Appendices

Appendix A: Scope of partial update

A.1 Guideline title

Infection: prevention and control of healthcare-associated infections in primary and community care (update of NICE clinical guideline 2)

A.1.1 Short title

Infection prevention and control (update)

A.2 The remit

NICE has commissioned the National Clinical Guidelines Centre for Acute and Chronic Conditions to partially update 'Infection control: prevention of healthcare-associated infection in primary and community care' (NICE clinical guideline 2 [2003]).

A.3 Clinical need for the guideline

A.3.1 Epidemiology

a) In 2004, the Department of Health reported that approximately 300,000 healthcare-associated infections occurred per year in hospital and primary care in the UK. In 2007, infectious diseases accounted for 70,000 deaths, 150,000 hospital admissions and 40 per cent of GP consultations in the UK. In the same year, methicillin resistant Staphylococcus aureus (MRSA) bloodstream infections and Clostridium difficile infections were recorded as the underlying cause of, or a contributory factor to, approximately 9000 deaths in hospital and primary care.

b) Healthcare-associated infections are estimated to cost the NHS approximately £1 billion a year; £56 million of this is estimated to be incurred following discharge of patients from hospital.

A.3.2 Current practice

a) Advances in healthcare mean that many more people now survive serious illness. Although infection is still one of the many risks associated with treatment and/or care, this risk can be minimised if preventive measures are in place.

b) The risk of patients acquiring a healthcare-associated infection is increased by the rapid turnover of patients from acute care settings to community care, and by the increasing number of complex procedures performed in primary and community care. Healthcare-associated infections can exacerbate existing or underlying conditions, delay recovery and adversely affect quality of life.

c) Healthcare associated infections arise across a wide range of clinical conditions and can affect patients of all ages. Healthcare workers, families and carers are also at risk of acquiring an infection as a result of exposure to infections when caring for patients.

d) Healthcare-associated infections are commonly linked with invasive procedures or devices. For example:

- indwelling urinary catheters are the most common cause of urinary tract infections

- bloodstream infections are often associated with vascular-access devices.

e) Healthcare-associated infections are caused by a wide range of microorganisms. These are often carried by the patients themselves, but have taken advantage of a route into the body provided by an invasive device or procedure.

f) In certain circumstances asepsis is very important, particularly when dealing with invasive devices. Yet the principles of asepsis are poorly understood.

g) This clinical guideline is a partial update of 'Infection control: prevention of healthcare-associated infection in primary and community care', NICE clinical guideline 2 (2003), and will address areas in which clinical practice for preventing healthcare-associated infections in primary and community care has changed. The aspects that will be updated are identified in section 4.3.1. Any recommendations from the previous guideline not mentioned below will be incorporated into this updated guideline to form an up-to-date guideline on infection prevention and control in primary and community care. This guideline will not cover aspects of infectious diseases addressed by related NICE guidance, but will refer to them as appropriate.

A.4 The guideline

The guideline development process is described in detail on the NICE website (see section 6, 'Further information').

This scope defines what the guideline will (and will not) examine, and what the guideline developers will consider. The scope is based on the referral from the Department of Health.

The areas that will be addressed by the guideline are described in the following sections.

A.4.1 Population

A.4.1.1 Groups that will be covered

a) All adults and children receiving healthcare where standard infection control precautions apply in primary and community care.

b) Healthcare professionals, family members and carers who provide healthcare in primary and community settings.

c) Guideline developers will pay particular attention to the needs of different age groups, different genders, people with disabilities and minority ethnic groups.

A.4.1.2 Groups that will not be covered

a) People receiving healthcare in secondary care settings.

A.4.2 Healthcare setting

a) Primary-care settings, such as general practices, dental clinics, health centres and polyclinics. This also includes care delivered by the ambulance service.

b) Community-care settings (such as care homes, patient's own home, schools and prisons) where NHS healthcare is provided or commissioned.

c) This guideline is commissioned for the NHS, but people providing healthcare in other settings, such as private settings, may find the guidance relevant.

A.4.3 Clinical management

A.4.3.1 Key clinical issues that will be covered

a) Standard infection control precautions:

- Hand hygiene:
  - When to decontaminate hands in relation to patient care in different healthcare settings, including after the removal of gloves.
  - Choice of hand-cleaning preparation (alcohol-based decontamination products, non-alcohol based decontamination products, antimicrobial/antiseptic hand-washes or agents, or liquid soap and water).
  - What is the most effective hand decontamination technique?
- Personal protective equipment:
  - Safe disposal of personal protective equipment in line with European Union (EU) legislation.
  - Appropriate use of plastic aprons and fluid-repellent gowns.
  - Which gloves provide the best protection against infections?
- Safe use and disposal of sharps:
  - Choice of sharps equipment.
  - Safe disposal of sharp instruments and needles in relation to patient care in different healthcare settings, in line with current EU legislation.

b) Long-term (more than 28 days) urinary catheters:

- Use of antibiotics when changing urinary catheters.
- Does bladder irrigation, instillation or washout reduce encrustations/blockages?
- Does bladder irrigation, instillation or washout reduce symptomatic urinary tract infections?
- Which catheters provide the best protection against urinary tract infections (impregnated catheters, silicon catheters or latex catheters)?

c) Percutaneous gastrostomy feeding:

- Use of syringes in enteral feeding systems.

d) Vascular-access devices:

- Which dressings provide the best protection against centrally and peripherally inserted catheter-related bloodstream infection (impregnated dressings, patch, patch plus plain dressings or plain dressings)?
- What is the most clinically- and cost-effective solution for:
  - Decontaminating peripheral and centrally inserted catheter ports and hubs before access?
  - Decontaminating skin when changing dressings?
- What are the most clinically- and cost-effective methods for administering infusions or drugs in order to prevent contamination?

e) Asepsis:

- What are the most clinically- and cost-effective principles of asepsis when handling long-term urinary catheters and vascular access devices?

f) Information and support for healthcare professionals, patients and carers:

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

A.4.3.2 Clinical issues that will not be covered

a) Advice on the diagnosis, treatment or management of specific infections.

b) Procedures for the insertion of urinary catheters, percutaneous gastrostomies or vascular-access devices.

c) Infection prevention measures for invasive procedures carried out by paramedic services, such as at a major trauma, other than in the clinical areas listed in 4.3.1.

d) Decontamination or cleaning of the healthcare environment and equipment, other than the clinical devices listed in 4.3.1.

A.4.4 Main outcomes

a) All cause mortality.

b) Short- and long-term infection-related mortality.

c) Short- and long-term infection-related morbidity.

d) Rates of patients presenting with a healthcare-associated infection or colonisation, such as MRSA.

e) Length of time to treat infection.

f) Infection related hospital admittance rates.

g) Short-, medium- and long-term quality of life.

h) Rates of needle stick injuries.

i) Costs (prevention costs net of treatment cost savings).

A.4.5 Economic aspects

Developers will take into account both clinical and cost effectiveness when making recommendations involving a choice between alternative interventions. A review of the economic evidence will be conducted and analyses will be carried out as appropriate. The preferred unit of effectiveness is the quality-adjusted life year (QALY), and the costs considered will usually be only from an NHS and personal social services (PSS) perspective. Further detail on the methods can be found in 'The guidelines manual' (see ‘Further information’).

A.4.6 Status

A.4.6.1 Scope

This is the final scope.

A.4.6.2 Timing

The development of the guideline recommendations will begin in March 2010.

A.5 Related NICE guidance

A.5.1 Published guidance

A.5.1.1 NICE guidance to be updated

This guideline will update and replace the following NICE guidance:

- Infection control. NICE clinical guideline 2 (2003). Available from www.nice.org.uk/guidance/CG2

A.5.1.2 Other related NICE guidance

- Needle and syringe programmes. NICE public health guidance 18 (2009). Available from www.nice.org.uk/guidance/PH18
- Surgical site infection. NICE clinical guideline 74 (2008). Available from www.nice.org.uk/gudiance/CG74
- Antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures. NICE clinical guideline 64 (2008). Available from www.nice.org.uk/guidance/CG64
- Urinary tract infection in children. NICE clinical guideline 54 (2007). Available from www.nice.org.uk/guidance/CG54
- Urinary incontinence. NICE clinical guideline 40 (2006). Available from www.nice.org.uk/guidance/CG40
- Tuberculosis. NICE clinical guideline 33 (2006). Available from www.nice.org.uk/guidance/CG33
- Nutrition support in adults. NICE clinical guideline 32 (2006). Available from www.nice.org.uk/guidance/CG32

A.6 Further information

Information on the guideline development process is provided in:

- 'How NICE clinical guidelines are developed: an overview for stakeholders the public and the NHS'
- 'The guidelines manual'.

These are available from the NICE website (www.nice.org.uk/GuidelinesManual). Information on the progress of the guideline will also be available from the NICE website (www.nice.org.uk).

Appendix B: Declarations of interests

B.1 Introduction

All members of the GDG and all members of the NCGC staff were required to make formal declarations of interest at the outset of each meeting, and these were updated at every subsequent meeting throughout the development process. No interests were declared that required any actions.

B.2 Declarations of interests of the GDG members

B.2.1 Carol Pellowe

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	CP declared she knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No Interests to declare
Ninth GDG Meeting (8th February 2011)	No Interests to declare
Tenth GDG Meeting (18th March 2011)	No Interests to declare
Eleventh GDG Meeting (7th April)	No Interests to declare
Twelfth GDG Meeting (10th May)	No Interests to declare
Thirteenth GDG Meeting (4th October)	CP declared personal pecuniary interest – members yo the advisory group to Veneacare (pulpable products and maceration) Advisor to Pfizers e learning antibiotics prescription model.
Fourteenth GDG Meeting (20th December)	

B.2.3 Elizabeth Gibbs

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	EG declared she knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	Did not attend meeting
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	No Interests to declare
Tenth GDG Meeting (18th March 2011)	No Interests to declare
Eleventh GDG Meeting (7th April)	No Interests to declare
Twelfth GDG Meeting (10th May)	No Interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.4 Ellie Hayter

GDG meeting	Declaration of Interests
First GDG meeting (17th March - 18th March 2010)	EH did not attend meeting on 17th, no interests to declare on 18th.EH declared she knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	Did not attend meeting
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	Did not attend meeting
Ninth GDG Meeting (8th February 2011)	No Interests to declare
Tenth GDG Meeting (18th March 2011)	No Interests to declare
Eleventh GDG Meeting (7th April)	Did not attend
Twelfth GDG Meeting (10th May)	No Interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.5 Zara Head

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	ZH did not attend meeting on 17th and had no interests to declare on the 18th. ZH declared she knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	Did not attend meeting
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	No interests to declare
Tenth GDG Meeting (18th March 2011)	Did not attend meeting
Eleventh GDG Meeting (7th April)	Did not attend meeting
Twelfth GDG Meeting (10th May)	Did not attend meeting
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.7 Eugenia Lee

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	EL declared she knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	Did not attend meeting
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	Did not attend meeting
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	EL declared a personal non-pecuniary interest in Greenwich commissioning
Tenth GDG Meeting (18th March 2011)	Did not attend meeting
Eleventh GDG Meeting (7th April)	Did not attend
Twelfth GDG Meeting (10th May)	No interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.8 Michael Nevill

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	MN declared he knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	No interests to declare
Tenth GDG Meeting (18th March 2011)	No interests to declare
Eleventh GDG Meeting (7th April)	No interests to declare
Twelfth GDG Meeting (10th May)	No interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.9 Brian Pullen

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	BP declared he knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	Did not attend meeting
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	No Interests to declare
Tenth GDG Meeting (18th March 2011)	Did not attend
Eleventh GDG Meeting (7th April)	No Interests to declare
Twelfth GDG Meeting (10th May)	No Interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.10 Godfrey Smith

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	GS declared he knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	Did not attend meeting
Fourth GDG Meeting (16th July 2010)	Did not attend meeting
Fifth GDG Meeting (6th September 2010)	Did not attend meeting
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare

B.2.11 Julian Spinks

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	JS declared he knew of no personal pecuniary interests in the past 12 months. JS declared upcoming personal pecuniary interests. He is due to record an educational video on overactive bladder on 1st April 2010 and will receive an honorarium indirectly from Pfizer UK. On 5th May 2010 he will lecture on overactive bladder and receive an honorarium from Pfizer UK. JS declared non-personal pecuniary interests. Since 2008 he has been an ongoing member of the faculty of Sense of Leadership, a conference supported by Pfizer. He was an editorial board member of Continence UK (2007 – June 2010), a journal and conference which received sponsorship and advertising revenue from a number of pharmaceutical and healthcare product manufacturers. JS declared personal non-pecuniary interests; since October 2008 he has been a GP advisor to the Association for Continence Advice; since June 2008 an elected member of the Kent Local Medical Committee of the BMA; since October 2008 a press officer of the Dartford, Gravesham and Medway Division of the BMA; and since August 2009 he has also been a member of 'Devices 4 Dignity', an organisation that promotes development of devices supporting patients with urinary problems. These personal non-pecuniary interests are all ongoing. No action for any of the above declarations was deemed necessary, as no evidence for any clinical area stated in the scope was presented at this two day meeting.
Second GDG Meeting (28th April 2010)	JS declared no new interests to those declared at the previous meeting. No action was deemed necessary for the previous declarations, as any payment received for consultancy work did not relate to the clinical area of types of long term urinary catheters presented at the meeting.
Third GDG Meeting (10th June 2010)	JS declared a personal pecuniary interest; he received an honorarium from Pfizer and Novartis for speaking at lectures and advisory boards on overactive bladder. He declared that he knew of no other personal family interest, non-personal pecuniary interest or personal non-pecuniary interest above those already declared. No action for these declarations was deemed necessary, as any payment received for consultancy work did not relate to the clinical areas for long term urinary catheters presented at the meeting.
Fourth GDG Meeting (16th July 2010)	Did not attend meeting
Fifth GDG Meeting (6th September 2010)	JS declared a personal pecuniary interest; he received payment from Novartis in September 2010 for consultancy work on an overactive bladder treatment, which included reviewing documents and offering advice on a clinical pathway. He declared that he knew of no other personal family interest, non-personal pecuniary interest or personal non-pecuniary interest above those already declared. No action for these declarations was deemed necessary, as any payment received for consultancy work did not relate to the clinical areas for types of long term urinary catheters, VADs or PEGs presented at the meeting.
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting	No interests to declare

GDG meeting	Declaration of Interests
(17th November 2010)	
Eighth GDG Meeting (17th December 2010)	Did not attend meeting
Ninth GDG Meeting (8th February 2011)	No interests to declare
Tenth GDG Meeting (18th March 2011)	No interests to declare
Eleventh GDG Meeting (7th April)	No interests to declare
Twelfth GDG Meeting (10th May)	Did not attend meeting
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.12 Sally Stucke

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	SS declared she knew of no personal family interests, personal pecuniary interests, non-personal pecuniary interest or personal non-pecuniary interest in the past 12 months or upcoming month.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	Did not attend meeting
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	Did not attend meeting
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	Did not attend meeting
Tenth GDG Meeting (18th March 2011)	Did not attend meeting
Eleventh GDG Meeting (7th April)	Did not attend meeting
Twelfth GDG Meeting (10th May)	Did not attend meeting
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.13 Graham Tanner

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	GT declared he knew of no personal pecuniary interests, personal family interests, non-personal pecuniary interests or personal non-pecuniary interests in the past 12 months or upcoming months.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	No interests to declare
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	No interests to declare
Eighth GDG Meeting (17th December 2010)	Did not attend meeting
Ninth GDG Meeting (8th February 2011)	No interests to declare
Tenth GDG Meeting (18th March 2011)	No interests to declare
Eleventh GDG Meeting (7th April)	No interests to declare
Twelfth GDG Meeting (10th May)	Did not attend meeting
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.2.14 Sue Wright

GDG meeting	Declaration of Interests
First GDG meeting (17th March -18th March 2010)	SW declared she knew of no personal pecuniary interests, personal family interest, non-personal pecuniary interest or personal non-pecuniary interest in the past 12 months or upcoming month.
Second GDG Meeting (28th April 2010)	No interests to declare
Third GDG Meeting (10th June 2010)	No interests to declare
Fourth GDG Meeting (16th July 2010)	No interests to declare
Fifth GDG Meeting (6th September 2010)	Did not attend meeting
Sixth GDG Meeting (19th October 2010)	No interests to declare
Seventh GDG Meeting (17th November 2010)	Did not attend meeting
Eighth GDG Meeting (17th December 2010)	No interests to declare
Ninth GDG Meeting (8th February 2011)	Did not attend meeting
Tenth GDG Meeting (18th March 2011)	No interests to declare
Eleventh GDG Meeting (7th April)	No interests to declare
Twelfth GDG Meeting (8th May)	No interests to declare
Thirteenth GDG Meeting (4th October)	No Interests to declare
Fourteenth GDG Meeting (20th December)	

B.3 Declarations of interests of the cooptees

Cooptee	Declaration of Interests
Ms Kelly Alexander	Personal pecuniary interest: consultancy work for advisory board for pharmacy management, sponsored by Baxter.
Dr Paul Averley	None declared
Ms Daphne Colpman	None declared
Mr Andrew Jackson	Non-personal pecuniary interest: Manage an IV website and consultancy company (IVTEAM.com).
Ms Vera Todorvic	Personal non-pecuniary interests: I am a member of both the PENG (Parenteral and Enteral Nutrition Group) of the British Dietetic Association and BAPEN (British Association for Parenteral and Enteral Nutrition
Proffessor Mark Wilcox	Personal pecuniary interests: received research support from Actelion, bioMerieuc, Cerexa, Novacta, Pfizer, Summit and the Medicines company. Received paid consultancies or lecture honoraria from Actelion, Astellas, AstraZeneca, Bayer, bioMerieuc, Cerexa, MSD, Nabriva, Novacta, Pfizer, Photopharmica, the Medicines company and Viropharma.

Appendix C: List of stakeholders

3M Health Care Limited

Abbott Laboratories Limited

African Health Policy Network

Alder Hey Children's NHS Foundation Trust

Anglian Community Enterprise

Ark Therapeutics Ltd

Aspen Medical Europe Ltd

Association for Continence Advice

Association of British Health-Care Industries

Association of Dance Movement Psychotherapy UK

Association of Paediatric Anaesthetists of Great Britain and Ireland

Astellas Pharma Ltd

Augustine Biomedical International

Barchester Healthcare

Bard Limited

Barnsley Hospital NHS Foundation Trust

Baxter Healthcare Ltd

BD (Beckton, Dickinson and Company)

Berkshire Healthcare NHS Foundation Trust

Birmingham City University

BMJ

Bolton PCT

Brighton and Sussex University Hospitals Trust

British Association of Otolaryngologists Head and Neck Surgeons (ENT UK)

British Association of Social Workers

British Dental Association

British Dietetic Association

British Elbow and Shoulder Society (BESS)

British Healthcare Trades Association

British In Vitro Diagnostics Association

British Infection Association (formerly Association of Medical Microbiologists)

British Infection Association (formerly British Infection Society)

British Medical Association (BMA)

British National Formulary (BNF)

British Orthopaedic Association

British Paediatric Allergy, Immunity & Infection Group

British Pain Society

British Psychodrama Association

British Psychological Society, The

British Renal Society

British Society of Immunology

Cambridge Temperature Concepts Ltd

Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)

Camden and Islington Mental Health and Social Care Trust

Cancer Voices

Care Quality Commission (CQC)

Central & North West London NHS Foundation Trust

CJD Support Network

CLIC Sargent

Cochrane Wounds Group

Colchester Hospital University NHS Foundation Trust

College of Optometrists

Coloplast Limted

Connecting for Health

ConvaTec

Cook Medical

Cornwall & Isles of Scilly PCT

County Durham PCT

Covidien UK Commercial

Craegmoor

Danone UK Limited

Dental Practitioners Association

Department for Communities and Local Government

Department of Health

Department of Health Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI)

Department of Health, Social Services & Public Safety, Northern Ireland (DHSSPSNI)

Derbyshire Mental Health Services NHS Trust

Dermal Laboratories Ltd

DH Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection

Diving Diseases Research Centre, The

Dorset PCT

Dyson Ltd

Elective Orthopaedic Centre, The

English Community Care Association (ECCA)

Enturia Ltd

Eusapharma (Europe) Ltd

Faculty of Dental Surgery

Faculty of General Dental Practice

Faculty of Intensive Care Medicine

Federation of Ophthalmic & Dispensing Opticians (FODO)

Forest Laboratories UK Limited

Fresenius Medical Care

General Dental Council

George Eilot Hosptal Trust

Gloucestershire Hospitals NHS Trust

Gloucestershire LINk

Great Western Hospitals NHS Foundation Trust

Greater Manchester West Mental Health NHS Foundation Trust

Greater Manchester West Mental Health NHS Foundation Trust

Guy's and St Thomas NHS Foundation Trust

Haag-Streit UK

Hampshire Partnership NHS Foundation Trust

Hayward Medical Communications

HCAI SURF(service Users in Research Forum)

Health Protection Agency

Health Protection Scotland

Healthcare Improvement Scotland

Healthcare Quality Improvement Partnership

Herpes Viruses Association

Hertfordshire Partnership NHS Trust

Hospital Infection Society

Hull and East Yorkshire Hospitals NHS Trust

Humber NHS Foundation Trust

ICNet International

Infection Prevention Society

Insitute of Biomedical Science

Interhealth Canada

Janssen

JBOL Ltd

Johnson & Johnson Medical

Karomed Limited

KCI Europe Holding B.V.

