CVC Appendix 3). The summary reports along with the primary evidence from the Expert Review of the HICPAC Guidelines, were used as the basis for guideline writing.

Previously, a similar process had informed the development of national guidelines for preventing CRBSI in hospitals associated with the insertion and maintenance of CVCs commissioned by the Department of Health (England) and published in 2001.⁽⁴⁾ It is expected that patients in primary and community care settings would have a CVC inserted or replaced in hospital where these guidelines apply. Consequently, recommendations for the selection of the best type of catheter and insertion site and the optimum aseptic technique required during CVC placement are not included in guidance for community and primary healthcare personnel* as these issues are addressed in the above guidelines for acute care facilities. However, it is good practice for hospital and relevant community nursing staff to discuss in advance the selection of the most appropriate type of catheter in relation to the available skills and resources in the community to care for patients with different types of central vascular access devices.

Following our reviews, guidelines were drafted which described 29 recommendations within the below 4 intervention categories:

- Education of patients, their carers and healthcare personnel;
- General asepsis;
- Catheter site care;
- Standard principles for catheter management.

These guidelines apply to caring for all adults and children in the community with CVCs which are being used for the administration of fluids, medications, blood components and/or total parenteral nutrition (TPN). They should be used in conjunction with the recommendations on Standard Principles for preventing healthcare-associated infections (HAI).

Although these recommendations describe general principles of best practice that apply to all patients in the community using long-term central vascular access devices, they do not specifically address the more technical aspects of the care of patients receiving haemodialysis, who will generally have their CVCs managed in dialysis centres.

Because these recommendations describe broad general statements of best practice, they need to be adapted and incorporated into local practice guidelines.

References

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Intervention 1 Education of patients, their carers and healthcare personnel

To improve patient outcomes and reduce healthcare costs, it is essential that everyone involved in caring for patients with CVCs is educated about infection prevention. Healthcare personnel, patients and their carers need to be confident and proficient in infection prevention practices and to be equally aware of the signs and symptoms of clinical infection and how to access expert help when difficulties arise. Well-organised educational programmes that enable healthcare personnel to provide, monitor, and evaluate care and to continually increase their competence are critical to the success of any strategy designed to reduce the risk of infection. Evidence reviewed by HICPAC consistently demonstrated that the risk for infection declines following the standardisation of aseptic care and increases when the maintenance of intravascular catheters is undertaken by inexperienced healthcare personnel.⁽¹⁾

IV

Recommendations

- CVC1. Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a central venous catheter.**
- CVC2. Community healthcare personnel caring for a patient with a central venous catheter should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline.**
- CVC3. Follow-up training and support should be available to patients with central venous catheters and their carers.**

D

D

D

References

1. Centers for Disease Control and Prevention. Guidelines for the prevention of intravascular-catheter-related infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Intervention 2 General Asepsis

Good standards of hand hygiene and antiseptic technique can reduce the risk of infection

Because the potential consequences of CRBSI are so serious, enhanced efforts are needed to reduce the risk of infection to the absolute minimum. For this reason, hand antisepsis and proper aseptic technique are required for changing catheter dressings and for accessing the system.^(1,2)

Ib

Hand antisepsis can be achieved by washing hands with an antimicrobial liquid soap and water or by using an alcohol-based hand rub. When hands are visibly dirty or contaminated with organic material, such as blood and other body fluids or excretions, they must first be washed with soap and water if alcohol-based hand rubs are going to be used to achieve hand antisepsis. In community and primary care settings, alcohol-based hand rubs are the most consistently accessible and appropriate agent to use for hand antisepsis.

Ib

Appropriate aseptic technique does not necessarily require sterile gloves; a new pair of disposable nonsterile gloves can be used in conjunction with a 'no-touch' technique, for example, in changing catheter site dressings.⁽¹⁾ The 'Standard Principles for Preventing HAI' previously described in these guidelines gives additional advice on hand decontamination and the use of gloves and other protective equipment.

IV

Recommendations

CVC4. An aseptic technique must be used for catheter site care and for accessing the system.

B

CVC5. Before accessing or dressing central vascular catheters, hands must be decontaminated either by washing with an antimicrobial liquid soap and water, or by using an alcohol handrub.

A

CVC6. Hands that are visibly soiled or contaminated with dirt or organic material must be washed with soap and water before using an alcohol handrub.

A

CVC7. Following hand antisepsis, clean gloves and a no-touch technique or sterile gloves should be used when changing the insertion site dressing.

D

References

- Centers for Disease Control and Prevention. Guidelines for the prevention of intravascular-catheter-related infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>
- Centers for Disease Control and Prevention. Guidelines for hand hygiene in health-care settings. Recommendations of the Healthcare Infection Control Practices Advisory

Committee and the HICPAC/SHEA/APIC/IDSA Hand Hygiene Task Force. *MMWR* 2002;**51**(No.RR-16):1-45. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5116.pdf>

Intervention 3 Catheter Site Care

Use the right dressing regimen to protect the catheter site

Following CVC placement, one of two types of dressings is used to protect the catheter site; sterile gauze and tape or sterile transparent semipermeable polyurethane dressings.

HICPAC reviewed the evidence up to the end of 1999 related to which type of dressing provided the greatest protection against infection and found little difference.⁽¹⁾ They concluded that the choice of dressing can be a matter of preference. If blood is oozing from the catheter insertion site, a gauze dressing might be preferred. Our systematic review did not identify any additional evidence which conflicted with HICPAC's conclusions.

Ib

Gauze dressings are not waterproof and require frequent changing in order to inspect the catheter site. They are rarely useful in patients with long-term CVC. Sterile transparent, semipermeable polyurethane dressings have become a popular means of dressing catheter insertion sites. These reliably anchor the CVC, permit continuous visual inspection of the catheter site, allow patients to bathe and shower without saturating the dressing, and require less frequent changes than do standard gauze and tape dressings, saving healthcare personnel time.