KCI Medical Ltd

Kent & Medway NHS and Social Care Partnership Trust

King's College London Dental Institute

Lambeth Community Health

Lancashire Care NHS Foundation Trust

Launch Diagnostics Limited

Leeds PCT

Leicestershire Partnership NHS Trust & Managed Clinical Network for PD

Letterkenny General Hospital

Leukaemia & Lymphoma Research

Liverpool Community Health

Liverpool PCT

Liverpool PCT Provider Services

London Ambulance Service NHS Trust

Lothian University Hospitals Trust

Luton & Dunstable Hospital NHS Foundation Trust

Maidstone and Tunbridge Wells NHS Trust

Manchester Community Health

MAST Group

Medicines and Healthcare Products Regulatory Agency (MHRA)

Medihoney (Europe) Ltd

Medway Community Centre

Medway NHS Foundation Trust

Ministry of Defence (MoD)

Monitor - Independent Regulator of NHS Foundation Trusts

Mother and Child Foundation

MRSA Action UK

National Care Forum

National Concern for Healthcare Infections (NCHI)

National Day Nurseries Association

National Electronic Library for Infection

National Infusion & Vascular Access Society

National Patient Safety Agency (NPSA)

National Pharmacy Association

National Treatment Agency for Substance Misuse

Nestor Healthcare Group Ltd

NETSCC, Health Technology Assessment

Newcastle and North Tyneside Community Health

NHS Clinical Knowledge Summaries Service (SCHIN)

NHS Direct

NHS East of England

NHS Forth Valley

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North Essex Partnership NHS Foundation Trust

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North Staffordshire Combined Healthcare NHS Trust

North West London Perinatal Network

Northampton Primary Care NHS Trust

Nottingham University Hospitals NHS Trust

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Nutricia Ltd (UK)

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Patient's Association

Patients Council

Pennine Healthcare

PERIGON Healthcare Ltd

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Pilgrims Hospices in East Kent

PINNT

Plymouth Local Involvement Network

Poole and Bournemouth PCT

Public Health Medicine Environmental Group (PHMEG)

Public Health Wales

Queen Victoria Hospital NHS Trust

Retreat, The

Reusable Healthcare Textiles Association

Richard Wells Research Centre

Robinson Healthcare Ltd

Roche Diagnostics

Rotherham NHS Foundation Trust

Royal Berkshire NHS Foundation Trust

Royal Brompton & Harefield NHS Foundation Trust

Royal College of Anaesthetists

Royal College of General Practitioners

Royal College of General Practitioners Wales

Royal College of Midwives

Royal College of Nursing

Royal College of Obstetricians and Gynaecologists

Royal College of Paediatrics and Child Health

Royal College of Pathologists

Royal College of Physicians London

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Surgeons of England

Royal Free Hospital NHS Trust

Royal Pharmaceutical Society of Great Britain

Royal Society of Medicine

Sanctuary Care

Sandwell PCT

Sanofi-Aventis

Scottish Intercollegiate Guidelines Network (SIGN)

Sheffield Children's NHS Foundation Trust

Sheffield Health and Social Care Foundation Trust

Sheffield PCT

Sheffield Teaching Hospitals NHS Foundation Trust

Sickle Cell Society

Smith & Nephew Healthcare

Social Care Institute for Excellence (SCIE)

Social Exclusion Task Force

Society and College of Radiographers

Society for Acute Medicine

Society of British Neurological Surgeons

Society of Chiropodists & Podiatrists

Solent Healthcare

South Asian Health Foundation

South East Coast Ambulance Service

South Essex Partnership NHS Foundation Trust

South Staffordshire & Shropshire NHS Foundation Trust

South Staffordshire PCT

South West Yorkshire Partnership NHS Foundation Trust

South Western Ambulance Service NHS Foundation Trust

Southport & Ormskirk Hospital NHS Trust

Spinal Injuries Association

St Andrew's Healthcare

St Marys Hospital, Manchester

StickSafe

Sue Ryder Care

Surgical Dressing Manufacturers Association (SDMA)

Sussex Partnership NHS Foundation Trust

Synergy Healthcare (UK) Limited

Tees Esk & Wear Valleys NHS Trust

The Association of safe Aseptic practice

The Society and College of Radiographers

The Urology Trade Association

Trafford NHS Provider Services

Turning Point

UK Clinical Pharmacy Association (UKCPA)

UK Ophthalmic Pharmacy Group

UNISON

United Kingdom Clinical Pharmacy Association (UKCPA)

United Lincolnshire Hospitals NHS Trust

University Hospitals Birmingham NHS Foundation Trust

University of Southampton

Urgo Medical Ltd

Urology User Group Coalition

Vifor Pharma UK Ltd

Welsh Government

Welsh Scientific Advisory Committee (WSAC)

West Hertfordshire PCT & East and North Hertfordshire PCT

Western Cheshire Primary Care Trust

Western Health and Social Care Trust

Wirral University Teaching Hospital NHS Foundation Trust

Worcestershire Acute Hospitals NHS Trust

Worcestershire PCT

Wound Care Alliance UK

Xpand Medical Ltd

York Teaching Hospital NHS Foundation Trust

Appendix D: 2003 guideline appendices

D.1 Methods and systematic review process

D.1.1 Methods

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)[116] and reproduced below:

Catagories 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 grading scheme suggested by Eccles and Mason (2001)[116] 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).

D.1.2 Systematic review process

D.1.2.1 Standard principles

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[466]. The appraisal for the

epic phase 1 guidelines was undertaken by three external independent appraisers[381]. 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: antisepsis; 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.

D.1.2.2 Urinary catheterisation

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.[466] The appraisal for the epic phase 1 guidelines was undertaken by two external independent appraisers.[381] 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 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 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; uretheral 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.

D.1.2.3 Enteral feeding

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.[466] 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.

D.1.2.4 Central venous catheters

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:

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?

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.[381] 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;

1. General asepsis;
2. Catheter site care;
3. 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.

D.2 Full scope (2003)

D.2.1 Objective

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.

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.

D.2.2 Title

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

D.2.3 Clinical Need and Practice

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.

This guideline will assist clients and all healthcare providers involved in direct patient care to minimise the risk of infection.

Guideline developers will work closely with service users and carers to ensure that the guidelines are understandable to clients and their carers.

D.2.4 Population

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

D.2.5 Health care setting

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.

The guideline will also be compatible with guidelines for the prevention of hospital-acquired infections, and will influence discharge planning.

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.

D.2.6 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.

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.

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.

This guideline will not include advice on the diagnosis, treatment and management of specific infections.

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.

D.2.7 Presentation

The guideline will be available in three forms:

4. The full guideline containing the evidence base used by the developers.
5. A short form version, using a standard template, which will form the Institute's guidance to the NHS including a clinical practice algorithm.
6. 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.

D.2.8 Status

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.

Information on the guidelines development process, stakeholder involvement and the progress of this guideline is available on the website http://www.nice.org.uk/.

D.3 Search strategy (2003)

D.3.1 Hand Hygiene - Systematic Review Process

D.3.1.1 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?

D.3.1.2 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

antisepsis; sterilisation; decontamination

D.3.1.3 Search Results

Total number of articles located = 21219

Sift 1 Criteria

Abstract indicates that the article: relates to infections associated with hand hygiene, 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 = 160

Sift 2 Criteria

Full Text confirms that the article relates to infections associated with hand hygiene 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 = 24

D.3.1.4 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

D.3.1.5 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.

D.3.2 Protective Clothing - Systematic Review Process

D.3.2.1 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?

D.3.2.2 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

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

D.3.2.3 Search Results

Total number of articles located = 8611

Sift 1 Criteria

Abstract indicates that the article: relates to infections associated with protective clothing, 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 = 95

Sift 2 Criteria

Full Text confirms that the article relates to infections associated with protective clothing 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 = 7

D.3.2.4 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 = 7

Total number of articles rejected after critical appraisal = 0

D.3.2.5 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.

D.3.3 Sharps - Systematic Review Process

D.3.3.1 Systematic Review Questions

D.3.3.2 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?

D.3.3.3 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.

D.3.3.4 Search Results

Total number of articles located = 7938

Sift 1 Criteria

Abstract indicates that the article: relates to infections associated with sharps, 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 = 84

Sift 2 Criteria

Full Text confirms that the article relates to infections associated with protective clothing 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 = 7

D.3.3.5 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

D.3.3.6 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.

D.3.4 Long-term Indwelling Urinary Catheters - Systematic Review Process

D.3.4.1 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; morganella.

THESAURUS AND FREE TEXT TERMS

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

D.3.4.2 Search Results

Total number of articles located = 7387

D.3.5 Enteral Feeding - Systematic Review Process

D.3.5.1 Databases and Search Terms Used

DATABASES

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

D.3.5.2 Search results

Total number of articles located = 19639

D.3.6 Central Venous Catheters - Systematic Review Process

D.3.6.1 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.

D.3.6.2 Search Results

Total number of articles located = 4,650

D.4 Key audit criteria (2003)

D.4.1 Standard principles

Aim	Criteria
To ensure all healthcare personnel have access to appropriate hand decontamination equipment and protective clothing wherever they deliver care	All healthcare personnel should have an appropriate supply of hand decontamination equipment, gloves, aprons and protective clothing in their care setting. Standard 100% Data collection: self audit
Ensure that all healthcare personnel are trained and competent in hand decontamination and risk assessment.	All healthcare personnel involved in care are trained and updated. Standard 100% Data collection: review of staff education records
To ensure that all healthcare personnel respond appropriately to any sharps injury	All healthcare personnel should be aware of their local sharps injury policy and how to access appropriate help should they sustain a sharps injury. Standard 100% Data collection: direct questioning
To ensure patients and carers are informed and educated about standard principles.	All patients and carers are aware of the need to: Decontaminate their hands; Use protective clothing; Dispose of sharps safely. Standard 100% Data collection: direct questioning of patients and carers.

D.4.2 Urinary catheterisation

Aim	Criteria
Identify all patients with LTC, their clinical need for catheterisation, assessed and documented.	All patients should have a patient record that documents the reason for catheterisation, type of catheter, catheter insertion, changes and care. Standard 100% Data collection: review of patient notes
Ensure that all healthcare personnel are trained and competent in urinary catheterisation.	Healthcare personnel receive training and updates in the management of urinary catheters. Standard 100% Data collection: review of staff education records

Aim	Criteria
To prevent catheter-related urinary tract infections (CR-UTI) associated with LTC	All healthcare personnel decontaminate their hands and wear a new pair of non-sterile gloves before manipulating the system. Standard 100% Data collection: observation/ self audit
To reduce the incidence of CR-UTI by maintaining a closed system.	All long-term catheters must be connected to a sterile closed drainage system or valve Standard 100% Data collection: observation
To reduce the incidence of CR-UTI caused by blocking.	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. Standard 100% Data collection: review of patient notes
To ensure patients and carers are informed and educated about catheter management	All patients and carers are aware of the need to: Decontaminate their hands; Keep the system closed. Standard 100% Data collection: direct patient questioning of patients and carers.

D.4.3 Enteral feeding

Aim	Criteria
Identify all patients undergoing HETF are linked to a Nutrition Support Team or community specialist for ongoing support.	All patients should have a patient record that documents their contact person for ongoing support. Standard 100% Data collection: Review of patient notes
Ensure that all healthcare personnel are trained and competent in administration of HETF.	All healthcare personnel involved in the care of people receiving enteral feeding are trained and updated Standard 100% Data collection: Review of staff education records
To prevent infections associated with the administration of HETF.	All healthcare personnel decontaminate their hands before starting feed preparation and manipulating the system.

Aim	Criteria
	Standard 100% Data collection: Observation/ self audit, incidence of HETF related infection.
To prevent infections associated with the administration of HETF by maintaining a closed system.	Ready–to-hang feeds are used wherever possible, and hung for no longer than the maximum recommended time. Standard 100% Data collection: Observation/ patient records, incidence of HETF related infection.
To prevent infections associated with the administration of HETF caused by blocking.	All patients should have a patient record that documents the care of their enteral tube, including flushing regimen Standard 100% Data collection: Review of patient notes, incidence of HETF related infection.
To ensure patients and carers are informed and educated about HETF.	All patients and carers are aware of the need to: Decontaminate their hands; Keep the system closed. Standard 100% Data collection: direct patient questioning of patients and carers.

D.4.4 Central venous catheters

Aim	Criteria
Identify all patients with central venous catheters.	All patients should have a patient record that documents the reason for CVC placement, type of catheter, catheter insertion site, catheter replacements and care. Standard 100% Data collection: Review of patient notes
Ensure that all healthcare personnel are trained to implement these guidelines and assessed as competent. Support healthcare personnel to consistently adhere to guideline recommendations.	All healthcare personnel involved in the care of people with CVCs receive training and updates in the management of CVCs. Standard 100% Data collection: Review of staff education records/direct observation/self-audit
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.	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.

Aim	Criteria
	Standard 100% Data collection: Review of patient notes
Ensure that patients and carers are informed and educated about the management of their CVC.	All patients and carers are aware of the need to: Decontaminate their hands when manipulating the system; Use aseptic technique when manipulating or accessing the system. Standard 100% Data collection: direct patient questioning of patients and carers.

D.5 AGREE Monitoring Appraisal Forms (2003)

D.5.1 Standard precautions

Table 1: 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)

Table 2: Domain scores

Domain	**Score**
Domain 1	Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (43/48) x 100 = 90%
Domain 2	Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (28/64) x 100 = 44%
Domain 3	Maximum possible score = 4 x 7 x 4 = 112 Standardised domain score is: (81/112) x 100 = 72%
Domain 4	Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (58/64) x 100 = 91%

Domain	Score
Domain 5	Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (42/48) x 100 = 88%
Domain 6	Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (16/32) x 100 = 50%

Table 3: 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

Table 4: Domain scores

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

Domain	Score
	Standardised domain score is: (17/24) x 100 = 71%

Table 5: 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)

Table 6: Domain scores

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

Domain	Score
Domain 6	Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (17/32) x 100 = 53%

Table 7: 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)

Table 8: Domain scores

Domain	Score
Domain 1	Maximum possible score = 4 x 3 x 4 = 48 Standardised domain score is: (38/48) x 100 = 79%
Domain 2	Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (30/64) x 100 = 47%
Domain 3	Maximum possible score = 4 x 7 x 4 = 112 Standardised domain score is: (36/112) x 100 = 32%
Domain 4	Maximum possible score = 4 x 4 x 4 = 64 Standardised domain score is: (39/64) x 100 = 61%
Domain 5	Maximum possible score = 4 x 3 x 4 = 48

Domain	Score
	Standardised domain score is: (16/48) x 100 = 33%
Domain 6	Maximum possible score = 4 x 2 x 4 = 32 Standardised domain score is: (11/32) x 100 = 34%

Table 9: 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)

Table 10: Domain scores

Domain	Score
Domain 1	Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (15/24) x 100 = 63%
Domain 2	Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (12/32) x 100 = 38%
Domain 3	Maximum possible score = 4 x 7 x 2 = 56 Standardised domain score is: (15/56) x 100 = 27%
Domain 4	Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (20/32) x 100 = 63%
Domain 5	Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (7/24) x 100 = 29%
Domain 6	Maximum possible score = 4 x 2 x 2 = 16 Standardised domain score is: (8/16) x 100 = 50%

D.5.2 Urinary catheterisation

Table 11: 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)

Table 12: Domain scores

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

Table 13: 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

Table 14: Domain scores

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

D.5.3 Enteral feeding

Table 15: 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

Table 16: Domain scores

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

Table 17: 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

Table 18: Domain scores

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

Table 19: 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

Table 20: Domain scores

Domain	Score
Domain 1	Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (11/24) x 100 = 46%
Domain 2	Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (9/32) x 100 = 28%
Domain 3	Maximum possible score = 4 x 7 x 2 = 56 Standardised domain score is: (17/56) x 100 = 30%
Domain 4	Maximum possible score = 4 x 4 x 2 = 32 Standardised domain score is: (20/32) x 100 = 63%
Domain 5	Maximum possible score = 4 x 3 x 2 = 24 Standardised domain score is: (6/24) x 100 = 25%
Domain 6	Maximum possible score = 4 x 2 x 2 = 16 Standardised domain score is: (4/16) x 100 = 25%

D.5.4 Central venous catheterisation

Table 21: 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)

Table 22: Domain scores

Domain	Score
Domain 1	Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (35/36) x 100 = 97%
Domain 2	Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (34/48) x 100 = 90%
Domain 3	Maximum possible score = 4 x 7 x 3 = 84 Standardised domain score is: (60/84) x 100 = 71%
Domain 4	Maximum possible score = 4 x 4 x 3 = 48 Standardised domain score is: (46/48) x 100 = 96%
Domain 5	Maximum possible score = 4 x 3 x 3 = 36 Standardised domain score is: (32/36) x 100 = 89%
Domain 6	Maximum possible score = 4 x 2 x 3 = 24 Standardised domain score is: (18/24) x 100 = 75%

D.6 Evidence tables (2003)

D.6.1 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	Lucet JC, Riguad F, Mentre F, Kassis N, Deblangy C, Andremont A, Bouvet E. 2002. France.[274] 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.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Hospital 516 specimens, 258 beforehand hygiene and 258 after. 33 Healthcare Workers (HCWs) and Intensive Care Units (ICUs) and 10 from medical wards (14M, 29F)	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 disinfectatnt. 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.	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. Presumably depended on where the health care worker worked. Standard times for length of the procedure, the volume of product used, method of drying hands
H11	2	Herruzo-Cabrera R, Garcia-Cabballero J, Martin- Moreno JM, Graciani-Perez-Regadera	Design:	1.Randomised Control Trial	1.The alcoholic solution of NPD was highly germicidal in vivo, destroying organisms better than classic hand	In vivo component demonstrated effect of NDP intervention in non-clinical setting