Ib

Recommendations

CVC8. Preferably, a sterile, transparent, semipermeable polyurethane dressing should be used to cover the catheter site.

A

CVC9. If a patient has profuse perspiration, or if the insertion site is bleeding or oozing, a sterile gauze dressing is preferable to a transparent, semi-permeable dressing.

D

CVC10. Gauze dressings should be changed when they become damp, loosened or soiled, and the need for a gauze dressing should be assessed daily. A gauze dressing should be replaced by a transparent dressing as soon as possible.

D

CVC11. Transparent dressings should be changed every 7 days, or when they are no longer intact or moisture collects under the dressing.

A

CVC12. Dressings used on tunnelled or implanted CVC sites should be replaced every 7 days until the insertion site has healed, unless there is an indication to change them sooner.

A

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of Intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Use an appropriate antiseptic agent for disinfecting the catheter insertion site during dressing changes

HICPAC described compelling evidence that aqueous chlorhexidine 2 percent was superior to either 10% povidone iodine or 70% alcohol in lowering CRBSI rates when used for skin antiseptics prior to CVC insertion. They made no recommendation for the use of any disinfectant agent for cleaning the insertion site during dressing changes.⁽¹⁾

Ib

A recent meta-analysis assessed studies that compared the risk for CRBSI following insertion-site skin care with either any type of chlorhexidine gluconate (CHG) solution vs. povidone iodine (PI) solution.⁽²⁾ This analysis indicated that the use of CHG rather than PI can reduce the risk for CRBSI by approximately 49% (risk ratio, 0.51 [CI, 0.27 to 0.97]) in hospitalised patients who require short-term catheterisation, i.e., for every 1000 catheter sites disinfected with CHG rather than PI, 71 episodes of catheter colonization and 11 episodes of CRBSI would be prevented. In this analysis, several types of CHG solutions were used in the individual trials, including 0.5 percent or 1 percent CHG alcohol solution and 0.5 percent or 2 percent CHG aqueous solution. All of these solutions provided a concentration of CHG that is higher than the minimal inhibitory concentration (MIC) for most nosocomial bacteria and yeasts. Subset analysis of aqueous and non-aqueous solutions showed similar effect sizes, but only the subset analysis of the five studies that used alcoholic CHG solution produced a statistically significant reduction in CRBSI. Because few studies used CHG aqueous solution, the lack of a significant difference seen for this solution compared with PI solution may be a result of inadequate statistical power.

Ia

Alcohol and other organic solvents and oil-based ointments and creams may damage some types of polyurethane and silicon CVC tubing. The manufacturer's recommendations for only using disinfectants that are compatible with specific catheter materials must be followed.

IV

Recommendations

CVC13. An alcoholic chlorhexidine gluconate solution should be used to clean the catheter site during dressing changes, and allowed to air dry. An aqueous solution of chlorhexidine gluconate should be used if the manufacturer's recommendations prohibit the use of alcohol with their product.

A

CVC14. Individual sachets of antiseptic solution or individual packages of antiseptic-impregnated swabs or wipes should be used to disinfect the dressing site.

D

CVC15. Healthcare personnel should ensure that catheter-site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations.

D

References

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Intervention 4 General Principles for Catheter Management

Aseptic technique is important when accessing the system

Following their review of the evidence, HICPAC stressed the importance of minimising the risk of introducing infection by using an appropriate antiseptic to decontaminate the access port before accessing the system with sterile devices. As most modern catheter hubs, luer connectors and other access ports are made from alcohol-resistant materials, the use of alcohol wipes, chlorhexidine gluconate or an iodophor for this purpose are recommended by HICPAC. However, they stress the importance of ensuring that any antiseptic agent used is chemically compatible with catheter hubs, ports and connectors.⁽¹⁾

III

Recommendation

CVC16. The injection port or catheter hub should be decontaminated with either alcohol or an alcoholic solution of chlorhexidine gluconate before and after it has been used to access the system.

C

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Inline filters do not help prevent infections

Although in-line filters reduce the incidence of infusion-related phlebitis, HICPAC could find no reliable evidence to support their efficacy in preventing infections associated with intravascular catheters and infusion systems. Infusate-related BSI is rare and HICPAC concluded that filtration of medications or infusates in the pharmacy is a more practical and less costly way to remove the majority of particulates. Furthermore, in-line filters might become blocked, especially with certain solutions, e.g., dextran, lipids, mannitol, thereby increasing the number of line manipulations and decreasing the availability of administered drugs.⁽¹⁾ In our systematic review we found no additional good quality evidence to support their use for preventing infusate-related BSI. However, there may be a role for the use of in-line filtration of parenteral nutrition solutions for reasons other than the prevention of infection but these are beyond the scope of these guidelines.

IV

Recommendation

CVC17. In-line filters should not be used routinely for infection prevention purposes.

D

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Antibiotic lock solutions have limited uses in preventing infection

Antibiotic lock prophylaxis, i.e., flushing and then filling the lumen of the CVC with an antibiotic solution and leaving it to dwell in the lumen of the catheter, is sometimes used in special circumstances to prevent CRBSI, e.g., in treating a patient with a long-term cuffed or tunneled catheter or port who has a history of multiple CRBSI despite optimal maximal adherence to aseptic technique. Evidence reviewed by HICPAC ⁽¹⁾ demonstrated the effectiveness of this type of prophylaxis in neutropenic patients with long-term CVCs. However, they found no evidence that routinely using this procedure in all patients with CVCs reduced the risk of CRBSI and may lead to increasing numbers of antimicrobial resistant microorganisms.