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		MA, Perez-Rodriguez J. 2001. Spain.[190] To study the effectiveness of an alcohol solution of N-duopropenide (NDP) in vivo and its effect on the control of a multi-resistant Klebsiella pneumoniae outbreak in NICU that had persisted for 13 months.	 Setting: Sample: Popn:	2.DescriptiveStudy – before and after follow up study Neonatal Intensive Care Unit (NICU) and Paediatric Intensive Care Unit (PICU) 45 health care workers in NICU and 24 HCW in PICU (gender not stated) Health care workers.	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. 2. Before NDP use the cumulative incidence of infection of Klebsiella pneumonae infection 25%. After NDP introduction reduced to 6.5% and then 0% after 5 months (p<0.0000001)	Similar results were obtained for the different study periods Colonisation prevalence was tallied twice. The practice of surveillance and measurement could have led the HCW to modify their practice The results of plate cultures obtained were shown to staff to motivate them to wash their hands.
H12	2	Herruzo-Cabrera R, Garcia-Caballero J, Fernandez Acenero MJ. 2001. Spain.[189] Is fast disinfection with an alcohol solution better than hand washing and can it improve compliance?	Design: Setting: Sample: Popn:	1.Laboratory Experiment 2.Quasi-experiment 1.Laboratory 2.Hospital 52 healthy volunteers 102 healthcare personnel from burn ICU and 4 other ICU	Laboratory component established that: Ethylsulphate and NPD-alcohol produced a 0.9-1.2 log10 reduction in colony forming units. 60° alcohol/phenol alcohol 0.4 – 0.6 log10 reduction in colony forming units. Classic hand washing resulted in 0.1-0.3 log10 reduction in colony forming units. In use component demonstrated: NPD alcohol 95% mean reduction in colony forming units (>2log10) compared to 50%) 0.1 log10) in classic hand wash. P<0.00001 reduction for	Laboratory study, and an in use component.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				Healthy volunteers health care personnel	both NPD and hand washing, but always greater with NPD alcohol.	
H13	5	Pietsch H. 2001. Germany.[367] To compare the dermal tolerance and antimicrobial efficacy of a chlorhexidine antiseptic (Hibiscrub) and a alcohol hand rub (Sterillium).	Design: Setting: Sample: Popn:	Laboratory experiment Laboratory 60 (gender not stated) Volunteers, no other details.	Alcohol rub was found to cause significantly less skin irritation than a chlorhexidine based antiseptic.	Volunteers not healthcare workers. Author works for a chemical company therefore possible bias.
H14	2	Kramer A, Rudolf P, Kampf G, Pittet D. 2002. Switzerland. [235] To investigate antimicrobial efficacy of 10 gels and 4 rinses according to European standards.	Design: Setting: Sample: Popn:	Laboratory experiment Laboratory (Industry) 15 volunteers Volunteers, details unknown	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%. Ethanol content of up to 70% is not as effective as 2 propanol 60%. In terms of bacterial efficacy, 1-propanol can be regarded as the most effective alcohol, followed by 2 propanol and ethanol. Comparison of 2 propanol with ethanol showed that the efficacy of	Non-clinical study that may not replicate in use conditions.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
					2 propanol 60% is almost equivalent to ethanol 80%. Therefore ethanol based hand formulations should contain at least 80% ethanol.	
H15	2	Moadab A, Rupely KF, Wadhams P. 2001. USA.[300] 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.	Design: Setting: Sample: Popn:	Laboratory experiment College of podiatric medicine 40 (gender not stated) Volunteer Students	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 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 sanitzer 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.	Non-clinical study that may not replicate in use conditions.
H16	2 & 5	Winnefeld M, Richard MA, Darncourt, Grob JJ. 2000.	Design:	Randomised Controlled Trial	Q2. Alcohol based rinse significantly more effective than liquid soap at	Study conducted under clinical use conditions.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		France.[507] To assess skin tolerance and antimicrobial effects of two widely accepted hand hygiene measures under in use conditions.	Setting: Sample: Popn:	Hospital 52 (2M, 49F) Volunteer nurses in 12 medical and 4 surgical departments	removing transient microorganisms p=0.016. 20/50 hand washes with antiseptic soap resulted in residual bacterial contamination of hands. 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. The rate of successful hand decontamination was low, 20% in hand wash group and 31% in handrub group. 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.	Skin assessment on 1st and last day of study using 3 scores 2 determined by the same observer
H17	1 & 2	Gould D, Gammon J, Donnelly M, Batiste L, Ball E, De Melo AMSC, Alidad V, Miles R, Halablab M. 2000. UK.[162] To establish whether the potential for cross infection during home visits could be reduced by supplying nurses	Design: Setting: Sample:	Descriptive Study Community. Clients' homes and clinic settings. 17 Nurses working in	Q1. Poor conditions in patients' homes compromise nurse's ability to perform adequate hand hygiene effectively and thereby increase risks of cross infection. Q2. Application of an antiseptic cream (chlorhexidine based) exhibited residual effectiveness in reducing bacteria	Complex but comprehensive research in that it uses 3 methods to assess the risk of cross infection. Unclear how many nurses the data relates to.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		with an antiseptic cream to be used in addition to their routine hand hygiene precautions	Popn:	the community delivering various procedures and care.		
H18	1	Pittet D, Dharan S, Touveneau S, Sylvie RN, Sauvan V, Perneger TV. 1999. Switzerland.[371] To study the process of bacterial contamination of health care worker's hands during routine patient care in a large teaching hospital.	Design: Setting: Sample: Popn:	Descriptive Study Hospital 266 hospital staff, 417 episodes of care Health care workers	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 $p=0.03$). Simple hand washing before patient care without hand antisepsis is associated with a higher colony count 52 CFU $p=0.03$	Standard definitions of patient care activities were used. There may have been some observational bias. 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 Findings may not be generalisable to non-dominant hand.
H20	2	Guilhermetti M, Evandro S, Hernandes D, Fukushigue Y, Garcia LB, Cardoso CL. 2001. Brazil[169] To investigate the effectiveness of hand cleansing agents in removing a hospital strain of	Design: Setting: Sample:	Laboratory experiment Laboratory (University) 5 (2M, 3F)	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	Non-clinical study that may not replicate in use conditions.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		Methicillin Resistant Staph. Aureus (MRSA) from artificially contaminated hands of five volunteers.	Popn:	Volunteers		
H21	2	Faoagali J, Narelle G, Fong J, Davy J, Dowser M. 1999. Australia.[128] 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.[43] To compare the frequency of skin irritation and dryness associated with using an alcohol – hand gel regimen for hand antisepis 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 $p=0.05$).	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

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
					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.	condition reduced opportunity for bias.
H50	4	Gustavson DR, Vetter EA and Larson DR, Ilstrup DM, Maker MD, Thompson RL, Cockerill FR. 2000. USA.[170] To evaluate the effects of 4 different drying methods to remove bacteria from washed hands	Design: Setting: Sample: Popn:	Laboratory experiment Laboratory (Healthcare) 100 (gender not stated) Volunteers (no break down)	No statistically significant differences were noted in the numbers of colony forming units for each drying method p=0.72	Non-clinical study that may not replicate in use conditions. Glove juice method permits sampling of inter-digital areas and is a more comprehensive measure of sampling skin bacteria
H51	2	Paulson DS, Fendler EJ, Dolan MJ, Williams RA. 1999. USA.[352] 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	Design: Setting: Sample: Popn:	Experimental Laboratory (industry) 25 adults between 18-70 years (both sexes, though gender specifics not stated) Adults	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.	Laboratory setting rather than in use. 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. The authors reported that the study was based on small sample sizes and therefore precision may have been compromised.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		sanitizer.				
H52	2 & 5	Larson E, Siberger M, Jakob K, Whittier S, Lena L, Latta PD, Saiman L. 2000. USA.[249] 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).	Design: Setting: Sample: Popn:	Prospective quasi experimental Hospital neonatal intensive care unit 16 nurses (gender not stated) Nurses	Q2. The use of mild soap for cleaning and an alcohol-based waterless product provided antimicrobial effectiveness comparable to traditional antiseptic hand washing. Q5. The use of mild soap for cleaning and an alcohol-based waterless product significantly improved skin condition p<0.005.	
H53	2 & 5	Larson E, Aiello A, Bastyr J, Lyle C, Stahl J, Cronquist A, Lai L, Della-Latta P. 2001. USA.[250] 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.	Design: Setting: Sample: Popn:	Randomised controlled trial 2 critical care units 50 (before dropouts, 7 physicians, 36 nurses, 7 other staff) (11M, 39F) Health care workers	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.	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).

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
H54	2	Girou E, Loyeau S, Legrand P, Oppein F, Brun-Buisson C. 2002. France.[154] 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.	Design: Setting: Sample: Popn:	Randomised Controlled Trial 94 bedded university hospital 23 Health care workers.	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.	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,
H55	2	Zaragoza M, Salles M, Gomez J, Bayas JM, Trilla A. 1999. Spain.[528] 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.	Design: Setting: Sample: Popn:	Randomised Control Trial Clinic wards and ICU in 1 hospital. 50 Hospital health care workers	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.	Larger sample needed. One observer monitored healthcare worker activity and may have been some observer bias.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
H56	1	Fendler EJ, Ali Y, Hammond BS, Lyons MK Kelley MB, Vowell NA. 2002. USA.[130] To determine the effect of the use of alcohol gel hand sanitizer by caregivers on infection types and rates in an extended care facility.	Design: Setting: Sample: Popn:	Controlled Ttudy Hospital 265 employees Employees in a 275 bed extended care facility specialising in rehabilitation and subacute care.	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.	In use study in normal clinical conditions over an extended period of time. Standardised protocol used for hand hygiene. 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.
H65	1	Ryan MAK, Christian RS, Wohlrabe J. 2001, USA.[415] 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.	Design: Setting: Sample: Popn:	Controlled Trial Navy Training Centre 1,089,800 person-weeks reviewed. Navy Trainees. 80% men average age 20 years.	Overall rate of respiratory illness in post intervention period was 45% lower than in the year prior to intervention.	A well designed controlled experiment.
H66	2	Cardoso CL, Pereira HH, Zequim JC, Guilhermetti M. 1999. Brazil.[60] To explore the effectiveness of hand-cleansing agents (plain	Design: Setting: Sample:	Laboratory experiment Laboratory (University) 5 (2M, 3F)	Results suggest 70% ethyl alcohol and 10% povidone iodine may be the most effective agents for removing A. baumenii strain from heavily contaminated hands.	A well controlled laboratory experiment.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		liquid soap, 70% ethyl alcohol, 10% povidone-iodine, 4% chlorhexidine gluconate) for removing a hospital strain Acinetobacter baumanii from artificially contaminated hands of 5 volunteers.	Popn:	5 healthy adults with no skin problems aged 10-47 years.		
H67	2	Kampf G, Jarosch R, Ruden H. 1998. Germany.[214] 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=<0.05against MRSA than Hibiscrub.	A well controlled laboratory experiment.
H68	5	Forrester BG, Roth VS. 1998. USA.[134] 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 p0.005 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.[114]	Design:	Laboratory experiment	All 3 hand products were equally effective after a single application. After repeated use the alcohol containing	The company producing one of the products carried out the research study which may have biased the

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		To evaluate the immediate and persistent effectiveness of two alcohol- containing hand sanitizers to supplement normal hand washing.	Setting: Sample: Popn:	Laboratory (Industry) 56% male and 44% women aged between 18-47. Volunteers.	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	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
H193	ALL	Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.[382] Systematic review of hand hygiene practice and the reduction of HAI.	Design: Setting: Sample: Popn:	Systematic Review Laboratory and hospital settings Study Designs: RCT, CCT, Experimental laboratory studies were a major component 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 studies 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.

D.6.2 Hands rejected studies

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
H19	2	Chudleigh J and Buckingham C. 1999. UK.[73]	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: Setting: Sample: Popn:	Observational Hospital – special care baby unit. 12 nurses (3 unqualified) Nurses	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

D.6.3 Personal protective equipment accepted studies

ID	Quest	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
G4	4	Callaghan I. 1998. UK.[57] To examine the levels of contamination on nurses' uniforms and the role if any of plastic aprons.	Design: Setting: Sample: Popn:	Descriptive Study 2 urban hospitals 88 (48 in pilot, 40 in comparative study) Nurses' uniforms.	Uniforms were found to be equally and heavily contaminated at all sites sampled and at all times. 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.	Variable not well controlled. Data and statistical analysis missing.
G5	4	Perry C, Marshall R, Jones E. 2001. UK.[360] 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 unitform.	Design: Setting: Sample: Popn:	Descriptive Study City hospital 57 (gender not stated) Staff from five different ward areas in one hospital	22 (39%) uniforms contaminated prior to shift. Three had not put on clean uniforms and these had MRSA. By the end of the shift 31 (54%) were positive for one or more organism, VRE on 22. Levels of contamination varied between ward areas, highest medical 92% lowest surgical 7.7% No difference between trained and untrained staff. 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	Study over one day only No link made with infection prevalence on ward,
G6	3	Godin G, Naccache H, Fortin C. 1998. Canada.[157]	Design: Setting:	Descriptive Study Hospital physicians	Those who supported and considered glove use a norm had 14.61 times greater odds of wearing them compared	Poor response to survey Responses do not necessarily match practice.

ID	Quest	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		To identify factors explaining the intention of physicians to wear gloves when contact with blood or body fluids was possible.		throughout Canada. Sample: 667 (504M, 163F) Popn: Physicians	with those with a moderate or negative perception p<0.001.	
G34	2	Tenorino AR, Badri SM, Sahgal NB, Hotta B, Matushek M, Hayden MK, Trenholme GM, Weinstein RA. 2001. USA.[463] To assess the effectiveness of routine gloving in the prevention of hand carriage of VRE by health care workers during patient care activities.	Design: Setting: Sample: Popn:	Descriptive Study. Urban Hospital 60 (50 healthcare workers and the 10 patients with VRE infection in the hospital) HCW hands and gloves before and after contact with a patient with VRE	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.	Study limited by the number of patients infected and no control group, otherwise a thorough study.
G35	4	Huntley DE, Campbell J. 1998. USA.[200] To assess bacterial contamination of uniforms by aerosols during dental procedures.	Design: Setting: Sample: Popn:	Descriptive Study Dental Clinic 26 (1M, 25F) Senior students treating 145 patients.	Aerosol contamination is produced during dental procedures, supporting OSHA's standard that long sleeves be worn to protect exposed skin during exposure prone procedures. Bacterial filters applied to arms and chest before patient appointment and removed after. Control filters 2.67 when clinic in session CFU on dominant arm 31.13, median 29	Contamination established but not risk to patient.

ID	Quest	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
					(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.	
G37	3	Kearns HPO, Burke FJT, Cheung SW. 2001. Eire.[217] To examine the infection control procedures used in general dental practice in the Republic of Ireland.	Design: Setting: Sample: Popn:	Descriptive Study National Survey 177 (145M, 32F) Data collected on demographics, glove and mask use, sterilising and cleaning procedures and needlestick injuries.	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	Reported use may not reflect practice. High rate of compliance to glove wearing but reported practice does not necessarily reflect actual practice.
G39	5	Murray CA, Burke FJT, Mc Hugh S. 2001. UK.[312] Pilot study to compare the number of glove punctures occurring in latex and nitrile gloves.	Design: Setting: Sample: Popn:	Controlled Trial Suggests 5 sites 200 used and 200 unused gloves. 5 right handed dentists in general practices used 200 of each kind of glove	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. This could be considered to indicate good puncture resistance of the gloves tested in clinical use.	Small number of dentists involved in study though extensive use of the gloves

ID	Quest	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				200 unused gloves of each type also tested.		
G193	ALL	Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.[382] Systematic review of the selection and use of personal protective clothing and the reduction of HAI.	Design: Setting: Sample: Popn:	Systematic Review Hospital acute settings. Study Designs: RCT, NRCT, Experimental Laboratory studies (Gloves), Descriptive Before and After Studies. N/A	There is a comprehensive description of the methodology used for the review. Search included 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.

D.6.4 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	Reddy SG, Emery RJ. 2001. USA.[394] Evaluation of the effect of engineering controls (safety syringes and needleless IV systems) in reducing rates of nosocomial sharps injury (NSI).	Design: Setting: Sample: Popn:	Descriptive Study Hospital 550 Staff reporting NSI	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 x2 63.1 df =5	Not conducted in primary care/ community setting, but controls could be applied in setting. The introduction of needle safety devices should logically reduce the incidence of NSI. The introduction of an education programme and the OSHA standard may have had some impact on rates.
S9	2 & 3	Gershon RRM, Pearse L, Grimes M, Flanagan PA, Vlahov D. 1999. USA.[145] To determine the impact of a multifocused interventional programme on sharps injury rates.	Design: Setting: Sample: Popn:	Descriptive Study Community Hospital 693 Staff reporting sharps injuries.	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)	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.
S42	2,3,4	Peate WF. 2001. USA.[356] Evaluation of the introduction of a safety lancet for use with glucometers.	Design: Setting: Sample:	Descriptive Study Urban fire service 477 (Age range from 20 to 61	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.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				years; 81% male, 9% female)		
			Popn:	Active-duty EMS workers.		
S43	2,3,4	Zakrzewska JM, Greenwood I, Jackson J. 2001. UK.[527] 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.[382] 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.

D.6.5 Urinary catheter accepted tables

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
UC6	1	Bakke A, Vollset SE. 1993. Norway.[27] To study factors that may predict the occurrence of bacteriuria and clinical urinary tract infection in patients using clean intermittent catheterisation.	Design: Setting: Sample: Popn:	Descriptive Study – 1 year follow-up study Not stated 302 (149M, 153F) Residents in Norway carrying out CIC	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%. More serious infection problems, including upper urinary tract infection, were noted in 17%. 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. 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.	Complicated descriptive study possibly compromised by the fact that infection rates and severity relied on self reporting. Large sample size. 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.
UC14	6	Getliffe KA, Hughes SC, Le Claire M. 2000. UK[149]	Design: Setting:	Experimental Laboratory	Under controlled laboratory conditions, smaller (50 ml) volumes of acidic bladder washout solution are as	Has not been tried in clinical practice but clinical implications considered.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		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.	Sample: Popn:	24 Pooled urine from 4 volunteers.	effective as the 100 ml commonly used, but two sequential washouts with 50 ml are more effective than a single washout. Optiflow as effective as the other devices.	A well conducted study, each experiment repeated 5 times. Washout followed standard procedure.
UC32	1	Horgan AF, Prasad B, Waldron DJ et al. 1992. Eire.[196] 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.	Design: Setting: Sample: Popn:	Descriptive Study – Prospective Follow-up Urban Hospital Accident and Emergency Unit and Home 86 (Males) Men with acute retention due to prostatomegaly.	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. Prostatic symptoms – mean duration 10 months Makes recommendation that suprapubic catheters be used rather than urethral for the treatment of acute urinary retention.	A well conducted study. Mean duration of catheterisation is misleading due to large range.
UC34	6	Kennedy AP, Brocklehurst JC, Robinson JM. et al. 1992. UK.[220] To compare the use of acidic	Design: Setting:	Randomised Controlled Trial 3 urban hospitals	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.	The study addresses an appropriate and clearly focused question. Small study but the fact that it includes total population and crossover trial strengthens its

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		washout solutions with neutral saline in a group of elderly catheterized females.	Sample: Popn:	25 (Females) All female patients with long-term catheters.	Catheters changed at the end of each period. 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). Uric acid identified in Suby G and Solution R. Overall Solution R produced the best results and Suby G the worst. 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. Acidic washouts may be contra-indicated for patients with dehydration or low urine output.	validity. Only 14 completed full trial.
UC35	1	Bakke A; Vollset SE; Hoisarter PA et al. 1993. Norway.[28] 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	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).	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.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				carrying out CIC.	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.	
UC36	5	Roberts J, Kaak B, Fussell E. 1993. USA[402] 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.[240] 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.
UC41	6	Getliffe K. 1994 (a). UK.[148]	Design:	Experimental	Saline washout has no effect.	Laboratory study – well controlled and thorough.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		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.	Setting: Sample: Popn:	Laboratory 15 samples Not relevant as synthetic urine.	Suggests both Suby G and mandelic acid make it difficult for P mirabilis to adhere to sides and therefore reduce encrustation	
UC43	1	Webb RJ, Lawson AL, Neal DE. 1990. UK.[495] Follow up of 172 patients using Clean Intermittent Self-Catheterisation (CISC).	Design: Setting: Sample: Popn:	Descriptive study – Retrospective Follow-up Hospital out-patients at one urban hospital 170 (gender not stated) Out-patients using CIC.	145 patient were successfully using CISC at time of writing/ Seven patients were either "unable or unwilling to master the techniques" 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.	General study of CIC that contributes to the evidence.
UC52	1,2,6,7	Saint S and Lipsky BS. 1999. USA.[419] To provide 'an evidence based synthesis of the literature on	Design: Setting:	Systematic synthesis of literature Various (mainly hospital)	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. Aseptic catheter insertion and a	Only 1 database (Medline used). Other references identified by expert consideration and review of references in retrieved articles.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		preventing catheter-associated urinary tract infections to develop recommendations for clinicians'.	Sample: Popn:	N/A Adults	properly maintained closed drainage system are critical to reducing risk of bacteriuria. 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. Systemic antibiotic drug therapy seems to prevent UTIs but primarily in patients catheterised for 3-14 days.	Preference given to RCT, data on prevention summarised qualitatively. Therefore no formal metanalysis.
UC55	3	Bregenzer T, Frei R, Widmer A et al. 1997. Switzerland.[50] To determine the incidence and clinical relevance of bacteraemia induced by urinary catheter replacements.	Design: Setting: Sample: Popn:	Descriptive 2 Long-term care hospital facilities 39 (26M, 13F). 120 routine catheter replacements. Geriatric patients in long-term care facilities.	Minimal increase in bacteraemia (27/480, 5.6%) and bacteriuria (5/120, 4.2%). 0/120 had clinical symptoms or signs of infection. Catheter replacement does not necessarily increase the chance of colonisation.	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). However there was no comparison group to test this.
UC61	1	Bakke A Digranes A. 1991,.Norway.[26] To assess the occurrence of bacteriuria in all patients	Design: Setting:	Descriptive Study-Prospective. Hospital Out Patients	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	1 year follow-up of a total CIC population. Epidemiological study.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		using CIC in a defined population over a period of one year.	Sample: Popn:	407 (206M, 201F) Adult out-patients using CIC Feb-Aug 1988.	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.	
UC66	2	Hardyck C, Petrinovich L. 1998. USA.[175] 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).	Design: Setting: Sample: Popn:	Descriptive Study Patient's Homes 82 (36M, 27F) Home care patients	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.	Selection of sample unclear. Data collection based on retrospective reports from multiple informants.
UC72	6	Stickler DJ, Clayton CL, Chawla JC, 1987, UK.[450] 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	Design: Setting: Sample: Popn:	Experimental Laboratory 48 samples Sterile pooled urine.	With the exception of phenoxyethanol against Pv Stuartii and possibly Ps aeruginosa, all washouts only temporarily reduced bacterial growth. 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.	A well reported laboratory study.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
UC74	4 & 5	Getliffe KA. 1994 (b). UK.[147] A prospective long-term study of 47 community patients with long-term catheters, identifying them as blockers and non-blockers.	Design: Setting: Sample: Popn:	Descriptive Study Community 42 (18M, 24F). Community patients living at home or in warden controlled community settings across three health authorities.	Q4: Blocker status was significantly associated with high urinary pH and high urinary ammonia. 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. Blocker status associated with females, poor mobility and with high urinary pH and ammonium, and catheters needed replacing <6 weeks. Q5: Blockers were significantly less mobile than non-blockers. Q5: There was no relationship between blocking and fluid intake.	The study addresses an appropriate and clearly focused question. All relevant outcomes are measured in standard, valid and reliable way.
UC75	5	Roe BH, Brocklehurst J. 1987. UK.[405] A preliminary investigation of patients' understanding and	Design: Setting:	Qualitative Study A community study in one health authority	Patients with a catheter of at least 18 Charriere were more likely to experience pain 32 (89%) experienced leakage at least once a week	Data collected from medical/nursing records and carers as well as patients though results not clearly linked to source.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		knowledge of their catheter's location and function, its acceptance, problems associated with its use, social implications and its subsequent management.	Sample: Popn:	36 (20M, 16F) Patients over 50 years with long-term catheter.	23 (64%) blocked with a median occurrence of between 1 and 3 months.	
UC87	1	Duffy LM, Cleary J, Ahern SA et al. 1995. USA.[110] 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.[407] 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.[146]	Design:	Descriptive Study	Despite all catheters being susceptible to encrustation and blockage, the length	All relevant outcomes are measured in a standard, valid and

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		To examine a number of issues related to catheter blockage in patients at home.	Setting: Sample: Popn:	Community settings (patients homes in one district authority). 81 (47M, 34F) Patients with indwelling urinary catheters for more than four weeks.	of time a catheter remains functional can vary and requires individual care regimens. Over 50% of patients suffer from recurrent encrustation and blockage.	reliable way. However it relies on the nurses completing the questionnaire accurately and fully.
UC96	2	Wilson C, Sandhu SS, Kaisary AV. 1997. UK[505] To compare the use of a catheter-valve with the standard drainage system in terms of morbidity and patient preference.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Hospital (one follow up at home) 100 (84M, 16F) Patients undergoing long term catheterisation.	17 involved in crossover study, all preferred valve system. No significance in UTI rate between groups. Patient satisfaction significantly higher in valve group, 92% compared with those in the standard drainage group. Use of valve was more cost effective.	Lacking detail as to underlying conditions or how patient preference collected.
UC99	4	Burr RG, Nuseibeh I. 1995. UK.[55] To relate blockage of the urinary catheter to urine chemistry.	Design: Setting: Sample: Popn:	Descriptive Study Spinal Injuries Unit 44 (46M, 18F) Patients with spinal cord lesions with	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.	Convenience sample.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				indwelling urinary catheters.	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%). Urinary pH and calcium levels were higher in patients who had a more recent spinal injury.	
UC100	1	Charbonneau-Smith R. 1993. Canada.[70] To assess the effectiveness of the O'Neil Sterile FieldTM 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.[465] To assess colonization and infection with methicillin-resistant Staphylococcus aureus (MRSA), high-level gentamicin-resistant enterococci (R-ENT) and	Design: Setting: Sample:	Descriptive Study – Prospective Before and After Nursing home care unit 551 (542M, 9F)	Catheterisation is a significant risk factor. Infection rates tend to be lower with intermittent catheterisation that with indwelling. Statistically significant catherisation 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.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		gentamicin and/or ceftriaxone-resistant Gram-negative bacilli (R-GNB) and the factors that are associated with colonization and infection with these organisms.	Popn:	Patients admitted to unit June 1989 – May 1991.		
UC116	8	Moore KN. 1990. Canada.[304] 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.
UC122	8	Griffith D, Nacey J, Robinson R, et al. 1993. New Zealand.[167] 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.	Design: Setting: Sample: Popn:	Experimental Laboratory 2 groups of catheters in batches of 6 tested at 5 different times periodically. Total number not specified. Not stated.	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.	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.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
UC124	4	Kunin C. 1989. USA.[238] To study the blocker/non blocker 'phenomenon': How consistently do patients remain as blockers or non blockers? Do blockers have more febrile episodes? Is there a relationship between formation of encrustations and: urinary microbial sp.; production of urease; pH and constituents of urine? Do some organisms protect against encrustations? 5 Does antimicrobial therapy alter formation of encrustations?	Design: Setting: Sample: Popn:	Descriptive Study 260 bed nursing home. 65 (Females) Nursing home patients with indwelling catheters.	Urine of blockers was significantly more alkaline and contained less Mg PO4 and urea than non blockers.	No comment on the advisability of monitoring urinary pH.
UC125	7	Firestein M, Mendelson D, Gronich E et al. 2001. Israel.[132] 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	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	Patients recruited had no antibiotics for previous 2 weeks. Random allocation to treatment. Treatment and control groups similar. Regular follow-up over 28 days.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				catheters.	groups at 3, 7, 14 or 28 days.	
UC128	4	Choong S, Wood S, Fry C et al. 2001. UK.[72] 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.[359] To evaluate the overall rate of complications of CIC. 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.
UC138	1 & 8	Moore KN, Kelm M, Sinclair O et al. 1993. Canada.[306] To test the hypothesis that	Design:	Crossover Study (Randomised Controlled Trial)	Q1: 6 months crossover using sterile single-use catheters or clean reused. A comparable group used sterile catheters only.	Crossover design adds to internal validity. Only conducted amongst subjects

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		bacteriuria would be reduced in subjects who used single-use rather than clean reused catheters for intermittent self catheterisation.	Setting: Sample: Popn:	Clinic at children's hospital 2 samples. 30 in crossover (15M, 15F). 23 comparisons. Spina bifida children age range: 3-16 years.	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. Q8: Soapy water and rinsing can be used as method of cleaning a catheter for re-use.	with spinabifida and therefore generalisability may be limited.
UC140	1	Sheriff MK, Foley S, Mc Farlane J et al. 1998. UK.[434] 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.	Design: Setting: Sample: Popn:	Descriptive Study Neurological unit 157 (80M, 77F) Patients referred to neurological unit.	9 (6%) developed recurrent UTI. 28 (18%) experienced blockages. 12 (8%) leakage. Overall 30% of patients had catheter related complaints. Suggests suprapubic catheterisation is an effective and well tolerated method for patients with neuropathic bladder for whom surgery is the only option.	Well designed study conducted in a standard, valid and reliable way.
UC143	3	White MC, Ragland KE. 1995. USA.[499] To determine in home care patients on long term urinary catheterisation:	Design: Setting: Sample:	Historical Cohort Study Patient's Home 106 (gender not	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. Of those whose catheters were changed at intervals of 2 weeks or less – 15.4% remained free of infection after 4	Limitations: retrospective chart review; data on other risk factors for infection e.g. co-morbidities not collected/not available.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		the urinary catheter infection rate, the characteristics of patients who get UTI's compared with those who do not, the influence of catheter change interval on the length of time patients remain infection free.	Popn:	stated) Home care patients	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 </= 4 weeks versus catheter change >4 weeks. This analysis controlled for age, sex, severity of illness and number of nurses changing catheter.	
UC145	4	Burr RG, Nuseibeh IM. 1997. UK[56] To study the relationship between urine pH and calcium to catheter blockage and suggest how to reduce encrustation.	Design: Setting: Sample: Popn:	Descriptive Study Spinal Injuries Centre 60 (42M, 18F) Spinal injuries patients	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.	Included newly injured patients whose calcium levels may have been higher than normal. No information on patient selection.
UC149	1	Shekelle PG, Morton SC, Clark KA, Pathak M, Vickrey BG. 1999. USA.[432] To identify controlled clinical trials, cohort and cross sectional studies that assessed risk factors for UTI and included bacteriuria or UTI as an outcome.	Design: Setting: Sample: Popn:	Systematic Review Not reported Multiple studies Adults and adolescents over the age of 13 years with	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.	Well-conducted systematic review but the many of studies are quite old. Databases searched and selection criteria clearly stated.

ID	Quest.	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				neurogenic bladder due to spinal cord dysfunction.		
UC193	All	Pratt RJ, Pellowe C, Loveday HP et al. 2001. UK.[381] To develop national evidence-based guidelines for preventing hospital acquired infections associated with the use of short–term indwelling urethral catheters.	Design: Setting: Sample: Popn:	Systematic Review Acute care settings Study Designs: Mainly controlled trials, some experimental and descriptive. N/A	Comprehensive description included in technical report [382]. All databases included, 7 in total. No hand searching. All articles subjected to clinical review and critical appraisal.	For some areas only low grade evidence available

D.6.6 Enteral feeding accepted studies

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
P1	1	Dentinger B, Faucher KJ, Ostrom SM et al. 1995. USA.[98] Assess the contamination in a closed system of enteral feeding over 36 hours.	Design: Setting: Sample: Popn:	Experimental Laboratory Study Care Centre 211 containers were used to simulate continuous enteral feeding for 36 hours. In-patients of care facility.	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.
P2	1	Beattie TK and Anderton A. 1998. UK.[36] 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: Setting: Sample: Popn:	Experimental Laboratory 7 experimental protocols reported 5 times per protocol. NB sampling variable for each protocol. Total samples=90 (5x11) + baseline:- 7x5. Laboratory Study	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.
P6	1	Weenk GH, Kemen M and Werner HP. 1993. Germany.[497]	Design: Setting:	Experimental 2 hospital intensive	NB ">" indicates the system(s) on the left of the sign had higher levels of counts – which is worse - than the	The main issue in the interpretation of this paper is whether total absence of cfus is

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		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.	Sample: Popn:	care units (ICUs) and 2 simulated ward conditions 48 cultures Not stated	system(s) to the right of the sign. 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) 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% 3: number of bags with no counts after incubation for 72hrs: Bag>Crown cork, container, Steriflo significant at 5% Steriflo system emerged as safest in this study. BUT NOTE: 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	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.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
P7	1	Wagner DR, Elmore MF, Knoll DM. 1994. USA.[485] 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: preparation time total formula waste bacterial contamination	Design: Setting: Sample: Popn:	Random Controlled Trial Two critical care units in a community hospital Samples: 87 closed system (CS), 72 open system can (OS-Can), 60 open system powder (OS-powder). Critical care patients requiring enteral feeding	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. 2: initial contamination: No high contamination (defined as >10,000cfu/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. 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. 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).	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.
P8	1	Herlick SJ, Vogt C, Pangman et al. 2000. Canada.[188] Compare open and closed systems in two long-term care facilities (each with two units) on the following: a) Bacterial contamination b) Diarrhoea	Design: Setting: Sample:	Randomised Crossover Experiment 4 chronic care units in two long-term care facilities 36. Facility A-13, B-23	Bacterial contamination: 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). High contamination (greater than 10,000 cfu/ml) found in 78% open samples compared with 39% from closed system (p<0.05) Coliform found in 5.6% of closed	It would appear that differences between sites can be larger than differences between systems. 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. The study is, perhaps, a little small

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
			Popn:	People with brain injury	system compared with 28% open system (significant at p<0.05) BUT: there were no significant differences in facility A compared with very highly significant differences in facility B between the two systems.	in size, but appears well-conducted with major sources of confounding identified or removed.
P9	1	Vanek VW. 2000. USA.[479] 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.	Design: Setting: Sample: Popn:	Descriptive One hospital site many different units 138 (69M, 69F) In-patients requiring enteral feeding	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.	Many different sites within the hospital but all patients included.
P12	1 & 2	Lee CH, Hodgkiss IJ. 1999. Hong Kong.[259] 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.	Design: Setting: Sample: Popn:	Experimental Laboratory 2 experimental protocol repeated 3 times per protocol. Total sample = 24 (3x6) + (baseline x 6) Laboratory Study	Suggests a complete ready assembled system is best to reduce risk of contamination and wearing of gloves. No bacterial contamination with sterile gloves even when manipulation faulty Bare hand contamination noted at 4 hours and rising Contaminated hands contamination noted at 4 hours at a higher level than bare hands No differences between the 2 systems “to resist bacterial challenge”. No contamination was detected when clean non-sterile gloves were used but	No details of control.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
					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.	
P13	2	Graham S, McIntyre M, Chicoine J et al. 1993. Canada.[163] To determine whether more prolonged intervals between bag and tubing changes adversely affected patient health.	Design: Setting: Sample: Popn:	Randomised Trial 417 bed long-term care facility 11 patients for the first study period and 12 for the second. Elderly, clinically stable and suffering neurological disease.	No significant differences in morbidity when 24 hour tube changes compared with 72 hours. 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.	A range of feeding access was used, including nasogastric which may have had some bearing on the result. 2 study periods, data collection and definition. Consistent sampling frame known. Randomisation method satisfactory and explicit.
P15	2	McKinlay J, Anderton A, Wood W et al. 1995. UK.[289] 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.	Design: Setting: Sample: Popn:	Randomised Controlled Trials Urban hospital 42 (gender not stated) In-patients requiring enteral feeds.	Number of days feeds contaminated: 3/30 (10%) 500ml 2/30 (7%) 1000ml Most frequently and heavily contaminated from distal end. The results indicate that the more frequently the bags are changed the more likely it is that the feed will become infected.	No information on patients' underlying conditions.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
P16	2	Patchell CJ, Anderton A, Holden C et al. 1998. UK.[349] To examine the effects of improvements in the enteral feeding protocol, coupled with an intensive staff training programme on bacterial contamination.	Design: Setting: Sample: Popn:	Descriptive Study Urban Hospital/Some patients' homes 21 children (gender not stated) All patients receiving Nutrison paediatric standard as an enteral feed.	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 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. 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.	No patient details given. Small sample. Cannot identify which changes to the protocol are the most important.
P17	2	Rupp MM, Weseman R, Nedra M et al. 1999. USA.[412] To determine whether prolonged infusion of a sterile, closed system, non-air dependent enteral feeding solution was associated with bacterial contamination or nosocomial infection.	Design: Setting: Sample: Popn:	Descriptive study Urban hospital 15(7M, 8F) Patients who underwent liver transplantation	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.	The patients were particularly ill in this study and sample small. Met power calculation.
P19	2	Patchell CJ, Anderton A, MacDonald A, George I et al. 1994. UK.[350]	Design: Setting:	Randomised Trial One Urban Hospital	Inpatients: Although no contamination of the modular feeds was detected immediately after mixing 14% had	Research on home patients using PEGs however, no information is given about the diseases the

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		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.	Sample: Popn:	in-patients compared with home patients 35 children (21M, 14F) Children 1-5 years or weighing 8-20 Kg receiving at least 50% energy needs via enteral feeding.	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. 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 ($p<0.01$). The study highlights the importance of hygiene training for parents and the desirability of a ready-to-use formula.	children are suffering from.
P20	2	Anderton A and Aidoo KE. 1991. UK.[18] The effect of handling procedures on microbial contamination of enteral feeds – a comparison of the use of sterile vs non-sterile gloves.	Design: Setting: Sample: Popn:	Experimental Laboratory 40 (gender not stated) Volunteers with uninfected and	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.	Needs to be repeated in a clinical setting.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				undamaged skin.		
P22	2	Beattie TK, Anderton A. 1999. UK.[37] 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 >104 cfu/ml. 'Closed' systems do become contaminated, especially when manufacturers instructions are not followed.	Experimental study.
P23	3	Anderton A, Nwoghu CE. 1991. UK.[19] 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.[443] To assess the microbiological colonization of the Ross Hide-A-Port extension tubes challenged with 4 separate organisms S. epiudermis, Entereobacter aerogenes, Candida Albicans and	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 <105. Use of ammonia sanitizer significantly reduced organisms.	Lab study, use of sanitizer needs to be demonstrated in clinical practice.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		Acinetobacter.				
P25	2	Kohn CL. 1991. USA.[230] 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.	Design: Setting: Sample: Popn:	Descriptive study Urban hospital and Laboratory 21 (10M, 11F) Patients requiring continuous, full strength Osmolite feeds in a pump.	Of 21 delivery sets 23.8% unacceptably contaminated at 24 hours and by 48 hours 42.9% unacceptable. 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.	No universal definition of unacceptable contamination. This study used 105 cfu/ml.
P30	5	Sturgis TM. Yancy W, Cole JC et al. 1996. USA.[454] To determine whether prophylactic antibiotic treatment with Cefazolin reduces the incidence of peristomal infection after percutaneous gastrostomy.	Design: Setting: Sample: Popn:	Randomised Controlled Trials Hospital and follow-up nursing home 115patients, 30 Cefazolin, 31 placebo and 54 already on antibiotics. Patients referred for PEG.	Wound infections:- 4/30 (13%) cefazolin Placebo 6/31 (19%) 2/54 (3%) on antibiotics 58% infections occurred 72 hours after insertion. 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.	Wound evaluation on patients discharged were by telephone though seen by an investigator if an infection was thought to be developing.
P32	5	Kozarek RA, Payne M, Barkin J et al. 1995. USA.[234]	Design:	Descriptive Study	Peristomal infection before 1 week: 7, after 4 weeks: 4.	Study largely about insertion but contains important infection data.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		A prospective multicentre trial to establish the use, ease of insertion and short and long term safety profile of the One-step button gastrostomy	Setting: Sample: Popn:	5 urban hospitals 86 (gender not stated) Patients with CVA, neurological problems, Cancer, including head and neck	Suggests the theoretical advantages on one-step gastrostomies are outweighed by placement problems and subsequent complications and suggests further work is needed Follow up longer than usually reported, mean 1.5 months range 2-180 days	
P74	1	Duncan HD, Bray MJ, Kapadia SA et al. 1996. UK.[112] To determine if UK size is important in affecting the complications of percutaneous endoscopic gastrostomy (PEGs), i.e infection and leakage.	Design: Setting: Sample: Popn:	Randomised Uncontrolled Trial Urban district general hospital 52 (18M, 34F) Patients referred for PEGs.	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. 12 FG–Minor peristomal infection 5, serious 3. 20 FG–Minor peristomal infection 6, serious 6.	21 deaths during follow-up though no significant difference between tubes.
P75	1	Van den Hazel S, Mulder C and Den Hartog G et al. 2000. Netherlands.[477] 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	Design: Setting: Sample: Popn:	Randomised Trial Hospital 106 (gender not stated) All patients requiring PEG catheters.	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). 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 reinstitution of oral feeding. The	No analysis is done about whether the different surgeons have different rates of infection. The mean period for PEG placement was considerably less for the polyurethane PEG than for the silicone PEG.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		complications and PEG survival.			median complication-free survival was 916 days for the polyurethane PEG and 354 days for the silicone PEG (Log rank test: P=0.24).	
P77	2	Anderton A and Aidoo KE. 1990. UK.[17] 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	Design: Setting: Sample: Popn:	Experimental Laboratory 160 (80 feed containers disinfected, 80 not disinfected) Laboratory Study	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. The main source of contamination seemed to come from the experimenter's hands and counts up to 10 2 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.	An experimental setting.
P78	2 & 4	Fagerman KE. 1992. USA.[127] To describe the effect of enteral quality control (QC) programs on bacterial levels within the enteral nutrition service in two institutional settings	Design: Setting:	Descriptive Study Hospital A – 500 bed tertiary care facility. Hospital B – 100 primary care referring hospital.	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. Q4: Use of Potassium Sorbate as a	This is really 2 studies reported in one paper.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
			Sample: Popn:	Incomplete information. Hosp A – 6000 feeds. No details given.	preservative was effective in maintaining feeds sterile at 12 hours in room temperature.	
P80	1	McKinlay J, Wildgoose A, Wood W et al.. 2001. UK.[290] 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	Design: Setting: Sample: Popn:	Randomised Trial Urban Hospital 85 (gender not stated) In-patients requiring enteral feeds.	Contamination found in 14/120 (12%) Nutrison packs compared with 25/120 (21%) Ross ($p<0.05$). On 19 occasions similar organisms were isolated from both the feed and patient specimens. Most frequently and heavily contaminated specimens were collected from the distal end of giving set. 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. System design is important re contamination.	A useful clinical study Randomisation not blinded
P82	1&2	Bott L, Husson MO, Guimber D et al. 2001. France.[41] To evaluate the risk of contamination of enteral feeding systems in children fed at home via gastrostomy	Design: Setting: Sample: Popn:	Descriptive Study Homes 20 children (12M, 8F) Children with a gastrostomy and	45% distal giving sets showed overgrowth and 30% were contaminated. Manipulation error observed in 40% cases though this was not associated with contamination of feeds. No difference in contamination between gastrostomy button or tube. Gastric bacterial over growth was not	All observations and samples taken by one person during a normal procedure. Defined overgrowth as 104 cfu/ml. Observation by study operator may have influenced outcome. Small sample but a limited population.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				fed at home	associated with retrograde colonization. Demonstrates that to avoid /minimise contamination, closed systems should be used in preference to open systems for feeding at home.	
P86	3	Grunow JE, Christenson JC, Doris Moutous D. 1989. USA.[168] To determine the incidence of contamination in a delivery system reused in vitro simulating nocturnal supplemental enteral feeding.	Design: Setting: Sample: Popn:	Laboratory Experiment 'Vacant room' in a children's hospital Flexiflo Top Fill Enteral Nutrition Systems (Ross Laboratories) Not Applicable	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.	Well conducted laboratory study.
P89	2	Freedland CP, Roller RD, Wolfe BM et al. 1989. USA.[136] Evaluation of an open, continuous enteral tude 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.	Design: Setting: Sample: Popn:	Descriptive Study Urban hospital 33 patients (gender not specified) 82 enteral feeding cultures. All hospital patients (except neonates) undergoing	Contaminated enteral feeds may constitute reservoirs for contamination of other body sites. Contamination of feeds with Serratia marcescens correlated with cultures for the same organisms in patient's other body sites ($p<0.01$). Undiluted canned feeds were significantly less contaminated at 24hrs than those requiring mixing of powder ($p<0.0001$).	Well conducted study.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				continuous enteral pump feeding for a minimum of 3 days without interruption >24 hours.		
P92	2	Skiest DJ, Khan N, Feld R et al. 1996. USA.[441] To determine whether administering enteral feeding intermittently (IEF) as opposed to continuously (CEF) results in decreased rates of gastric colonisation in mechanically ventilated patients.	Design: Setting: Sample: Popn:	Randomised Controlled Trial 2 urban hospitals 16 CEF (4M, 3F), IEF (5M, 4F)] ICU patients about to begin enteral feeding	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).	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)
P94	2	Schroeder P, Fisher D, Volz M et al. 1983. USA.[425] To estimate the type and amount of contamination that occur in nutrient feeding solutions in a community hospital using normal procedures.	Design: Setting: Sample: Popn:	Descriptive Study Community hospital 9 in study 5. The others were Laboratory and simulated clinical studies. Not reported	Enteral feeding systems can support considerable microbial contamination that varies in type and amount. Awareness of study and education did not reduce contamination. Study 1 looked at the sterility of unrefrigerated NFS using 5 cans and samples taken at 4 hr intervals (laboratory) Study 2 contamination due to decanting(laboratory) Study 3 contamination due to decanting and nurses unaware they were being monitored (simulated clinical) Study 4 duplicated study 3(different	Effect of enteral contamination on patients not measured Samples small