Ib

Recommendation

CVC18. Antibiotic lock solutions should not be used routinely to prevent catheter-related bloodstream infections (CRBSI).

A

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Systemic antibiotic prophylaxis does not reliably prevent CRBSI

No studies appraised by HICPAC demonstrated that oral or parenteral antibacterial or antifungal drugs might reduce the incidence of CRBSI among adults. However, among low birth weight infants, two studies reviewed by HICPAC had assessed vancomycin prophylaxis; both demonstrated a reduction in CRBSI but no reduction in mortality. They noted that because the prophylactic use of vancomycin is an independent risk factor for the acquisition of vancomycin-resistant enterococcus (VRE), the risk for acquiring VRE probably outweighs the benefit of using prophylactic vancomycin.⁽¹⁾

Ib

Recommendation

CVC19. Systemic antimicrobial prophylaxis should not be used routinely to prevent catheter colonisation or CRBSI, either before insertion or during the use of a central venous catheter.

A

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

A dedicated catheter lumen is needed for parenteral nutrition

HICPAC reviewed evidence from a prospective epidemiologic study examining the risk for CRBSI in patients receiving Total Parenteral Nutrition (TPN). They concluded that either using a single lumen CVC or a dedicated port in a multilumen

III

catheter for TPN would reduce the risk for infection.⁽¹⁾

Recommendation

CVC20. Preferably, a single-lumen catheter should be used to administer parenteral nutrition. If a multilumen catheter is used, one port must be exclusively dedicated for TPN, and all lumens must be handled with the same meticulous attention to aseptic technique.

D

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002;**51**(No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Maintaining catheter patency and preventing catheter thrombosis may help prevent infections

Indwelling central venous and pulmonary artery catheters are thrombogenic. Thrombus forms on these catheters in the first few hours following placement⁽¹⁾ and may serve as a nidus for microbial colonization of intravascular catheters.⁽²⁾ Thrombosis of large vessels occurs after long-term catheterisation in 35 to 65% of patients.⁽³⁻⁷⁾ Prophylactic heparin and warfarin have been widely used to prevent catheter thrombus formation and catheter related complications, such as deep venous thrombosis (DVT).^(8,9)

Ia

Two types of heparin can be used: unfractionated (standard) heparin and low molecular weight heparins. Although more expensive, low molecular weight heparins have a longer duration of action than unfractionated heparin and are generally administered by subcutaneous injection once daily. The standard prophylactic regimen of low molecular weight heparins are at least as effective and as safe as unfractionated heparin in preventing venous thrombo-embolism and does not require laboratory monitoring.⁽¹⁰⁾

Systemic Anticoagulation

A meta-analysis of randomised controlled trials⁽⁹⁾ evaluating the benefit of infused prophylactic heparin through the catheter, given subcutaneously or bonded to the catheter in patients with CVCs found that prophylactic heparin:

- was associated with a strong trend for reducing catheter thrombus (RR, 0.66; 95% confidence interval [CI], 0.42,1.05). The test for heterogeneity of variance was not significant (p=0.681);
- significantly decreased central venous catheter-related venous thrombosis by 57% (RR, 0.43; 95% CI, 0.23,0.78). The test for heterogeneity of variance was not significant (p=0.526). Significant reduction of deep venous thrombosis was still present after excluding one trial of heparin-bonded catheters (RR, 0.44; 95% CI, 0.22,0.87);
- significantly decreased bacterial colonisation of the catheter (RR, 0.18; 95% CI, 0.06, 0.60). The test for heterogeneity of variance was not significant

Ia

($p=0.719$). The significant benefit for heparin remained after excluding one trial of heparin-bonded catheters (RR, 0.19; 95% CI, 0.04, 0.86).

- showed a strong trend for a reduction in CRBSI (RR, 0.26; 95% CI, 0.07,1.03). The test for heterogeneity of variance was not significant ($p=0.859$); This trend decreased when one trial of heparin-bonded catheters was excluded (RR,0.33; 95% CI, 0.07,1.56).

The authors of this meta-analysis concluded that heparin administration effectively reduces thrombus formation and may reduce catheter-related infections in patients who have central venous and pulmonary artery catheters in place. They suggest that various doses of subcutaneous and intravenous unfractionated and low molecular weight heparins and new methods of heparin bonding need further comparison to determine the most cost-effective strategy for reducing catheter-related thrombus and thrombosis.

Ia

There are many different preparations and routes of administration of heparin, and as yet there is no definite evidence that heparin reduces the incidence of CRBSI, but this may reflect the heterogeneity of heparin and its administration.

Warfarin has also been evaluated as a means for reducing catheter-related thrombosis. A controlled trial of 82 patients with solid tumours randomised to receive or not to receive low-dose warfarin (1 mg a day) beginning 3 days prior to catheter insertion and continuing for 90 days, warfarin was shown to be effective in reducing catheter-related thrombosis.⁽¹¹⁾ The rates of venogram-proved thrombosis 4 of 42 in the treatment group versus 15 of 40 in the control group with 15 having symptomatic thromboses. In this study, warfarin was discontinued in 10% of patients due to prolongation of the prothrombin time.

Ib

Heparin versus Normal Saline Intermittent Flushes

Although many clinicians use low dose intermittent heparin flushes to fill the lumens of CVCs locked between use in an attempt to prevent thrombus formation and to prolong the duration of catheter patency, the efficacy of this practice is unproven. Despite its beneficial antithrombotic effects, decreasing unnecessary exposure to heparin is important to minimise adverse effects associated with heparin use, e.g., autoimmune-mediated heparin-induced thrombocytopenia, allergic reactions and the potential for bleeding complications following multiple, unmonitored heparin flushes.⁽¹²⁾ The risks of these adverse effects can be avoided by using 0.9 percent sodium chloride injection instead of heparin flushes. A systematic review and meta-analysis of randomised controlled trials evaluating the effect of heparin on duration of catheter patency and on prevention of complications associated with the use of peripheral venous and arterial catheters concluded that heparin at doses of 10 U/ml for intermittent flushing is no more beneficial than flushing with normal saline alone.⁽¹³⁾ This finding was in agreement with two other meta-analyses.^(14,15) Manufacturers of implanted ports or opened-ended catheter lumens may recommend heparin flushes for maintaining catheter patency and many clinicians feel that heparin flushes are appropriate for flushing CVCs that are infrequently accessed.

Ia

HICPAC reviewed all of the evidence ^(1-7,9,11-15) for intermittent heparin flushes and systemic heparin and warfarin prophylaxis and concluded that no data demonstrated that their use reduces the incidence of CRBSI and did not recommend them.⁽⁸⁾ Although their use for preventing CRBSI remains controversial, patients who have CVCs may also have risk factors for DVT and systemic anticoagulants may be prescribed for DVT prophylaxis.

Ia

Recommendations

CVC21. Preferably, sterile 0.9 percent sodium chloride injection should be used to flush and lock catheter lumens.

D

CVC22. When recommended by the manufacturer, implanted ports or opened-ended catheter lumens should be flushed and locked with heparin sodium flush solutions.

D

CVC23. Systemic anticoagulants should not be used routinely to prevent CRBSI.

D

References

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Needleless devices require vigilance

Needleless infusion systems have been widely introduced into clinical practice to reduce the incidence of sharp injuries and the potential for the transmission of bloodborne pathogens to healthcare personnel. HICPAC examined evidence that these devices may increase the risk for CRBSI and concluded that when they are used according to the manufacturers' recommendations, they do not substantially affect the incidence of CRBSI.⁽¹⁾

IV

Recommendations

CVC24. If needleless devices are used, the manufacturer's recommendations for changing the needleless components should be followed.

D

CVC25. When needleless devices are used, healthcare personnel should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system.

D

CVC26. When needleless devices are used, the risk of contamination should be minimised by decontaminating the access port with either alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system.

D

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002; **51** (No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Change intravenous administration sets appropriately

The optimal interval for the routine replacement of intravenous (IV) administration sets has been examined in three well-controlled studies reviewed by HICPAC. Data from each of these studies reveal that replacing administration sets no more frequently than 72 hours after initiation of use is safe and cost-effective. When a fluid that enhances microbial growth is infused, e.g., lipid emulsions, blood products, more frequent changes of administration sets are indicated as these products have been identified as independent risk factors for CRBSI.⁽¹⁾

Ib

Recommendations

CVC27. In general, administration sets in continuous use need not be replaced more frequently than at 72 hour intervals unless they become disconnected or if a catheter-related infection is suspected or documented.

A

CVC28. Administration sets for blood and blood components should be changed every 12 hours, or according to the manufacturer's recommendations.

D

CVC29. Administration sets used for total parenteral nutrition (TPN) infusions should generally be changed every 24 hours. If the solution contains only glucose and amino acids, administration sets in continuous use do not need to be replaced more frequently than every 72 hours.

D

Reference

1. Centers for Disease Control and Prevention. Guidelines for the Prevention of intravascular-catheter-related Infections. *MMWR* 2002; **51** (No.RR-10):1-29. Available from: <http://www.cdc.gov/mmwr/PDF/rr/rr5110.pdf>

Areas for Further Research

This is a well researched area and few realistic research needs were identified in developing these guidelines. The following investigations, along with a health economic assessment, may inform future clinical practice.

Current issues

The effectiveness of subcutaneous low molecular weight heparins or low dose warfarin to prevent catheter thrombus, colonisation and CRBSI.

Emerging Technologies

The efficacy of antimicrobial impregnated CVCs and catheters with new forms of heparin bonding to provide sustained protection against CRBSI in patients with long-term CVCs in the community.

Key Audit Criteria

| Aim | Criteria |
|---|--|
| <p>Identify all patients with central venous catheters.</p> | <p>All patients should have a patient record that documents the reason for CVC placement, type of catheter, catheter insertion site, catheter replacements and care.</p> <p>Standard 100%</p> <p>Data collection: Review of patient notes</p> |
| <p>Ensure that all healthcare personnel are trained to implement these guidelines and assessed as competent.</p> <p>Support healthcare personnel to consistently adhere to guideline recommendations.</p> | <p>All healthcare personnel involved in the care of people with CVCs receive training and updates in the management of CVCs.</p> <p>Standard 100%</p> <p>Data collection: Review of staff education records/direct observation/self-audit</p> |
| <p>Assess the need for continuing venous access on a regular basis and remove a CVC as soon as clinically possible in order to reduce the risk for infection.</p> | <p>Evidence of regular and frequent assessment of the need for CVC and catheter discontinuation rates when the catheter is no longer essential for medical management.</p> <p>Standard 100%</p> <p>Data collection: Review of patient notes</p> |
| <p>Ensure that patients and carers are informed and educated about the management of their CVC.</p> | <p>All patients and carers are aware of the need to:</p> <ul style="list-style-type: none"> • Decontaminate their hands when manipulating the system; • Use aseptic technique when manipulating or accessing the system. <p>Standard 100%</p> <p>Data collection: direct patient questioning of patients and carers.</p> |