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
					systems) Study 5 contamination in gavage feeding bags without nurses being aware of the study (clinical) Study 6 contamination in gavage feeding bags with nurses aware of the study (clinical) Study 7 contamination as a result of organisms travelling from a colonoised nasogastric tube into gavage tubing (laboratory). Study 1 Ensure did not reveal growth over 24 hours. Study 2 No bacterial growth over 48 hours regardless of delivery systems. Study 3 Contamination in all systems by 24 hours Study 4 Less growth than study 3 even at 36 hours. Study 5 All but one system contaminated at 24 hours Study 6 Considerable growth at 24 hours Study 7 No bacterial growth in any tube samples	
P97	2	Elston-Hurdle BJ, Grey C, Roy I et al. 1989. USA.[121] To evaluate the extent of bacteriological contamination following low-level contamination of enteral feed preparation with	Design: Setting: Sample:	Experimental Acute setting, possibly ICU 58 infusion sets,	Suggests feeds may be hung for 24 hours without reservoir bag change with no major risk of reservoir contamination. Little risk to patient and reduction in costs if reservoir bags and connection	Several details missing, numbers small.

ID	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		Pseudomonas aeruginosa, Klebsiella pneumoniae orEnterobacter clocae.	Popn:	patient details missing Not stated	tubes are hung with good technique. In vivo: No growth at 12 hours in bag or reservoir end of tubing. At 24 hours 2/58 had growth In vivo: no growth in bag or reservoir end tubing at 24 hours. Patient end of tubing all contaminated with challenge bacteria	

D.6.7 Central venous catheter studies

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
CVC2	2	Chaiyakunapruk N, Veenstra D, Lipsky A et al. 2002. USA.[67] To evaluate the efficacy of skin disinfection for vascular catheter-site care using chlorhexidine gluconate (CHXG) compared with povodine-iodine (PI) in preventing catheter related blood stream infection (CR-BSI).	Design: Setting: Sample: Popn:	Meta-analysis Hospital in-patients both on general ward and ICU 8 studies involving a total of 4143 vascular catheters were accepted into the MA (from 302 initially retrieved and assessed). Trials used 4143 vascular catheters (1493 CVC & 75 peripherally inserted	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.	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

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
				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.		true bacteraemia from blood culture contamination. 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.
CVC3	9	Newall F, Ranson K, Robertson J. 1998. Australia.[322] 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.

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
CVC4	1	Little K, Palmer D. 1998. UK.[268] To conpare 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.[430] 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.

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
CVC7	8	Raad I, Hanna HA, Awad A et al. 2001. USA.[390] 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.	Design: Setting: Sample: Popn:	Randomised Controlled Trial A tertiary university cancer centre. 512 patients (276 M, 236 F) Cancer patients requiring IV therapy	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.	Authors acknowledge underpower in study.
CVC10	1	Nikoletti S, Leslie G, Gandossi S et al. 1999. Australia.[330] To evaluate the risk of infection associated with a thin, transparent hydrocolloid dressing (Comfeel) compared with conventional transparent polyurethane dressing (Tegaderm).	Design: Setting: Sample: Popn:	Randomised Controlled Trial Intensive care unit 204 patients (92 M, 112F) Patients older than 18 years who required insertion of a multi-lumen central venous catheter.	The study indicates that there is an increased risk of catheter colonization associated with the use of hydrocolloid dressings.	Authors acknowledge that a) the number of dressing changes varied between patients and, b) the dressing changes were not recorded. Sample weakened through high attrition rate.
CVC177	3	Randolph AG, Cook DJ, Gonzales CA et al. 1998. USA.[392] To evaluate the effect of heparin on thrombus formation and infection	Design: Setting: Sample:	Meta-analysis N/A 12 RCTs of CVCs and 2 RCTs of pulmonary artery catheters	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	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

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		associated with the use of central venous and pulmonary artery catheters.		were included. Both used bonded heparin. Participants were adults or paediatric patients whose treatment included the insertion of central venous catheters and pulmonary artery catheters.	weight heparin and warfarin are needed.	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. 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.
CVC179	9	Cookson ST, Ihrig M, O'Mara EM, Denny M, Volk H, Banerjee SN, Hartstein AI, Jarvis WR. 1998. USA.[81]	Design: Setting:	Retrospective follow-up and prospective survey Surgical and medical	The CVC associated BSI rate was significantly higher in the needleless device period than in the needle device period.	Reliance on retrospective medical records

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		To determine if an apparent increase in bloodstream infections in patients with CVCs was associated with the implementation of a needleless access device.		intensive care and transplant units in a 350 bed urban acute tertiary care hospital. (Retrospective study) Total = 53 (Gender not stated). (Survey) 99 respondents Intensive care and transplant patients.	Increase in BSI rate was associated with nurses' unfamiliarity with the device, and needleless device use and care practices different from the manufacturer's instructions.	
CVC183	1	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.[141] To ascertain the efficacy of a chlorhexidine impregnated dressing on the CVC sites of neonates for the prevention of catheter tip colonization.	Design: Setting: Sample: Popn:	Randomised Controlled Trial 6 neonatal intensive care units. Total = 705 (400 M, 305 F) Intervention Group = 335 Control Group = 370 Neonates requiring a CVC for a least 48hrs.	The two dressing regimes where 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. Although the neonates randomized to the intervention group were less likely to have colonized CVC tips than those in the control group15% vs 24% relative risk: 6.95% confidence interval:0.5-0.9. 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.	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.
CVC210	2	Humar A, Ostromecki A,	Design:	Randomised	No significant difference between	Data from three sites. No details

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population		Outcomes	Strengths and Limitations
		Direnfeld J, Marshall JC, Lazar N, Houston PC, Boiteau P, Conly JM. 2000. Canada.[199] 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.		Controlled Trial ICU's in three teaching hospitals Including: 2 medical surgical ICU's 1 medical ICU's 1 neurosurgical ICU's 242 150M, 92 F Povidone Group = 117 Chlorhexidine Group = 125 All patients over 18 years of age who had CVC's inserted for any purpose.	povidone iodine and chlorhexidine in terms of catheter related bacteraemia.	of sub analysis of data from each site / clinical area.
CVC238	9	Do AN, Ray BJ, Banerjee SN, Illian AF, Barnett BJ, Pham MH, Hendricks KA, Jarvis WR. 1999. USA.[104] To evaluate the influences of infection-control practices on BSI associated with the use of needleless devices in the HHC setting.	Design: Setting: Sample: Popn:	Case-control study Home health care (community) patients 124 (93M, 31F) Case Patients = 53 Case Controls = 71 Case patients defined as those	Results suggest that the risk for BSI was related to the frequency of changing the device end caps.	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.

ID.	Quest. Number	Author, Date, Country of Origin and Objective	Design, Setting, Sample Size and Population	Outcomes	Strengths and Limitations
			"with a central venous catheter or midline catheter who acquired a primary BSI during the study period.		

D.7 Rejected studies (2003)

D.7.1 Hand hygiene

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
H19	2	Chudleigh J and Buckingham C. 1999. UK.[73]	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: Setting: Sample: Popn:	Observational Hospital – special care baby unit. 12 nurses (3 unqualified) Nurses	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

D.7.2 Urinary catheter

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
UC5	6	Pearman JW, Bailey M, Harper WE. 1988. Australia.[354]	To compare the efficacy of Trisdine and Kanamycin-colistin in reducing bacteriuria in new spinal injuries patients.	Design: Setting: Sample:	Randomised Controlled Trial Spinal Injuries Unit 18 (15M, 3F)	The sample size is not appropriate.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
				Popn:	Spinal cord injury patients.	
UC9	1	Eika B, Frokiaer J. 1989. Denmark.[118]	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.[223]	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 Escherica coli.	Design: Setting: Sample: Popn:	Experimental Laboratory Not available. Not available.	Laboratory study using bladder model.
UC12	4	Mobley HLT, Warren JW. 1987. USA.[301]	To observe the incidence of urease production and blockage in women ≥ 65 years with silicone-latex coated catheters	Design: Setting: Sample:	Descriptive Study Setting not stated 32F > 65 years	Study question unclear. No details of recruitment or sample.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			in place for ≥100 days.	Popn:	Long-term catheterised	
UC23	6	Robertson MH, Norton MS, 1990, UK.[403]	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.[311]	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.[280]	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.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
UC28	4	Hedelin H, Larsson L, Eddeland A et al. 1985. Sweden.[184]	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.[299]	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.[186]	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.
UC45	4	Hedelin H, Bratt CG, Eckerdal G et al., 1991, Sweden.[183]	To correlate urinary pH with the precipitation of catheter encrustation and detect any unusual	Design: Setting:	Descriptive Study Hospital with 500 beds for long-term care and rehabilitation	Sample underpowered. No baseline measures.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			urea-splitting bacteria in catheter urine samples with a raised pH but without growth of urease-producing bacteria.	Sample: Popn:	11 (8M, 3F) No information	
UC47	6	Elliott TSJ, Reid L, Gopal Rao G et al. 1989. UK.[119]	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.[229]	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.	No information on gender, confounding conditions or catheter types. Analysis poor and incomplete.
UC58	7	Wiseman O. 1997. UK.[508]	To determine the management of long-term urinary catheter in asymptomatic patient in the Accident and Emergency department.	Design: Setting: Sample:	Descriptive Study (Retrospective) Accident and Emergency department 40 patients with 80 presentations (68M, 12F)	Audit though described as research. Flawed urine collection method.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
				Popn:	A&E	
UC71	8	Kurtz MJ, Van Zandt K, Burns JL. 1995. USA.[241]	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.[404]	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.
UC78	8	Mervine J, Temple R. 1997. USA.[297]	To determine the effect on: the concentration of bacteria of washing (with soap and water) red rubber and clear plastic intermittent-use catheters, the amount of time in a microwave oven required to eliminate stock bacteria from red rubber and clear plastic	Design: Setting: Sample: Popn:	Experimental Laboratory Urine from patients was used but it is not stated how many specimens were obtained. Patients in urban hospital giving urine for routine culture or on CIC.	No detail on sample size or patient details. No statistical analysis.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			catheters, the effect of repeated use of a microwave oven on the patency and pliability of red rubber and clear plastic catheters.			
UC79	1 & 7	Prieto-Fingerhut T, Banovac K, Lynne CM. 1997. USA.[383]	To determined the effect of sterile and nonsterile intermittent catheterisation on the incidence of urinary tract infection (UTI) in patients after spinal cord injury.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Medical Rehabilitation Centre 29 (16M, 13F) Spinal cord injury patients	Numbers are small. Method of randomisation not stated. No details of reliability of catheterisation techniques. No baseline measurements.
UC80	1	Terpenning MS, Allada R, Kauffman CA. 1989. USA.[464]	A prospective study of elderly patients receiving IC for development of bacteriuria and/or urinary tract infection.	Design: Setting: Sample: Popn:	Descriptive Study (Prospective Follow-up study) Veteran Administration Hospital and nursing home 35 (34M, 1F) Patients aged 60 years and over with long-term catheter.	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.[344]	To examine the relative frequency of urinary tract infection (UTI) and bacteriuria among male nursing home patients managed with and	Design: Setting: Sample:	Descriptive Study – Comparative Follow-up Nursing Home 92 (Males)	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.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			without catheters.	Popn:	Male nursing home residents.	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.[208]	To assess the safety and efficacy of a new external urine collection system for women.	Design: Setting: Sample: Popn:	Descriptive Study - Observational Hospital and a medical centre 26 (Females) All women over 65 years old not receiving antibiotics.	Insufficient description of methodology.
UC86	1	Quigley PA, Riggin OZ. 1993. USA.[389]	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.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Hospital rehabilitation 30 (gender not stated) Rehabilitation patients, spinal cord injuries and stroke patients.	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.[355]	To compare the incidence of "significant bacteriuria" following two different methods of intermittent catheterisation, a) nelaton catheter with Trisidine instillation and	Design: Setting: Sample: Popn:	Uncontrolled randomised trial Urban hospital spinal department 37 (30M, 7F) Patients with acute spinal cord	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

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			b) O'Neal catheter (Nelaton with introducer) in patients with acute spinal chord trauma.		trauma.	variable.
UC92	1	Wyndaele JJ, Maes D. 1990. Belgium.[518]	To study the long term effects and complications resulting in patients using intermittent self catheterisation.	Design: Setting: Sample: Popn:	Descriptive Study - Retrospective Follow-up Hospital Outpatients/rehabilitation 75 (33M, 42F) Patients using CISC.	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.
UC94	8	Silbar EC, Cicmanec JF, Burke BM et al. 1989. USA.[437]	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.[461]	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.	To determine whether an introducer tip	Design:	Descriptive Study	Small sample. Variability in number of

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
		1997. USA.[38]	catheter reduces urinary tract infection in spinal cord injured patients on intermittent catheterisation.	Setting: Sample: Popn:	Hospital 19 (gender not stated) Spinal cord injuries unit.	catheterisations was high. Sampling method unclear.
UC98	1	Perkash I, Giroux J. 1993. USA.[358]	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.
UC109	2	Joseph C, Jacobsen C, Strausbaugh L et al. 1991. USA.[210]	A pilot study of intermittent urinary catheterisation in elderly nursing home patients utilizing a new modification of clean technique and conventional sterile technique.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Elderly Nursing Home Care Unit. 14 (Males) Residents >50 years of age.	Pilot study which states sample inadequate. Study protocol not adhered to.
UC114	1 & 2	Oie S, Kamiya A, Seto T et al. 2000. Japan.[339]	To evaluate the microbial contamination of a widely used in-use lubricant for non-touch urethral catheters.	Design: Setting: Sample: Popn:	Descriptive Study Out patients department 46 Attendees at hospital outpatient department.	This system is not used in the UK. Potential sample bias.
UC117	1	Maynard FM and	To report on 5 year	Design:	Descriptive Study – Observational	Self reports of estimated frequency

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
		Glass J. 1987. USA.[287]	urological outcomes in a population of new spinal cord injury patients who were all managed initially by clean technique of intermittent catheterisation.	Setting: Sample: Popn:	Outpatients 40 (33M, 7F) Out-patients	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.
UC118	7	Orrett FA & Permanand N. 1993. Trinidad.[341]	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.[319]	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	To determine the	Design:	Descriptive study	Small study, two people had two sets

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
		A, Thompson BW. 1999. USA.[267]	effectiveness of neomycin/polymyxin bladder irrigations in asymptomatic spinal cord injury patients with resistant organisms.	Setting: Sample: Popn:	Rehabilitation Unit 10 (7M, 3F) Spinal cord injury patients who had undergone bladder irrigation.	of irrigation. Use of statistics inappropriate in this sample.
UC130	8	Sims L, Ballard N. 1993. USA.[439]	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	Polastri F, Auckenthaler R, Loew F et al. 1990. Switzerland.[378]	To quantify the micro-organisms present in blood at urinary catheter removal and reinsertion. To identify whether: Q3: there was an	Design: Setting: Sample: Popn:	Descriptive Study Geriatric Medical Centre 33 (15M, 18F) Patient's chronic indwelling catheter	Lack of clarity on sampling technique, e.g. 33 patients specified – 46 cases in group 2.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			increased risk of bacteriuria during UC removal and insertion, Q7: prophylactic antibiotics would be useful before this manipulation.		positive urine cultures.	
UC133	1	Kuhn W, Rist M, Zaech G. 1991. Switzerland.[237]	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.[517]	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.[520]	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.[416]	To investigate the current usage,	Design:	Descriptive Study (Survey)	Questionnaire study with poor response (48%) and reporting bias.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
			procedural differences, incidence of documented urinary tract infections and staff satisfaction with CIC in a long term care setting.	Setting: Sample: Popn:	Long term care facilities 103 facilities Patients in long term care using urinary catheters.	
UC141	2	Giannantoni A, Du Stasi SM. Scivoletto G et al. 2001. Italy.[150]	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.