APPENDIX CVC1 - AGREE SCORES

Monitoring Appraisal Form (Centres for Disease Control & Prevention. Guidelines for the Prevention of Intravascular Catheter Related Infections. 2002)

| Domain | 1 | | | total | 2 | | | | total | 3 | | | | | | total | 4 | | | | total | 5 | | | total | 6 | | total | |
|--------------|-----------|-----------|-----------|-----------|-----------|----------|-----------|----------|-----------|----------|----------|-----------|-----------|-----------|----------|----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|----------|----------|-----------------|
| Item | 1 | 2 | 3 | | 4 | 5 | 6 | 7 | | 8 | 9 | 10 | 11 | 12 | 13 | 14 | | 15 | 16 | 17 | 18 | | 19 | 20 | 21 | | 22 | 23 | |
| Appraiser 1 | 4 | 4 | 4 | 12 | 4 | 1 | 4 | 3 | 12 | 1 | 1 | 2 | 3 | 4 | 3 | 2 | 16 | 4 | 4 | 4 | 4 | 16 | 3 | 3 | 4 | 10 | 1 | 4 | 5 (71) |
| Appraiser 2 | 4 | 3 | 4 | 11 | 4 | 1 | 3 | 1 | 9 | 1 | 1 | 4 | 4 | 4 | 1 | 1 | 16 | 4 | 3 | 4 | 4 | 15 | 3 | 3 | 4 | 10 | 4 | 1 | 5 (66) |
| Appraiser 3 | 4 | 4 | 4 | 12 | 4 | 3 | 4 | 2 | 13 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 28 | 4 | 4 | 4 | 3 | 15 | 4 | 4 | 4 | 12 | 4 | 4 | 8 (88) |
| Total | 12 | 11 | 12 | 35 | 12 | 5 | 11 | 6 | 34 | 6 | 6 | 10 | 11 | 12 | 8 | 8 | 60 | 12 | 11 | 12 | 11 | 46 | 10 | 10 | 12 | 32 | 9 | 9 | 18 (225) |

Domain Scores

| | |
|---|---|
| <p>Domain 1 Maximum possible score = $4 \times 3 \times 3 = 36$ Standardised domain score is: $(35/36) \times 100 = 97\%$</p> | <p>Domain 4 Maximum possible score = $4 \times 4 \times 3 = 48$ Standardised domain score is: $(46/48) \times 100 = 96\%$</p> |
| <p>Domain 2 Maximum possible score = $4 \times 4 \times 3 = 48$ Standardised domain score is: $(34/48) \times 100 = 90\%$</p> | <p>Domain 5 Maximum possible score = $4 \times 3 \times 3 = 36$ Standardised domain score is: $(32/36) \times 100 = 89\%$</p> |
| <p>Domain 3 Maximum possible score = $4 \times 7 \times 3 = 84$ Standardised domain score is: $(60/84) \times 100 = 71\%$</p> | <p>Domain 6 Maximum possible score = $4 \times 2 \times 3 = 24$ Standardised domain score is: $(18/24) \times 100 = 75\%$</p> |

APPENDIX CVC2: Central Venous Catheters - Systematic Review Process

Systematic Review Questions

1. Should the catheter insertion site be protected by a dressing and, if so, which type of dressing should be used and how frequently should it be changed?
2. Which antiseptic/disinfectant was best for: preparation of the skin site (cutaneous antisepsis) prior to central venous catheter insertion; cleansing of the entry site once the catheter was in place (if any such evidence exists that routine cleansing prevents infections); cleaning the catheter hub and/or injection ports prior to accessing the system?
3. Should the catheter be routinely flushed before or after accessing. If so, which solution, e.g., heparin or normal saline, should be used.?
4. Would low-dose systemic anticoagulation reduce the risk of bloodstream infections?
5. Was the maintenance of a closed system, e.g., Vygon Bionector 2 Connection Accessory, practicable, effective in reducing infection complications, and cost-effective?
6. Did stopcocks and three-way taps increase the risk of catheter colonisation and/or bloodstream infections?
7. Did the use of inline filters (in-line filtration of microbes/endotoxins) prevent bloodstream infections?
8. How frequently should the intravenous catheter administration set be changed?



Databases and Search Terms Used

DATABASES

MEDLINE, CUMULATED INDEX OF NURSING AND ALLIED HEALTH LITERATURE (CINAHL), EMBASE, THE COCHRANE LIBRARY, THE NATIONAL ELECTRONIC LIBRARY FOR HEALTH, THE NHS CENTRE FOR REVIEWS AND DISSEMINATION (CRD), THE NATIONAL RESEARCH REGISTER, THE WEB OF SCIENCE, THE INSTITUTE OF HEALTH TECHNOLOGY, HEALTH CD DATABASE, HEALTH MANAGEMENT INFORMATION CONSORTIUM DATABASE.

MESH TERMS

Infection control; cross infection; universal precautions; equipment contamination; disease transmission; bacteremia; chlorhexidine; povidone-iodine; anticoagulants; sepsis; central venous catheterisation; indwelling catheters; parenteral nutrition.

THESAURUS AND FREE TEXT TERMS

PICC; TPN; catheter hub; catheter port; dressings; flushing solutions.



Search Results

Total number of articles located = 4,650



Sift 1 Criteria

Abstract indicates that the article: relates to infections associated with central venous catheters, is written in English, is primary research or a systematic review or a meta-analysis, and appears to inform one or more of the review questions.



Articles Retrieved

Total number of articles retrieved from sift 1 = 153



Sift 2 Criteria

Full Text confirms that the article relates to infections associated with urinary catheters, is written in English, is primary research or a systematic review or a meta-analysis, and informs one or more of the review questions.



Articles Selected for Appraisal

Total number of articles selected for appraisal during sift 2 = 18



Critical Appraisal

All articles which described primary research, a systematic review or, a meta-analysis and met the sift 2 criteria were independently critically appraised by two appraisers. Consensus and grading was achieved through discussion.



Accepted and Rejected Evidence

Total number of articles accepted after critical appraisal = 11

Total number of articles rejected after critical appraisal = 7



Evidence Tables

Evidence tables for accepted and rejected studies were generated and used to create **evidence summary reports**. The summary reports were, in turn, used as the basis for guideline writing.

APPENDIX CVC3 – CVC Evidence Tables

Accepted CVC Studies

| ID. | Quest. Number | Author, Date, Country of Origin and Objective | Design, Setting, Sample Size and Population | Outcomes | Strengths and Limitations |
|------|---------------|--|---|---|--|
| CVC2 | 2 | <p>Chaiyakunapruk N, Veenstra D, Lipsky A et al. 2002. USA.</p> <p>To evaluate the efficacy of skin disinfection for vascular catheter-site care using chlorhexidine gluconate (CHXG) compared with povidone-iodine (PI) in preventing catheter related blood stream infection (CR-BSI).</p> | <p>Design: Meta-analysis</p> <p>Setting: Hospital in-patients both on general ward and ICU</p> <p>Sample: 8 studies involving a total of 4143 vascular catheters were accepted into the MA (from 302 initially retrieved and assessed).</p> <p>Popⁿ: Trials used 4143 vascular catheters (1493 CVC & 75 peripherally inserted central catheters) inserted into patients whose average age was 50-65 years for duration 1.6-10 days using either PI or CHXG for site disinfection and subsequent catheter care.</p> | <p>The use of CHXG rather than PI can reduce the risk for CR-BSI by 49% (risk ratio, 0.51 [CI, 0.27 to 0.97]) in hospitalised patients who require short-term central venous catheterisation. Authors estimate that for every 1000 vascular catheter sites disinfected with CHXG rather than PI, 71 episodes of CR-BSI would be prevented. Although this MA included studies using all vascular catheter sites (central venous, peripheral venous, peripheral arterial, pulmonary arterial, peripherally inserted central venous, introducer sheaths and haemodialysis), the magnitude of the reduction in risk of CR-BSI attributed to CHXG use in the subgroup analyses were similar to those in the main analysis.</p> | <p>Well conducted MA except the means by which the quality of accepted studies not explicitly addressed but general quality remarks were included for all studies (authors being contacted for further information). Confounders, e.g., publication bias, heterogeneity of study participants, catheter type, outcome definitions well covered. Declared limitations: (1) disparate design of individual trials accepted into the analysis; (2) different types of CHXG sol. used in different trials; (3) different ways some studies defined CR-BSI; (4) none of the 8 included studies reported strategies to distinguish true bacteraemia from blood culture contamination.</p> <p>Several types of CHXG solution were used in individual trials, incl. 0.5% or 1% CHXG alcohol sol, & 0.5% or 2% CHXG aqueous sol. All of these solutions provided a concentration of CHXG that is higher than the MIC for most nosocomial bacterial & yeast. Subset analyses of aqueous & non-aqueous sol. Showed similar effect sizes, but only the subset analysis of the 5 studies that used alcoholic sol. Produced a statistically significant reduction in CR-BSI. Because few studies used CHXG aqueous sol, the lack of a significant difference seen for this solution compared with PI sol. May be a result of inadequate statistical power.</p> |

FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

| | | | | | | |
|------|---|---|--|---|---|--|
| CVC3 | 9 | Newall F, Ranson K, Robertson J. 1998. Australia. To determine whether the removal of in-line filters from central venous infusion lines changes the incidence of septicaemia associated with the presence of central venous access devices. | Design: Setting: Sample: Popⁿ: | Descriptive Study Paediatric oncology unit 88 patients (Gender not specified) Patients with cancer between the ages of 3 months and 18 years. | Results indicate that children with filters were at greater risk of infection. The difference between positive blood cultures associated with and without the use of filters was not statistically significant, $p = 0.8992$. | The reliability of data for period of filter possible compromised as it was collected retrospectively. |
| CVC4 | 1 | Little K, Palmer D. 1998. UK. To compare OpSite IV 3000 with a standard dressing (sterile dry dressing with Betadine ointment) for central venous catheter access sites. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial Combined gastro-enterology unit and intensive care unit 73 patients (Gender not specified) Patients requiring CVC | No statistical difference between two dressing regimes. Statistical measure of uncertainty not given. | Unclear whether baseline measurements were taken. Variable frequency of dressing changes but dressing changes recorded. Patients were from 2 different units - no account taken of this during allocation to groups. |
| CVC5 | 9 | Seymour VM, Dhallu TS, Moss HA et al. 2000. UK. To evaluate the microbial contamination of the Connecta Clave compared to conventional three-way taps in clinical practice. | Design: Setting: Sample: Popⁿ: | Controlled Trial Probably Intensive Care Unit but setting not explicitly identified. 77 patients (no details of gender given) Patients admitted for coronary artery bypass graft or heart valve replacement and who required CVC for management. | Comparison of contamination of three-way taps between the 2 groups = $p > 0.1$. | Subjects appear not to be randomised to study groups. Variable number of three-way taps, and therefore connectors, does not seem to have affected the outcomes. No baseline measurements seem to have been taken. |

FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

| | | | | | | |
|-------|---|--|---|---|--|---|
| CVC7 | 8 | <p>Raad I, Hanna HA, Awad A et al. 2001. USA.</p> <p>To determine the safety and cost-effectiveness of replacing intravenous (IV) tubing sets in hospitalised patients at 4- to 7-day intervals instead of every 3 days.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>A tertiary university cancer centre.</p> <p>512 patients (276 M, 236 F)</p> <p>Cancer patients requiring IV therapy See table 1 p.137</p> | <p>Study indicates that it may not be safe to extend use of IV administration sets beyond 72 hours for patients receiving total parenteral nutrition, blood transfusions or interleukin-2.</p> | <p>Authors acknowledge underpower in study.</p> |
| CVC10 | 1 | <p>Nikoletti S, Leslie G, Gandossi S et al. 1999. Australia.</p> <p>To evaluate the risk of infection associated with a thin, transparent hydrocolloid dressing (Comfeel) compared with conventional transparent polyurethane dressing (Tegaderm).</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>Intensive care unit</p> <p>204 patients (92 M, 112F)</p> <p>Patients older than 18 years who required insertion of a multi-lumen central venous catheter.</p> | <p>The study indicates that there is an increased risk of catheter colonization associated with the use of hydrocolloid dressings.</p> | <p>Authors acknowledge that a) the number of dressing changes varied between patients and, b) the dressing changes were not recorded.</p> <p>Sample weakened through high attrition rate.</p> |