D.7.3 Enteral feeding

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
P3	1	Iber, FI, Livak AL and Patel M. 1996. USA.[202]	To describe 111 PEG tubes with a view to learning more about the reasons for PEG failure	Design: Setting: Sample: Popn:	Descriptive study Hospital Department of Gastroenterology 111 PEGs removed, replaced or dislodged at the hospital during an 11 month period In-patients receiving PEG feedings.	Lack of control of possible confounders.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
P4	1	Payne-James, J; Rana SK, Bray MJ et al. 1992. UK.[353]	To compare contamination of enteral diet containers using three different giving sets.	Design: Setting: Sample: Popn:	Descriptive study Urban DGH 55 (gender not specified) 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.[160]	To investigate the prevalence of fungal colonization in a variety of PEG types.	Design: Setting: Sample: Popn:	Descriptive Study Veterans Administration Hospital 10 (Males) Patients from 2 wards with functioning PEGs in-situ.	The sample size is not appropriate
P21	2	Thurn J, Crossley K, Gerdts A et al. 1990. USA.[470]	A prospective study to determine the relationship between contamination of enteral feeds and nosocomial infection.	Design: Setting: Sample: Popn:	Descriptive Study One hospital but 3 different intensive care areas 24 patients (20M, 4F) Patients requiring enteral feeds between Sept 1986 - April 1987.	The sample size is not appropriate
P27	2 & 3	Donius MA. 1993. USA.[106]	To compare contamination of formula collected from	Design:	Descriptive study	Very small study, underpowered, though it confirms findings in another

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
			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.	Setting: Sample: Popn:	Long-term care facility 4 patients (gender not stated) Stable patients requiring enteral feeds.	study
P31	5	Nunley D, Berk SL. 1992. USA.[332]	A retrospective study to evaluate the gastrostomy site as source of MRSA colonization.	Design: Setting: Sample: Popn:	Descriptive Study Urban hospital 26 reports of Gastrostomy site cultures. Patients with gastrostomy	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.[496]	To assess the risks of using a ready-to-use 1 litre enteral feeding system in a centre for burns patients.	Design: Setting: Sample: Popn:	Descriptive Study Burns unit 5 patients (gender not specified) Patients with severe burns requiring enteral feeding.	The sample size is not appropriate
P81	2	Anderton A, Nwogh CE, McKune I et al. 1993. UK.[20]	To investigate and compare the levels and types of bacterial contamination in enteral feeds prepared and administered in hospital and the home	Design: Setting: Sample: Popn:	Descriptive Study Patients' homes and hospital 95 feeds sampled from 6 children (gender not stated) Children being fed at home and in	Patients and parents collected home samples which may have altered contamination levels. Parents and patients were responsible for collection and storage of home samples. Children received multiple doses of antibiotics for their cystic fibrosis

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
					hospital over a 3 month period.	
P83	2	Perez SK, Brandt K. 1989. USA.[357]	To explore the differences in bacterial growth in continuous enteral feeding when using tap water versus sterile water over 24 and 48 hours.	Design: Setting: Sample: Popn:	Quasi experimental Hospital Unclear – 32 surgical bedded but data only given for 10 people	Small study no controls. Findings inconclusive. No data on patients.
P87	3	Oie S, Kamiya A, Hironaga K, Koshiro A. 1993. Japan.[338]	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.	Design: Setting: Sample: Popn:	Controlled Experiment One hospital and two unspecified 'affiliated institutions' 22 samples from 22 patients No patient details given	Sample inadequate.
P90	1	Heyland DK. 1998. Canada.[191]	Examine the relationship between nutritional support and infectious morbidity and mortality in the critically ill patient	Design: Setting: Sample: Popn:	Systematic Review and Meta-analysis Adult patients undergoing major surgery, suffering major trauma.	This review offers little evidence of use for the guideline development.
P91	1	Eddy VA, Snell JE, Morris JA. 1996. USA.[117]	Determine short and long term complications associated with needle catheter jejunostomy	Design: Setting: Sample:	Descriptive Study University medical centre 122 (95M, 27F)	NEJ relevant but conduct of study means results are unreliable.

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size & Population		Reasons for Rejection
				Popn:	Patients who had received needle catheter jejunostomies included in study over 6 year period.	

D.7.4 Central venous catheters

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.[296] .	To review the literature on prevention of intravascular catheter related infections	Design: Setting: Sample: Popn:	Systematic Review Not reported Number of studies reviewed not reported (but 133 references cited) Not reported.	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).
CVC6	8	DeMoissac D, Jensen L. 1998. Canada[97]	To examine the effects of changing IV administration sets at 48 hrs versus 24 hrs on the incidence of infusion-related septicaemia in nutropenic patients with cancer.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Urban cancer setting 50 patients (14M, 36F)	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.
CVC8	8	Matlow AG, Kitai I, Kirpalani H et al. 1999.	To compare the microbial	Design:	Randomised Controlled Trial	There are numerous potential confounding variables, e.g.,

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
		Canada.[285]	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.	Setting: Sample: Popn:	35 bed Neonatal Intensive Care 1189 babies (709 M, 480 F) Neonates for whom IV lipid was ordered	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 a imbalance of samples between the two groups.
CVC9	1	Madeo M, Martin CR, Turner C et al. 1998. UK.[278]	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.	Design: Setting: Sample: Popn:	Randomised Controlled Trial Intensive care unit. 31 (16 M, 15 F) Patients admitted to an intensive care unit who required arterial and/or central venous catheterisation.	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.[273]	To compare the colonization of hubs with hub protection boxes and hubs with needleless closed connectors.	Design: Setting: Sample:	Randomised Controlled Trial Three medical or surgical ICUs 77 patients (Gender not stated) (Cultures obtained from 137 CVCs) No details given.	Report lacks detail regarding homogeneity of groups at the start of study and subsequent treatment of subjects, e.g., frequency of measurement. (1.6)

ID	Quest. Number	Author, Date and Country of Origin	Objective	Design, Setting, Sample Size and Population		Reasons for Rejection
				Popn:		
CVC181	8	Donaldson I. 1999. UK.[105]	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.	Design: Setting: Sample: Popn:	Systematic Review	No details of methodology, e.g., search strategy, appraisal or grading systems.
CVC182	3	Henrickson KJ, Axtell RA, Hoover SM, Kuhn SM, Pritchett J, Kehl SC, Klein JP. 2000. USA.[187]	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.

D.8 Summary of recommendations (2003)

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.

D.8.1 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.

D.8.1.1 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]

D.8.1.2 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]

D.8.1.3 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]

D.8.2 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.

D.8.2.1 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]

D.8.2.2 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]

D.8.2.3 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]

D.8.2.4 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]

D.8.2.5 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 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]

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. [A]

D.8.3 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.

D.8.3.1 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]

D.8.3.2 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]

D.8.3.3 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]

D.8.3.4 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 administrating 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]

D.8.4 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.

D.8.4.1 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]

D.8.4.2 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]

D.8.4.3 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]

D.8.4.4 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 alcohol or an alcoholic solution of chlorhexidine gluconate before and after using it to access the system. [D]

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]

D.9 Text removed from previous guideline (2003)

D.9.1 Scope and Purpose of the Guidelines

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.

D.9.2 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)[116] and reproduced below:

Categories of evidence

Ia	Evidence from 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 grading scheme suggested by Eccles and Mason (2001)[116] 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

D.9.2.1 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).

D.9.3 Standard Precautions

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.

The systematic review process is detailed in appendix D.1.2.

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

D.9.3.1 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.

D.9.4 Hand hygiene

D.9.4.1 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[44].

Guidance suggests that, in deciding when it is necessary to decontaminate hands, four key factors need to be considered[380]:

- 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[44,203,242].

Recommendation

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.

D.9.4.2 Is any one hand cleaning preparation better than another?

Our previous systematic review [380] 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[154,250,274,507,528]. Four RCTs demonstrated alcohol to be a more effective hand hygiene agent than non-medicated soap and antimicrobial handwash,[154,250,274,507] while a fifth study found no statistical difference between the use of alcohol and antiseptic soap[528]. 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[189,190,249] and seven controlled laboratory experiments[60,114,169,214,235,300,352] 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[128]. One descriptive study of the use of an antiseptic hand cream by community nurses showed sustained residual effect in reducing microbiological flora[162].

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[44,380] 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[44,380].

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,[377,380] and that alcohol gel reduces infection rate by 30%[130] or 25%[154] 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[320]) 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 [453]. 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[380].
- Using an antimicrobial liquid soap preparation will reduce transient microorganisms and resident flora, and result in hand antisepsis[44,380].
- 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[44], Alcohol handrubs offer a practical and highly acceptable alternative to handwashing when the hands are not grossly soiled and are recommended for routine use[44,154,250,274,507,528].

Recommendations

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

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.

D.9.5 Personal protective equipment

D.9.5.1 Do gloves leak?

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

D.9.5.2 Making choices

Expert opinion is quite clear about when gloves must be used by healthcare practitioners in general clinical practice[2,76,414]. Having decided that gloves should be used for a healthcare activity, the practitioner must make a choice between the use of:

- 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[76,381]. 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[76,381]. A pilot study of dentists using nitrile gloves in place of NRL found that they compared favourably in terms of puncture resistance[312]. 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[2,76,381,414].

Synthetic materials are generally more expensive than NRL and due to certain properties may not be suitable for all purposes[76]. 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[381]. Polythene gloves are not suitable for clinical use due to their permeability and tendency to damage easily[76,381].

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 glove
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

Gloves that are acceptable to healthcare personnel and that conform to European Community (CE) standards must be available.

Sensitivity to natural rubber latex in patients, carers and healthcare personnel must be documented, and alternatives to natural rubber latex gloves must be available.

Neither powdered gloves nor polythene gloves should be used in healthcare activities.

D.9.5.3 Aprons or gowns?

In our systematic review, three studies were identified that highlighted the potential for uniforms to become contaminated[57,200,360]. 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[57,360].

Our previous systematic review identified a variety of studies, none of which supported the routine use of gowns in general or specialist clinical settings[380]. 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[76,381].

Plastic aprons are recommended for general use, [76,381] but unused aprons need to be stored carefully, i.e., away from potential contamination[57,381]. 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[76,381].

D.9.5.4 Recommendations

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. 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).

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.9.6 Sharps

D.9.6.1 Sharps injuries – what's the problem?

National and international guidelines, are consistent in their recommendations for the safe use and disposal of sharp instruments and needles[65,126,336]. 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.[178] 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[125].

D.9.6.2 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[126]. The incidence of injuries related to needle devices has led to the development of prevention devices in eleven different product groups[179]. 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.

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.[145,356,394,527] 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.[145,356]

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:[179]

- 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.[66]

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.[324,381] 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.

Recommendations

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

D.9.7 Urinary catheterisation

D.9.7.1 Is one catheter better than another?

A systematic review identified three experimental studies that compared the use of coated latex with silicone catheters.[381] 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.[402] 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.

D.9.7.2 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.[146,405] 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.[55,56,72,147,238,239]

Systematic review[381] evidence and further evidence from one controlled trial[220] 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.[450] 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.[148]

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.[240]

Recommendations

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.

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

D.9.7.3 Changing catheters

Our systematic review suggests that antibiotic prophylaxis to prevent bacteraemia* at primary catheter insertion for acute retention is of proven value.[407] In the community setting however, a prospective survey of 120 catheter changes without chemoprophylaxsis found zero incidence of clinical complications, despite a 5.6 percent incidence of sub clinical bacteraemia detected by blood culture.[50] This descriptive finding is matched by the result of an experimental study of residents in a geriatric care centre.[132] Antibiotic prophylaxis was of no benefit in preventing or delaying bacteriuria following long-term catheter placement. A systematic review[419] and expert opinion[92,293] 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.

Recommendations

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.

D.9.7.4 Re-use of intermittent catheters

Many people use disposable single-use catheters for intermittent catheterisation. Reusable single patient use catheters need to be cleaned after use. Our systematic review identified two crossover studies of young people with neurogenic bladders which indicated that cleaning catheters with soap and water results in acceptably low rates of bacteriuria when compared with the use of sterile catheters[304,306] 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.

Recommendation

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

D.9.8 Enteral Feeding

D.9.8.1 Care of insertion site and enteral feeding tube

Keep the tube clear

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.[16,137] 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 immuncompetent patients.[4,457]

Recommendations

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

To prevent blockage, the enteral feeding tube should be flushed with fresh tap water before and after feeding or administrating 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.9.9 Central venous catheters

D.9.9.1 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.[44,334]

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.

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.[334] 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.

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

D.9.9.2 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.[334] 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.

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.

Recommendations

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

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.

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.

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

D.9.9.3 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 antisepsis prior to CVC insertion. They made no recommendation for the use of any disinfectant agent for cleaning the insertion site during dressing changes.[334]

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. povodine iodine (PI) solution.[67] 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.

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.

Recommendations

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.

D.9.9.4 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.[334]

Recommendation

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.

D.10 Deleted and amended recommendations (2003)

D.10.1 Deleted recommendations from from NICE clinical guideline 2

Recommendation in 2003 guideline	Comment
Hands that are visibly soiled, or potentially grossly contaminated with dirt or organic material, must be washed with liquid soap and water (Recommendation 1.1.2.2 in 2003 guideline)	Replaced by: 1.1.2.2 Decontaminate hands preferably with a handrub (conforming to current British standards[a]), except in the following circumstances, when liquid soap and water must be used: • when hands are visibly soiled or potentially contaminated with body fluids or • in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as norovirus, *Clostridium difficile*, or organisms that cause diarrhoeal illness).
Hands must be decontaminated, preferably with an alcohol-based handrub unless hands are visibly soiled, between caring for different patients and between different care activities for the same patient (Recommendation 1.1.2.3 in 2003 guideline)	Replaced by: 1.1.2.2 Decontaminate hands preferably with a handrub (conforming to current British standards[a]), except in the following circumstances, when liquid soap and water must be used: • when hands are visibly soiled or potentially contaminated with body fluids or • in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as norovirus, *Clostridium difficile*, or organisms that cause diarrhoeal illness).
Reusable intermittent catheters should be cleaned with water and stored dry in accordance with the manufacturer's instructions. (Recommendation 1.2.5.14 in 2003 guideline)	Removed to avoid confusion as single-use intermittent urinary catheters have been recommended: 1.2.3.3 Offer a choice of either single-use hydrophilic or gel reservoir catheters for intermittent urinary self catheterisation.
Hands that are visibly soiled or contaminated with dirt or organic material must be washed with soap and water before using an alcohol handrub (Recommendation 1.4.2.3 in 2003 guideline)	Replaced by: 1.1.2.2 Decontaminate hands preferably with a handrub (conforming to current British standards[a]), except in the following circumstances, when liquid soap and water must be used: • when hands are visibly soiled or potentially contaminated with body fluids or • in clinical situations where there is potential for the spread of alcohol-resistant organisms (such as *Clostridium difficile*, or organisms that cause diarrhoeal illness). The GDG did not consider it necessary to repeat this hand decontamination recommendation in the vascular access device chapter.
Following hand antisepsis, clean gloves and a no-	Replaced by:

[a] At the time of pre-publication of the guideline (December 2011): BS EN 1500: 1997

Recommendation in 2003 guideline	Comment
touch technique or sterile gloves should be used when changing the insertion site dressing (Recommendation 1.4.2.4 in 2003 guideline)	1.4.2.1 Hands must be decontaminated (see section 1.1.2) before accessing or dressing a vascular access device. 1.4.2.2 An aseptic technique, such as Aseptic Non Touch Technique (ANTT), must be used for vascular access device catheter site care and when accessing the system.

D.10.2 Amended recommendations (change to meaning)

Recommendations have been labelled [2003, amended 2012] if the evidence has not been reviewed but changes have been made (indicated by highlighted text) that change the meaning of the recommendation.

Recommendation in 2003 guideline	Recommendation in current guideline	Comment
1.1.4.1 Sharps must not be passed directly from hand to hand, and handling should be kept to a minimum.	1.1.4.1 Sharps should not be passed directly from hand to hand, and handling should be kept to a minimum.	The updated recommendation contains 'should' rather than 'must' because the GDG considered that the use of 'must' in the 2003 version is not covered by legislation (in accordance with the NICE guidelines manual, 2009).
1.2.5.4 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 1.1).	1.2.5.4 Patients managing their own catheters, and their carers, must be educated about the need for hand decontamination before and after manipulation of the catheter, in accordance with the recommendations in the standard principles section (section 1.1.).	This recommendation has been amended to reflect input from the NICE Patient and Public Involvement Programme: recommendations cannot be made directly about what patients and carers must do.
1.4.1.1 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. 1.4.1.2 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. 1.4.1.3 Follow-up training and support should be available to patients with central venous catheters and their carers.	1.4.1.1 Before discharge from hospital, patients and their carers should be taught any techniques they may need to use to prevent infection and safely manage a vascular access device. 1.4.1.2 Healthcare workers caring for a patient with a vascular access device should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline. 1.4.1.3 Follow-up training and support should be available to patients with a vascular access device and their carers.	The updated recommendations contain 'vascular access device' rather than 'central venous catheter'. This change has been made because peripherally inserted catheters were included in the scope of the guideline update.

D.10.3 Amended recommendations (no change to meaning)

Recommendation in current guideline	Comment
1.1.3.1 Selection of protective equipment musta be based on an assessment of the risk of transmission of microorganisms to the patient, and the risk of contamination of the healthcare worker's clothing and skin by patients' blood, body fluids, secretions or excretions. 1.2.1.2 Community and primary healthcare workers must be trained in catheter insertion, including suprapubic catheter replacement and catheter maintenance. 1.2.4.1 All catheterisations carried out by healthcare workers should be aseptic procedures. After training, healthcare workers should be assessed for their competence to carry out these types of procedures. 1.2.5.2 Healthcare workers should ensure that the connection between the catheter and the urinary drainage system is not broken except for good clinical reasons, (for example changing the bag in line with the manufacturer's recommendations). 1.2.5.3 Healthcare workers must decontaminate their hands and wear a new pair of clean, non-sterile gloves before manipulating a patient's catheter, and must decontaminate their hands after removing gloves. 1.3.1.2 Healthcare workers should be trained in enteral feeding and management of the administration system. 1.4.1.2 Healthcare workers caring for a patient with a vascular access device should be trained, and assessed as competent, in using and consistently adhering to the infection prevention practices described in this guideline. 1.4.3.7 Healthcare workers should ensure that catheter-site care is compatible with catheter materials (tubing, hubs, injection ports, luer connectors and extensions) and carefully check compatibility with the manufacturer's recommendations. 1.4.4.10 When needleless devices are used, healthcare workers should ensure that all components of the system are compatible and secured, to minimise leaks and breaks in the system.	All instances of 'healthcare personnel' have been changed to 'healthcare worker'. This is for consistency with other NICE clinical guidelines and is considered a more modern term. The GDG considered the term 'healthcare workers' to include a wider group of people than healthcare professionals, which they considered to be only those staff with professional qualifications. In recommendation 1.3.1.2, 'community staff' has been changed to 'healthcare workers', for consistency with this terminology. In recommendation 1.4.1.2, 'community healthcare personnel' has been changed to 'healthcare workers', for consistency with this terminology.

Appendix E: Review protocols

E.1 Standard principles - Education of patients, carers and their healthcare workers

Component	Description
Review question	What information do healthcare professionals, patients and carers require to prevent healthcare associated infections in primary and community care settings?
Objectives	The objective of this review is to obtain information and evidence that can help to inform the guideline development group (GDG) about what information should routinely be provided to patients to prevent health care associated infections. Recommendations can be then made to address important gaps in knowledge or behaviour. The GDG had decided to focus on patients and the lay people for this review question. Patients play an important role in reducing healthcare infection and hand hygiene was identified as an area that is of importance and applicable to all patients.
Setting (or situation)	Primary-care settings, such as general practices, dental clinics, health centres and polyclinics. This also includes care delivered by the ambulance service. Community-care settings (such as care homes, patient's own home, schools and prisons) where NHS healthcare is provided or commissioned. Exclusions: patients in the intensive care units
Population (perspective)	"Patients" who are being cared in the primary care and community care setting. This may involve people who are relatively well but receive occasional care in through the general practice and dental services. Exclusion: Health care professionals
Intervention	Hand hygiene practice
Comparison	None
Evaluation	Patient experiences; preferences; perceptions, including factors which encourage or prevent effective hand hygiene Qualitative studies (Interviews, focus groups, observations) and surveys about patient perception, experiences and preferences of hand hygiene practice, including factors which encourage or prevent hand hygience
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library, CINAHL and PsychInfo. Studies will be restricted to English language only. No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Studies were evaluated to assess their relevance to the question asked. The most relevant studies are those conducted in the UK, in the NHS settings, in the population of interest for the purpose of finding of what information is required to reduce health care associated infections through hand hygiene. Analysis began with studies that are most relevant to the review question in terms of population, setting (situation), context and objectives. Thematic analysis were conducted, common themes across studies were extracted and reported. Quality of studies was evaluated on three key components – methodological quality (study limitations), transferability (indirectness) and other considerations. The consistency of themes between various studies was also

Component	Description
	evaluated.