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| CVC177 | 3 | <p>Randolph AG, Cook DJ, Gonzales CA et al. 1998. USA.</p> <p>To evaluate the effect of heparin on thrombus formation and infection associated with the use of central venous and pulmonary artery catheters.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Meta-analysis</p> <p>N/A</p> <p>12 RCTs of CVCs and 2 RCTs of pulmonary artery catheters were included. Both used bonded heparin.</p> <p>Participants were adults or paediatric patients whose treatment included the insertion of central venous catheters and pulmonary artery catheters.</p> | <p>Heparin administration effectively reduces thrombus formation and may reduce catheter-related infections in patients who have central venous and pulmonary artery catheters in place. Cost-effectiveness comparisons of unfractionated heparin, low molecular weight heparin and warfarin are needed.</p> | <p>The aim and inclusion criteria were clearly stated. A number of sources were searched for relevant studies. Outcomes were defined. Details of methods used to assess validity and extract data were given. Heterogeneity was assessed statistically. In the absence of significant statistical heterogeneity a meta-analysis was appropriate. Results were clearly displayed. The discussion included consideration of the following limitations of the review: methods used to diagnose thrombosis in the studies (line-o-grams and ultrasound) are less sensitive than venography and may have underestimated the diagnosis of large vessel thrombosis; and studies used variable definitions of catheter-related infections.</p> <p>It is not stated if any language restrictions were applied to include studies. Fuller details of included studies such as sample size would have been welcome. It is not clear if the analysis was undertaken by intention-to-treat. The 95% confidence limits are wide for some outcomes, presumably reflecting small sample size, and do not exclude a result of no effect of heparin used with central venous catheters on catheter thrombus and catheter-related bacteraemia and sepsis.</p> |
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FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

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| CVC179 | 9 | <p>Cookson ST, Ihrig M, O'Mara EM, Denny M, Volk H, Banerjee SN, Hartstein AI, Jarvis WR. 1998. USA</p> <p>To determine if an apparent increase in bloodstream infections in patients with CVCs was associated with the implementation of a needleless access device.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Retrospective follow-up and prospective survey</p> <p>Surgical and medical intensive care and transplant units in a 350 bed urban acute tertiary care hospital.</p> <p>(Retrospective study) Total = 53 (Gender not stated). (Survey) 99 respondents</p> <p>Intensive care and transplant patients.</p> | <p>The CVC associated BSI rate was significantly higher in the needleless device period than in the needle device period.</p> <p>Increase in BSI rate was associated with nurses' unfamiliarity with the device, and needleless device use and care practices different from the manufacturers instructions.</p> | <p>Reliance on retrospective medical records</p> |
| CVC183 | 1 | <p>Garland JS, Alex CP, Mueller CD, Otten D, Shivpuri C, Harris MC, Naples M, Pellegrini J, Buck RK, McAuliffe TL, Goldman DA, Maki DG. 2001. USA.</p> <p>To ascertain the efficacy of a chlorhexidine impregnated dressing on the CVC sites of neonates for the prevention of catheter tip colonization.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>6 neonatal intensive care units.</p> <p>Total = 705 (400 M, 305 F) Intervention Group = 335 Control Group = 370</p> <p>Neonates requiring a CVC for a least 48hrs.</p> | <p>The two dressing regimes were equally effective in preventing CRBSI and BSI without a source. Some adverse reactions were associated with the chlorhexidine dressing, e.g., severe localised dermatitis in 7 of the first 118 recruited and pressure necrosis in 2 subjects.</p> <p>Although the neonates randomized to the intervention group were less likely to have colonized CVC tips than those in the control group 15% vs 24% relative risk: 6.95% confidence interval: 0.5-0.9.</p> <p>Rates of CRBSI (3.8% vs 3.2% RR: 1.2, CI 0.5-2.7) and BSI without a source (15.2% vs 14.3%, RR: 1.1, CI: 0.8-1.5) did not differ between the 2 groups.</p> | <p>A generally well controlled study but may be underpowered as recruitment was stopped short (705 neonates) of the intended 980 due to "funding constraints and low rate of CRBSI" in both groups.</p> |

FINAL GUIDELINE: Prevention of healthcare-associated infections in primary and community care

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| CVC210 | 2 | <p>Humar A, Ostromecki A, Direnfeld J, Marshall JC, Lazar N, Houston PC, Boiteau P, Conly JM. 2000. Canada.</p> <p>To determine which of two solutions, 10% Povidone-Iodine or 0.5% Tincture of Chlorhexidine was the most effective solution for preventing CVC exit site colonization.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Randomised Controlled Trial</p> <p>ICU's in three teaching hospitals Including: 2 medical surgical ICU's 1 medical ICU's 1 neurosurgical ICU's</p> <p>242 150M, 92 F Povidone Group = 117 Chlorhexidine Group = 125</p> <p>All patients over 18 years of age who had CVC's inserted for any purpose.</p> | <p>No significant difference between povidone iodine and chlorhexidine in terms of catheter related bacteraemia.</p> | <p>Data from three sites. No details of sub analysis of data from each site / clinical area.</p> |
| CVC238 | 9 | <p>Do AN, Ray BJ, Banerjee SN, Illian AF, Barnett BJ, Pham MH, Hendricks KA, Jarvis WR. 1999. USA.</p> <p>To evaluate the influences of infection-control practices on BSI associated with the use of needleless devices in the HHC setting.</p> | <p>Design:</p> <p>Setting:</p> <p>Sample:</p> <p>Popⁿ:</p> | <p>Case-control study</p> <p>Home health care (community) patients</p> <p>124 (93M, 31F)</p> <p>Case Patients = 53 Case Controls = 71</p> <p>Case patients defined as those "with a central venous catheter or midline catheter who acquired a primary BSI during the study period.</p> | <p>Results suggest that the risk for BSI was related to the frequency of changing the device end caps.</p> | <p>There are potential confounding factors arising from the fact that patients are un-supervised at home. Authors discuss the possible effects of showering routines. Patients also responsible for their own dressings.</p> |

Rejected CVC Studies

| ID | Quest. Number | Author, Date and Country of Origin | Objective | Design, Setting, Sample Size and Population | | Reasons for Rejection |
|------|---------------|--|---|---|--|--|
| CVC1 | 1,2,4,5,6 | Mermel L. 2000. USA | To review the literature on prevention of intravascular catheter related infections | Design: | Systematic Review | Does not meet SIGN criteria or NICE criteria to be accepted as a well-conducted systematic review, i.e., only one electronic database (MEDLINE) searched (Cochrane & EMBASE not searched). Although the characteristics of those studies accepted into the review were discussed, there was no description of how the quality of these studies were assessed. Finally, important search data missing, e.g., how many studies retrieved, rejected (& why) and accepted (& why). |
| | | | | Setting: | Not reported | |
| | | | | Sample: | Number of studies reviewed not reported (but 133 references cited) | |
| | | | | Popⁿ: | Not reported. | |
| CVC6 | 8 | DeMoissac D, Jensen L. 1998. Canada | To examine the effects of changing IV administration sets at 48 hrs versus 24 hrs on the incidence of infusion-related septicaemia in neutropenic patients with cancer. | Design: | Randomised Controlled Trial | Authors acknowledge that results may have been affected by lack of a standardised procedure for making and breaking connections in IV administration sets. Small sample. |
| | | | | Setting: | Urban cancer setting | |
| | | | | Sample: | 50 patients (14M, 36F) | |
| | | | | Popⁿ: | | |
| CVC8 | 8 | Matlow AG, Kitai I, Kirpalani H et al. 1999. Canada. | To compare the microbial contamination rate of infusate in the intravenous tubing of newborns receiving lipid therapy, replacing the intravenous delivery system at 72-hour versus 24-hour intervals. | Design: | Randomised Controlled Trial | There are numerous potential confounding variables, e.g., Authors identify differences between groups which "should be considered as potential confounders of the tubing change effect", e.g., birth weight. Sampling was not undertaken at weekends resulting in an imbalance of samples between the two groups. |
| | | | | Setting: | 35 bed Neonatal Intensive Care | |
| | | | | Sample: | 1189 babies (709 M, 480 F) | |
| | | | | Popⁿ: | Neonates for whom IV lipid was ordered | |

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| CVC9 | 1 | Madeo M, Martin CR, Turner C et al. 1998. UK. | To establish whether there is a difference in the rate of skin colonization when using Arglaes compared to Tegaderm; to establish whether there is a difference in adhesiveness, application and durability in the two dressings; and to determine if there is a difference in colonization of the catheter tips between the two groups. | <p>Design: Randomised Controlled Trial</p> <p>Setting: Intensive care unit.</p> <p>Sample: 31 (16 M, 15 F)</p> <p>Pop^a: Patients admitted to an intensive care unit who required arterial and/or central venous catheterisation.</p> | Study is underpowered. The researchers conducted a post hoc power analysis (0.8) and concluded 530 subjects would be needed for a future replication of the study. |
| CVC180 | 6 | Lucet J-C, Hayon J, Bruneel F, Dumoulin J-L, Joly-Guillou M-L. 2000. France. | To compare the colonization of hubs with hub protection boxes and hubs with needleless closed connectors. | <p>Design: Randomised Controlled Trial</p> <p>Setting: Three medical or surgical ICUs</p> <p>Sample: 77 patients (Gender not stated) (Cultures obtained from 137 CVCs)</p> <p>Pop^a: No details given.</p> | Report lacks detail regarding homogeneity of groups at the start of study and subsequent treatment of subjects, e.g., frequency of measurement. (1.6) |
| CVC181 | 8 | Donaldson I. 1999. UK | To determine whether the frequency of changing intravenous administration sets in critically ill adults with central venous catheters (CVCs) affects the incidence of CVC-related sepsis / systemic inflammatory response syndrome (SIRS) / bacteraemia. | <p>Design: Systematic Review</p> <p>Setting:</p> <p>Sample:</p> <p>Pop^a:</p> | No details of methodology, e.g., search strategy, appraisal or grading systems. |

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|--------|---|--|---|--|--|---|
| CVC182 | 3 | Henrickson KJ, Axtell RA, Hoover SM, Kuhn SM, Pritchett J, Kehl SC, Klein JP. 2000. USA. | To determine whether an antibiotic flush solution containing Vancomycin, Heparin and Ciprofloxacin (VHC) can prevent the majority of line infections. | Design: Setting: Sample: Popⁿ: | Randomised Controlled Trial 2 “Medical Centres” Total 126 Gender only specified in terms of number of lines rather than subjects. Paediatric oncology patients under 20 years of age. | Sample size is small when viewed in relation to risk sub groups. Wide age range may affect results despite fairly even distribution between groups given that authors acknowledge previous work which suggests infection rate is directly linked to infection rate. Again age banding produces very small numbers. |
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APPENDIX CVC4 – Reviewed evidence for this section

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