E.2 Hand Decontamination

Component	Description
Review question	What is the clinical and cost effectiveness of when to decontaminate hands, including after the removal of gloves, on hand decontamination compliance, MRSA and *C diff* reduction or cross infection, colony forming units and removal of physical contamination?
Objectives	To determine when hands should be decontaminated and to look at the implementation of hand decontamination guidance including the WHO 5 moments of hand hygiene to determine if infection have been reduced.
Population	Healthcare professionals Settings – primary care or community
Intervention	Implementation of a published hand decontamination guideline or policy e.g. CDC/WHO guidance. Exclusion criteria: Local policy not based on published guidance e.g. locally developed hand decontamination guidance.
Comparison	Implementation of a published hand decontamination guideline or policy No policy or guideline
Outcomes	Colony forming units (CFUs) Hand decontamination compliance MRSA reduction MRSA cross infection *C. diff* reduction *C. diff* cross infection Removal of physical contamination
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of cleaning preparations (soap and water, alcohol based rubs, non-alcohol products and wipes) for healthcare worker hand decontamination, on hand decontamination compliance, MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination?
Objectives	To determine which product should be used to decontaminated hands.
Population	Healthcare professionals Settings – primary care or community
Intervention	Alcohol based hand rubs Non-alcohol hand sanitizers Antimicrobial/ antiseptic hand washes or agents Liquid soap and water Skin wipes, hand wipes or wet wipes Exclusion criteria: surgical scrubs
Comparison	As above No hand cleaning products/ placebo
Outcomes	Colony forming units (CFUs) Hand decontamination compliance MRSA reduction MRSA cross infection *C. diff* reduction *C. diff* cross infection Removal of physical contamination
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers decontaminating wrists vs. not decontaminating wrists or usual practice on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?
Objectives	To determine the effectiveness of washing wrists on reduction of healthcare associated infection.
Population	Healthcare professionals Settings – primary care or community
Intervention	Decontaminating wrists Instructions/protocol to include decontaminating wrists
Comparison	Not decontaminating wrists Usual practice/ technique
Outcomes	Colony forming units (CFUs) Cross infection of MRSA Cross infection of *C. Diff* Hand decontamination compliance Removal of physical contamination (bodily fluids and dirt) Removal of transient organisms
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers following bare below the elbow policies (short sleeves or rolled up sleeves) vs. no bare below the elbow policy (long sleeves, not rolled up or no specific restrictions) on MRSA and *C. diff* reduction or cross infection, colony forming units and removal of physical contamination and transient organisms?
Objectives	To determine the effectiveness of following a bare below the elbow policy on reduction of healthcare associated infection.
Population	Healthcare professionals Settings – primary care or community, acute care settings
Intervention	Short sleeves Rolling up sleeves 'Bare below elbow' policies
Comparison	Not rolling up sleeves Long sleeves No specific restrictions/ standard practice
Outcomes	Colony forming units (CFUs)

Component	Description
	Cross infection of MRSA Cross infection of *C. Diff* Hand decontamination compliance Removal of physical contamination (bodily fluids and dirt) Removal of transient organisms
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.3 Personal protective equipment

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers wearing vinyl, latex or nitrile gloves on user preference and reduction of hypersensitivity, blood borne infections, glove porosity and tears?
Objectives	To determine which glove material is the most appropriate for protecting healthcare workers and patients from infection.
Population	Healthcare workers Subgroup: Healthcare workers who work in high risk units – HIV, Hepatitis Healthcare workers who undertake procedures with a risk of bodily contamination Settings – primary care or community
Intervention	Synthetic gloves: Vinyl gloves Nitrile gloves Latex gloves
Comparison	As above
Outcomes	Ability to perform task Blood borne infections Bodily fluid contamination Glove porosity Holes or tears in gloves Hypersensitivity User preference
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found

Component	Description
	well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers wearing plastic aprons or fluid repellent gowns vs. no aprons or gowns, gloves only or standard uniform on the reduction of blood and bodily fluid and pathogenic microorganism contamination?
Objectives	To determine which type of personal protective equipment (gowns or aprons) provides the best protection from infection.
Population	Healthcare workers Subgroup: Healthcare workers who work in high risk units – HIV, Hepatitis Healthcare workers who undertake procedures with a risk of bodily contamination Settings – primary care or community
Intervention	Disposable plastic apron Full body fluid repellent gown Disposable plastic apron plus gloves Full body fluid repellent gown plus gloves
Comparison	No protection Wearing disposable gloves only Standard uniform
Outcomes	Blood borne viruses Bodily fluid contamination
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.4 Safe use and disposal of sharps

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers using safety needle cannulae vs. standard cannulae on compliance and user preference, infection related mortality and morbidity and sharps injuries?
Objectives	To determine whether safety cannulae prevent sharps injuries and associated infections.
Population	Healthcare workers Settings – primary care or community
Intervention	Safety Cannulae
Comparison	Standard Cannulae
Outcomes	Blood borne viruses Compliance Infection related mortality Infection related morbidity Sharps injuries User preference
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of healthcare workers using safety needle devices (needle-free, retractable needles, safety re-sheathing devices) vs. standard needles on compliance and user preference, infection related mortality and morbidity and sharps injuries?
Objectives	To determine whether safety devices prevent sharps injuries and associated infections.
Population	Healthcare workers Settings – primary care or community
Intervention	Needle safety devices Needle removal devices Needleless/ needle-free devices Retractable needles Covered needles/ capped needles Safety lancets Safety re-sheathing devices

Component	Description
Comparison	Standard Needles/ fixed needles/ capped needles
Outcomes	Blood borne viruses Compliance Infection related mortality Infection related morbidity Sharps injuries User preference
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.5 Waste disposal

Component	Description
Review question	Are there any changes in the legislations which affect the disposal of personal protective equipments in relation to patient care in the primary and community care settings?
Objectives	To review and update the current recommendations about the safe disposal of personal protective equipment so that it is in line with the European Union (EU) and national legislations.
Population	Settings – primary care or community
Intervention	Disposal of PPE equipments
Comparison	N/A
Outcomes	N/A
Search strategy	Guidance documents from the Department of Health will be reviewed.
The review strategy	This question will be answered in accordance with EU legislation and therefore does not require a PICO. Guidance documents from the Department of Health will be reviewed. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063274

Component	Description
Review question	Are there any changes in the legislations which affect the disposal of sharp instruments and needles in relation to patient care in the primary and community care settings?
Objectives	To review and update recommendations about safe disposal of sharp instruments and needles in relation to patient care in primary and community care, in line with current EU legislations.
Population	Settings – primary care or community Healthcare workers.
Intervention	Disposal of sharp instruments and needles.
Comparison	N/A
Outcomes	N/A
Search strategy	Guidance documents from the Department of Health will be reviewed.
The review strategy	This question will be answered in accordance with EU legislation and therefore does not require a PICO. Guidance documents from the Department of Health will be reviewed. http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_063274

E.6 Long-term urinary catheters

Component	Description
Review question	What is the clinical and cost effectiveness of different types of long term indwelling urinary catheters (non-coated silicone, hydrophilic coated, or silver or antimicrobial coated/impregnated) on urinary tract infections, bacteraemia, frequency of catheter change, encrustations and blockages, mortality, and patient preference?
Objectives	To determine the most effective long term indwelling urinary catheter type to prevent infection.
Population	All patients with long term (>28days) urinary catheters • Catheter subgroups include suprapubic and urethral • At risk groups may include immunocompromised patients • Patients with previous history of UTI • Patients undergoing/had orthopaedic surgery Settings – primary care or community
Intervention	100% silicone catheter Hydrogel coated latex Hydrogel coated silicone Silicone coated latex catheter Impregnated silicone catheters Impregnated hydrogel coated latex catheter
Comparison	As above
Outcomes	Symptomatic UTI Number (or average number) of symptomatic recurrent UTIs (within 3 months, 6 months or 1 year) Bacteraemia Catheter replacement / frequency of catheter change

Component	Description
	Encrustations and blockages Mortality Patient preference/ comfort (secondary outcomes – blood in urine and pH changes)
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of different types of long-term intermittent urinary catheters (non-coated, hydrophilic or gel reservoir) on symptomatic urinary tract infections, bacteraemia, mortality, and patient preference?
Objectives	To determine the most effective long term urinary intermittent catheter type to prevent infection.
Population	All patients with long term (>28days) urinary catheters • Catheter subgroups include suprapubic and urethral • At risk groups may include immunocompromised patients • Patients with previous history of UTI • Patients undergoing/had orthopaedic surgery Settings – primary care or community
Intervention	Uncoated catheters (note: reusable up to 7 days) Hydrophilic catheters (note: not reusable) Catheters with gel reservoirs
Comparison	As above
Outcomes	Symptomatic UTI Number (or average number) of symptomatic recurrent UTIs (within 3 months, 6 months or 1 year) Bacteraemia Number of catheters used per day/week Mortality Patient preference/ comfort (secondary outcomes – blood in urine and pH changes)
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered.

Component	Description
	Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	In patients performing intermittent catheterisation, what is the clinical and cost effectiveness of non-coated catheters reused multiple times compared to single use on urinary tract infections, bacteraemia, mortality, and patient preference?
Objectives	To determine the most effective long term urinary intermittent catheter type (noncoated reused multiple times vs single use) to prevent infection.
Population	All patients with long term (>28days) urinary catheters • Catheter subgroups include suprapubic and urethral • At risk groups may include immunocompromised patients • Patients with previous history of UTI • Patients undergoing/had orthopaedic surgery Settings – primary care or community
Intervention	Uncoated catheters – single use, disposable
Comparison	Uncoated catheters – reusable (multi-use).
Outcomes	Symptomatic UTI Number (or average number) of symptomatic recurrent UTIs (within 3 months, 6 months or 1 year) Bacteraemia Mortality Patient preference/ comfort (secondary outcomes – blood in urine and pH changes)
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of bladder instillations or washouts on reduction of catheter associated symptomatic urinary tract infections and encrustations and blockages?
Objectives	To determine whether bladder instillations or washouts reduce catheter associated symptomatic urinary tract infections.
Population	All patients with long term (>28days) urinary catheters • Catheter subgroups include suprapubic and urethral • At risk groups may include Immunocompromised patients • Patients with previous history of UTI • Patients undergoing/had orthopaedic surgery Settings – primary care or community
Intervention	Saline Chlorhexidine CBG or CBR (citric acid based formulas) Sodium chloride Other solutions without active medications
Comparison	No instillations or washouts or placebo
Outcomes	Number (or average number) of symptomatic recurrent UTIs (within 3 months, 6 months or 1 year) Bacteraemia Catheter replacement / frequency of catheter change Encrustations and blockages Mortality Patient preference/ comfort Symptomatic UTI (secondary outcomes – blood in urine and pH changes)
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	In patients with long term urinary catheters (more than 28 days), what is the clinical and cost effectiveness of prophylactic antibiotics (single dose or short course) use during catheter change on reduction of urinary tract infections?
Objectives	To determine whether prophylactic antibiotics should be administered for patients with long term urinary catheters during catheter change.
Population	All patients with long term (>28days) urinary catheters • Catheter subgroups include suprapubic and urethral • At risk groups may include Immunocompromised patients • Patients with previous history of UTI • Patients undergoing/had orthopaedic surgery Settings – primary care or community
Intervention	Single dose Short course (24-72 hours, no longer than 3 days) (Inc. antibiotics administered on insertion and removal)
Comparison	Single dose Short course (24-72 hours, no longer than 3 days) No treatment (Inc. antibiotics administered on insertion and removal)
Outcomes	Antibiotic resistance Bacteraemia (< 1 week) Mortality Patient preference Symptomatic UTIs (< 1 week) Upper UTIs (< 1 week)
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.7 Enteral feeding

Component	Description
Review question	What is the clinical and cost effectiveness of single vs. reusable syringes used to flush percutaneous endoscopic gastrostomy tubes on reduction of tube blockages, diarrhoea, fungal colonisation, gastrostomy site infection, peritonitis and vomiting?
Objectives	To determine the effectiveness of single vs. reusable syringes syringes used to flush percutaneous endoscopic gastrostomy tubes on prevention of infection.
Population	All patients with PEGs. At risk groups may include: immunocompromised patients Settings – primary care or community
Intervention	Single use syringes (Subgroup: fresh tap water, cooled boiled water or freshly opened sterile water)
Comparison	Reusable syringes (Subgroup: fresh tap water, cooled boiled water or freshly opened sterile water)
Outcomes	Blockages/ tube occlusion Diarrhoea Fungal Colonisation Gastrostomy site infection Peritonitis Vomiting
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only Databases will be searched from 2002.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.8 Vascular access devices

Component	Description
Review question	What is the most clinical and cost effective product or solution for decontamination of the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?
Objectives	To determine which solution is the most effective for decontamination of the skin prior to insertion of peripherally inserted VAD.
Population	All patients with peripherally inserted VADs VAD subgroups: Peripheral cannula (IV)/ PICC/Mid-line At risk groups may include: patients receiving chemotherapy or immunocompromised patients Settings – primary care or community
Intervention	Decontamination solutions: Iodine 2% Alcoholic chlorhexidine 5% Alcoholic chlorhexidine Alcohol swabs/sponges/wipes
Comparison	As above
Outcomes	Catheter tip colonisation Infection-related mortality Septicaemia VAD line removal or frequency of line removal VAD related blood stream infection/Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found for certain outcomes such as adverse events, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of dressings (transparent semi-permeable, impregnated or gauze and tape) covering peripherally or centrally inserted vascular access device insertion site, including those that are bleeding or oozing, on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and phlebitis?
Objectives	To determine the effectiveness of types of dressings on prevention of infection.
Population	All patients with peripherally and centrally inserted VADs Insertion site subgroup: where insertion sites are bleeding or oozing At risk groups may include: patients receiving chemotherapy or immunocompromised patients Exclusion criteria: Intensive care or high dependency units if more relevant studies are found. Settings – primary care or community
Intervention	VAD dressings/IV dressings Cannula dressings Impregnated dressings Antimicrobial dressings Semi permeable dressings Transparent dressings Gauze dressings
Comparison	All of the above
Outcomes	Catheter tip colonisation Dressing change or frequency of dressing change Infection-related mortality Septicaemia VAD related blood stream infection/bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only No date restriction will be applied for peripheral catheters. Databases will be searched from their date of origin. Databases will be searched from 2002 for central catheters.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of frequency of dressing change (from daily up to 7 days) on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and phlebitis?
Objectives	To determine the effectiveness of frequency of dressing change on prevention of infection.
Population	All patients with peripherally and centrally inserted VADs Insertion site subgroup: where insertion sites are bleeding or oozing At risk groups may include: patients receiving chemotherapy or immunocompromised patients Settings – primary care or community
Intervention	Transparent dressings changed at daily intervals up to 7 days
Comparison	Standard frequency of change – every 7 days
Outcomes	Catheter tip colonisation Dressing change or frequency of dressing change Infection-related mortality Septicaemia VAD related blood stream infection/ Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only No date restriction will be applied for peripheral catheters. Databases will be searched from their date of origin. Databases will be searched from 2002 for central catheters.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the most clinical and cost effective product or solution for skin decontamination when changing VAD dressings on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?
Objectives	To determine the most effective solution for skin decontamination when changing VAD dressings.
Population	All patients with peripherally inserted VADs VAD subgroups: Peripheral cannula (IV)/ PICC/Mid-line At risk groups may include: patients receiving chemotherapy or immunocompromised patients Settings – primary care or community
Intervention	Iodine 2% Alcoholic chlorhexidine 5% Alcoholic chlorhexidine Alcohol swabs/sponges/wipes
Comparison	As above
Outcomes	Catheter tip colonisation Infection-related mortality Septicaemia VAD line removal or frequency of line removal VAD related blood stream infection/ Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found for certain outcomes such as adverse events, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only. No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the most clinical and cost effective duration of application of decontamination product/solution to the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?
Objectives	To determine the most effective duration of application of decontamination product/solution to the skin prior to insertion of peripherally inserted VAD.
Population	All patients with peripherally inserted VADs VAD subgroups: Peripheral cannula (IV)/PICC/Mid-line At risk groups may include: patients receiving chemotherapy or immunocompromised patients
Intervention	30 seconds for peripherally inserted VADs
Comparison	<30 seconds >30 seconds Standard or usual practice
Outcomes	Catheter tip colonisation Infection-related mortality Septicaemia VAD line removal or frequency of line removal VAD related blood stream infection/ Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found for certain outcomes such as adverse events, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only. No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the most clinical and cost effective product or solution for decontaminating VAD ports and hubs prior to access on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and frequency of line removal?
Objectives	To determine the most effective product or solution for decontaminating VAD ports and hubs prior to access.
Population	All patients with peripherally and centrally inserted VADs Insertion site subgroup: where insertion sites are bleeding or oozing At risk groups may include: patients receiving chemotherapy or immunocompromised patients Settings – primary care or community , or acute care
Intervention	Decontamination solutions: 2% Chlorhexidine 0.5% Chlorhexidine 70% Alcohol Isopropyl alcohol Providone iodine 2% Chlorhexidine -alcohol mix 2% Chlorhexidine -aqueous mix
Comparison	As above
Outcomes	Catheter tip colonisation Infection-related mortality Septicaemia VAD line removal or frequency of line removal VAD related blood stream infection/ Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found well conducted cohort studies may also be considered. Studies will be restricted to English language only No date restriction will be applied for peripheral catheters. Databases will be searched from their date of origin. Databases will be searched from 2002 for central catheters.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Component	Description
Review question	What is the clinical and cost effectiveness of multi dose vials vs. single use vials for administrating infusions or drugs on preventing contamination of the infusate and healthcare associated infection?
Objectives	To determine the effectiveness of multi dose vials vs. single use vials for administrating infusions or drugs to prevent infection.
Population	All patients with peripherally inserted VADs VAD subgroups: Peripheral cannula (IV)/ PICC/Mid-line At risk groups may include: patients receiving chemotherapy or immunocompromised patients Settings – primary care or community
Intervention	Multi-dose vials
Comparison	Single use vials
Outcomes	Catheter tip colonisation Infection-related mortality Septicaemia VAD line removal or frequency of line removal VAD related blood stream infection/ Bacteraemia VAD related phlebitis VAD related soft tissue infection/local infection/skin infection
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found for certain outcomes such as adverse events, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only. No date restriction will be applied. Databases will be searched from their date of origin.
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

E.9 Asepsis

Component	Description
Review question	What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling long-term urinary catheters to reduce colony forming units, urinary tract infections, compliance, MRSA or C. diff reduction and mortality? What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling vascular access devices to reduce infection related bacteraemia, phlebitis, compliance, MRSA or C. diff reduction and mortality? What is the most clinically and cost effective technique (such as aseptic technique, non-touch technique, aseptic non-touch technique or a clean technique) when handling PEGs to reduce healthcare associated infections?
Objectives	To determine the most effective aseptic technique to prevent infection.
Population	Healthcare workers Setting subgroup: • Primary care settings • Community settings
Intervention	Aseptic non touch technique or procedure or program Aseptic no touch procedure Aseptic technique
Comparison	Sterile technique Clean technique Standard techniques
Outcomes	Infection related bacteraemia Infection related mortality Colony forming units (CFUs) UTI (for LTUC) Phlebitis/ soft tissue infection/ local infection (for VAD) Compliance MRSA or C diff reduction
Search strategy	The databases to be searched are Medline, Embase, The Cochrane Library and CINAHL. Randomised controlled trials (RCTs) will be considered. If no RCTs are found for certain outcomes such as adverse events, well conducted cohort studies and observational studies may also be considered. Studies will be restricted to English language only. Databases will be searched from 2002
The review strategy	Meta-analyses will be conducted where possible. Only include hospital settings if no evidence is available from community settings. Only include intensive care settings if no other evidence is available from other hospital settings. If there is heterogeneity the following subgroups will be analysed separately: Age (adults, children)

Appendix F: Literature search strategies

Search strategies used for the Infection Prevention and Control guideline are outlined below and were run as per the NICE Guidelines Manual 2009 http://www.nice.org.uk/media/5F2/44/The_guidelines_manual_2009_-_All_chapters.pdf .

Searches for the **clinical reviews** were run in Medline (OVID), Embase (OVID), the Cochrane Library and Cinahl (EBSCO).

Usually, searches were constructed in the following way:

- A PICO format was used for **intervention** searches where population (P) terms were combined with Intervention (I) and sometimes Comparison (C) terms. An intervention can be a drug, a procedure or a diagnostic test. Outcomes (O) are rarely used in search strategies for interventions. Search Filters were also added to the search where appropriate.
- A PEO format was used for **prognosis** searches where population (P) terms were combined with exposure (E) terms and sometimes outcomes (O). Search filters were added to the search where appropriate.

Searches for **patient views** were run in Medline (Ovid), Embase (Ovid), PsychINFO (Ovid), Cinahl (EBSCO) and the Cochrane Library. Searches were constructed by adding a patient views search filter to the population terms.

Searches for the **health economic reviews** were run in Medline (Ovid), Embase (Ovid), the NHS Economic Evaluations Database (NHS EED), the Health Technology Assessment (HTA) database and the Health Economic Evaluation Database (HEED). NHS EED and HTA were searched via the Centre for Reviews and Dissemination (CRD) interface. Searches in NHS EED, HTA and HEED were constructed using only population terms. For Medline and Embase an economic filter (instead of a study type filter) was added to the same clinical search strategy.

All searches were run up to 18th April 2011 unless otherwise stated. Any studies added to the databases after this date were not included unless specifically stated in the text.

The search strategies are presented below in the following order:

Section F.1	Population terms by database for each key area. The same searches were used for all questions within that topic area and for both clinical and health economic searches. Order as presented in guideline.
F.1.1	Hand hygiene population
F.1.2	Long term urinary catheters population
F.1.3	Percutaneous endoscopic gastrostomy population
F.1.4	Vascular access devices population
F.1.5	Asepsis population
Section F.2	Study filter terms by database. These include filters for epidemiological study designs, health economic and quality of life studies and patient views.
Section F.3	Searches run for specific questions with the intervention or exposure terms by database. Order as presented in guideline
F.3.1	Standard principles (patient information)
F.3.2	Hand hygiene – when to decontaminate
F.3.3	Hand hygiene – cleaning preparations
F.3.4	Hand hygiene – wrist decontamination
F.3.5	Hand hygiene – bare below the elbows

F.3.6	Personal protective equipment – legislation
F.3.7	Personal protective equipment – gloves
F.3.8	Personal protective equipment – aprons
F.3.9	Sharps – legislation
F.3.10	Sharps – safety devices
F.3.11	Long term urinary catheters – catheter type
F.3.12	Long term urinary catheters – single versus multi use
F.3.13	Long term urinary catheters – bladder washout
F.3.14	Long term urinary catheters – antibiotic prophylaxis
F.3.15	Percutaneous endoscopic gastrostomy – syringes
F.3.16	Vascular access devices – dressings
F.3.17	Vascular access devices – decontamination
F.3.18	Vascular access devices – vials
F.3.19	Asepsis
Section F.4	Economic searches

F.1 Population search strategies

F.1.1 Hand hygiene population

Medline search terms

1.	Handwashing/
2.	(handwash$ or hand wash$ or hand hygiene).ti,ab.
3.	infection control/ or cross infection/ or universal precautions/ or disease transmission, infectious/ or equipment contamination/
4.	hand/
5.	4 and 3
6.	(hand$1 adj3 (clean$ or disinfect$ or decontaminat$ or antisepsis or wash$)).ti,ab.
7.	or/1-2,5-6

Embase search terms

1.	(handwash$ or hand wash$ or hand hygiene).ti,ab.
2.	(hand$1 adj3 (clean$ or disinfect$ or decontaminat$ or antisepsis or wash$)).ti,ab.
3.	hand washing/
4.	infection control/
5.	cross infection/
6.	exp disease transmission/
7.	hand/
8.	7 and (4 or 5 or 6)
9.	or/1-3,8

Cinahl search terms

S1	mh Handwashing or handwash* or hand wash* or hand hygiene
S2	(MH "Hand+")
S3	(MH "Equipment Contamination") or (MH "Infection Control") or (MH "Microbial Contamination+") or (MH "Cross Infection") or (MH "Universal Precautions") or (MH "Disease Transmission+")

S4	S2 and S3
S5	hand* n3 clean* or hand* n3 disinfect* or hand* n3 decontaminat* or hand* n3 antisepsis or hand* n3 wash*
S6	S1 or S4 or S5

Cochrane search terms

#1	MeSH descriptor Handwashing explode all trees
#2	(handwash* or hand wash* or hand hygiene):ti,ab,kw
#3	MeSH descriptor Hand, this term only
#4	MeSH descriptor Infection Control, this term only
#5	MeSH descriptor Cross Infection, this term only
#6	MeSH descriptor Universal Precautions, this term only
#7	MeSH descriptor Disease Transmission, Infectious, this term only
#8	MeSH descriptor Equipment Contamination, this term only
#9	(#4 OR #5 OR #6 OR #7 OR #8)
#10	(#3 AND #9)
#11	(hand* NEAR/3 (clean* or disinfect* or decontaminat* or antisepsis or wash*)):ti,ab,kw
#12	(#1 OR #2 OR #10 OR #11)

PsychInfo search terms

1.	hygiene/
2.	(handwash$ or hand wash$ or hand hygiene).ti,ab.
3.	(hand$1 adj3 (clean$ or disinfect$ or decontaminat$ or antisepsis or wash$)).ti,ab.
4.	or/1-3

F.1.2 Long term urinary catheters population

Medline search terms

1.	Urinary Catheterization/
2.	(((urinary or urethr$ or indwelling or suprapubic or bladder) adj catheter$) or (intermittent adj2 catheter$)).ti,ab.
3.	or/1-2

Embase search terms

1.	exp ureter catheter/ or exp urinary catheter/
2.	exp bladder catheterization/ or exp ureter catheterization/
3.	(((urinary or urethr$ or indwelling or suprapubic or bladder) adj catheter$) or (intermittent adj2 catheter$)).ti,ab.
4.	or/1-3

Cinahl search terms

S1	mh Urinary Catheterization
S2	urinary n1 catheter* or urethr* n1 catheter* or indwelling n1 catheter* or suprapubic n1 catheter* or bladder n1 catheter* or intermittent n2 catheter*
S3	S1 or S2

Cochrane search terms

#1	MeSH descriptor Urinary Catheterization, this term only
#2	(((urinary or urethr* or indwelling or suprapubic or bladder) NEAR catheter*) or (intermittent

	NEAR/2 catheter*)):ti,ab,kw
#3	(#1 OR #2)

F.1.3 Percutaneous endoscopic gastrostomy population

Medline search terms

1.	Enteral Nutrition/
2.	((PEG or tube or gastric or enteral or naso enteric or nasoenteric or intra gastric or intragastric or post pyloric or postpyloric or percutaneous or transpyloric or gastrointestin*) adj1 (feed* or nutrition* or intubat*)).ti,ab.
3.	Intubation, Gastrointestinal/
4.	or/1-3

Embase search terms

1.	enteric feeding/
2.	exp digestive tract intubation/
3.	((PEG or tube or gastric or enteral or naso enteric or nasoenteric or intra gastric or intragastric or post pyloric or postpyloric or percutaneous or transpyloric or gastrointestin*) adj1 (feed* or nutrition* or intubat*)).ti,ab.
4.	or/1-3

Cinahl search terms

S1	mh Enteral Nutrition or mh Intubation, Gastrointestinal
S2	PEG n1 feed* or PEG n1 nutrition* or PEG n1 intubat* or tube n1 feed* or tube n1 nutrition* or tube n1 intubat* or gastric n1 feed* or gastric n1 nutrition* or gastric n1 intubat* or enteral n1 feed* or enteral n1 nutrition* or enteral n1 intubat*
S3	naso enteric n1 feed* or naso enteric n1 nutrition* or naso enteric n1 intubat* or nasoenteric n1 feed* or nasoenteric n1 nutrition* or nasoenteric n1 intubat* or intra gastric n1 feed* or intra gastric n1 nutrition* or intra gastric n1 intubat* or intragastric n1 feed* or intragastric n1 nutrition* or intragastric n1 intubat*
S4	post pyloric n1 feed* or post pyloric n1 nutrition* or post pyloric n1 intubat* or postpyloric n1 feed* or postpyloric n1 nutrition* or postpyloric n1 intubat* or percutaneous n1 feed* or percutaneous n1 nutrition* or percutaneous n1 intubat* or transpyloric n1 feed* or transpyloric n1 nutrition* or transpyloric n1 intubat*
S5	gastrointestin* n1 feed* or gastrointestin* n1 nutrition* or gastrointestin* n1 intubat*
S6	S1 or S2 or S3 or S4 or S5

Cochrane search terms

#1	MeSH descriptor Enteral Nutrition, this term only
#2	MeSH descriptor Intubation, Gastrointestinal, this term only
#3	((PEG or tube or gastric or enteral or naso enteric or nasoenteric or intra gastric or intragastric or post pyloric or postpyloric or percutaneous or transpyloric or gastrointestin*) NEAR/1 (feed* or nutrition* or intubat*)):ti,ab,kw
#4	(#1 OR #2 OR #3)

F.1.4 Vascular access devices population

Medline search terms

1.	Catheters, Indwelling/
2.	(PICC or PIC or TPN).ti,ab.
3.	(((venous or intravenous or vascular or intravascular) adj (access or device$ or catheter$ or

	line$)) or venous-access or intravenous-access or vascular-access).ti,ab.
4.	catheterization, central venous/ or catheterization/
5.	(central$ adj2 (catheter$ or line$)).ti,ab.
6.	(catheter adj2 (hub$ or port$ or site$)).ti,ab.
7.	((tunnel?ed or non-tunnel?ed or non tunnel?ed or implanted) adj (catheter$ or line$)).ti,ab.
8.	(peripheral$ adj2 (catheter$ or line$)).ti,ab.
9.	exp catheterization, peripheral/
10.	or/1-7
11.	limit 10 to yr="2002 -Current"
12.	or/8-9
13.	11 or 12

Embase search terms

1.	artery catheter/ or central venous catheter/ or indwelling catheter/ or intravascular catheter/ or intravenous catheter/ or lung artery catheter/ or pulmonary artery catheter/ or subclavian vein catheter/
2.	exp blood vessel catheterization/ or vascular access device/
3.	(central$ adj2 (catheter$ or line$)).ti,ab.
4.	(catheter adj2 (hub$ or port$ or site$)).ti,ab.
5.	(((venous or intravenous or vascular or intravascular) adj (access or device$ or catheter$ or line$)) or venous-access or intravenous-access or vascular-access).ti,ab.
6.	(PICC or PIC or TPN or midline or mid-line).ti,ab.
7.	((tunnel?ed or non-tunnel?ed or non tunnel?ed or implanted) adj (catheter$ or line$)).ti,ab.
8.	or/1-7
9.	limit 8 to yr="2002 -Current"
10.	(peripheral$ adj2 (catheter$ or line$ or cannula$)).ti,ab.
11.	or/9-10

Cinahl search terms

S1	(MH "Catheterization, Central Venous+") or (MH "Catheters, Vascular+") or mh catheters or mh catheterization
S2	PICC or PIC or TPN or midline or mid-line or venous-access or intravenous-access or vascular-access or venous n access or venous n device* or venous n catheter* or venous n line*
S3	intravenous n1 access or intravenous n1 device* or intravenous n1 catheter* or intravenous n1 line* or vascular n1 access or vascular n1 device* or vascular n1 catheter* or vascular n1 line* or intravascular n1 access or intravascular n1 device* or intravascular n1 catheter* or intravascular n1 line*
S4	central* n2 catheter* or central* n2 line* or catheter n2 hub* or catheter n2 port* or catheter n2 site* or catheter* n1 tunnel#ed or catheter* n1 non-tunnel#ed or catheter* n1 non tunnel#ed or catheter* n1 implanted or line* n1 tunnel#ed or line* n1 non-tunnel#ed or line* n1 non tunnel#ed
S5	line* n1 implanted
S6	S1 or S2 or S3 or S4 or S5
S7	S1 or S2 or S3 or S4 or S5 Limiters - Published Date from: 20020101-20110418
S8	mh catheterization, peripheral+ or peripheral* n2 catheter* or peripheral* n2 line* or peripheral* n2 cannula*
S9	S7 or S8

Cochrane search terms

#1	MeSH descriptor Catheterization, Central Venous, this term only
#2	MeSH descriptor Catheters, Indwelling, this term only
#3	MeSH descriptor Catheterization, this term only
#4	(PICC or PIC or TPN or midline or mid-line):ti,ab,kw
#5	(((venous or intravenous or vascular or intravascular) NEAR (access or device* or catheter* or line*)) or venous-access or intravenous-access or vascular-access):ti,ab,kw
#6	(central* NEAR/2 (catheter* or line*)):ti,ab,kw
#7	(catheter NEAR/2 (hub* or port* or site*)):ti,ab,kw
#8	((tunnel?ed or non-tunnel?ed or non tunnel?ed or implanted) NEAR (catheter* or line*)):ti,ab,kw
#9	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8)
#10	(#9), from 2002 to 2011
#11	MeSH descriptor Catheterization, Peripheral explode all trees
#12	(peripheral* NEAR/2 (catheter* or line* or cannula*)):ti,ab,kw
#13	(#10 OR #11 OR #12)

F.1.5 Asepsis population

Medline search terms

1.	(antt or no touch or non touch or non-touch).ti,ab.
2.	((aseptic$ or aseps$ or sterile or clean) adj2 (technique$ or procedure$ or program$)).ti,ab.
3.	Asepsis/
4.	or/1-3

Embase search terms

1.	(antt or no touch or non touch or non-touch).ti,ab.
2.	((aseptic$ or aseps$ or sterile or clean) adj2 (technique$ or procedure$ or program$)).ti,ab.
3.	asepsis/
4.	or/1-3

Cinahl search terms

S1	(MH "Asepsis")
S2	antt or no touch or non touch or non-touch
S3	aseptic* n2 technique* or aseptic* n2 procedure* or aseptic* n2 program* or aseps* n2 technique* or aseps* n2 procedure* or aseps* n2 program* or sterile n2 technique* or sterile n2 procedure* or sterile n2 program* or clean n2 technique* or clean n2 procedure* or clean n2 program*
S4	S1 or S2 or S3

Cochrane search terms

#1	(antt or no touch or non touch or non-touch):ti,ab,kw
#2	((aseptic* or aseps* or sterile or clean) NEAR/2 (technique* or procedure* or program*)):ti,ab,kw
#3	MeSH descriptor Asepsis, this term only
#4	(#1 OR #2 OR #3)

F.2 Study filter search terms

F.2.1 Systematic review search terms

Medline search terms

1.	meta-analysis/
2.	(metaanalys$ or meta-analys$ or meta analys$).tw.
3.	exp "review literature"/
4.	(systematic$ adj3 (review$ or overview$)).tw.
5.	(selection criteria or data extraction).ab. and review.pt.
6.	(cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or cinhal or science citation index or bids or cancerlit).ab.
7.	(reference list$ or bibliograph$ or hand search$ or hand-search$ or manual search$ or relevant journals).ab.
8.	or/1-7
9.	(comment or letter or editorial).pt.
10.	exp animal/ not human/
11.	or/9-10
12.	8 not 11

Embase search terms

1.	meta analysis/
2.	(metaanalys$ or meta-analys$ or meta analys$).tw.
3.	systematic review/
4.	(systematic$ adj3 (review$ or overview$)).tw.
5.	(selection criteria or data extraction).ab. and Review.pt.
6.	(cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or cinhal or science citation index or bids or cancerlit).ab.
7.	(reference list$ or bibliograph$ or hand search$ or manual search$ or relevant journals).ab.
8.	or/1-7
9.	(letter or editorial or conference abstract).pt.
10.	(exp animal/ or nonhuman/ or exp animal-experiment/) not exp human/
11.	or/9-10
12.	8 not 11

F.2.2 Randomised controlled studies (RCTs) search terms

Medline search terms

1.	Randomized-Controlled-Trials/ or Random-Allocation/ or Double-Blind-Method/ or Single-Blind-Method/ or exp Clinical-Trials as topic/ or Cross-Over-Studies/ or Prospective-Studies/ or Placebos/
2.	(Randomized-Controlled-Trial or Clinical-Trial or Controlled-Clinical-Trial).pt.
3.	(((clinical or control or controlled) adj (study or trial)) or ((single or double or triple) adj (blind$3 or mask$3)) or (random$ adj (assign$ or allocat$ or group or grouped or patients or study or trial or distribut$)) or (crossover adj (design or study or trial)) or placebo or placebos).ti,ab.
4.	((Case-Reports not Randomized-Controlled-Trial) or Letter or Historical-Article or Review-Of-Reported-Cases).pt.
5.	exp Animal/ not Human/

6.	or/17-19
7.	or/20-21
8.	22 not 23

Embase search terms

1.	Clinical-Trial/ or Randomized-Controlled-Trial/ or Randomization/ or Single-Blind-Procedure/ or Double-Blind-Procedure/ or Crossover-Procedure/ or Prospective-Study/ or Placebo/
2.	(((clinical or control or controlled) adj (study or trial)) or ((single or double or triple) adj (blind$3 or mask$3)) or (random$ adj (assign$ or allocat$ or group or grouped or patients or study or trial or distribut$)) or (crossover adj (design or study or trial)) or placebo or placebos).ti,ab.
3.	Case-Study/ or Abstract-Report/ or Letter/ or (case adj report).tw. or conference abstract.pt.
4.	(exp Animal/ or Nonhuman/ or exp Animal-Experiment/) not exp Human/
5.	30 or 31
6.	32 or 33
7.	34 not 35

F.2.3 Observational studies search terms

Medline search terms

1.	Epidemiologic studies/
2.	exp case control studies/
3.	exp cohort studies/
4.	Case control.tw.
5.	(cohort adj (study or studies)).tw.
6.	Cohort analy$.tw.
7.	(Follow up adj (study or studies)).tw.
8.	(observational adj (study or studies)).tw.
9.	Longitudinal.tw.
10.	Retrospective.tw.
11.	Cross sectional.tw.
12.	Cross-sectional studies/
13.	or/1-12

Embase search terms

1.	Clinical study/
2.	Case control study/
3.	Family study/
4.	Longitudinal study/
5.	Retrospective study/
6.	Prospective study/
7.	Randomized controlled trials/
8.	6 not 7
9.	Cohort analysis/
10.	(Cohort adj (study or studies)).mp.
11.	(Case control adj (study or studies)).tw.

12.	(follow up adj (study or studies)).tw.
13.	(observational adj (study or studies)).tw.
14.	(epidemiologic$ adj (study or studies)).tw.
15.	(cross sectional adj (study or studies)).tw.
16.	or/1-5,8-15

F.2.4 Health economic, quality of life and model search terms

Medline search terms

1.	exp "costs and cost analysis"/
2.	economics/ or exp economics, hospital/ or exp economics, medical/ or economics, nursing/ or economics, pharmaceutical/
3.	exp "fees and charges"/ or exp budgets/
4.	budget$.tw.
5.	cost$.ti.
6.	(cost$ adj2 (effective$ or utilit$ or benefit$ or minimi$)).ab.
7.	(economic$ or pharmacoeconomic$ or pharmaco-economic$).ti.
8.	(price$ or pricing$).tw.
9.	(financial or finance or finances or financed).tw.
10.	(fee or fees).tw.
11.	(value adj2 (money or monetary)).tw.
12.	value of life/ or quality adjusted life year/
13.	quality adjusted life.tw.
14.	(qaly$ or qald$ or qale$ or qtime$).tw.
15.	disability adjusted life.tw.
16.	daly$.tw.
17.	Health Status Indicators/
18.	(sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw.
19.	(sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw.
20.	(sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw.
21.	(sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw.
22.	(sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw.
23.	(euroqol or euro qol or eq5d or eq 5d).tw.
24.	(hql or hqol or h qol or hrqol or hr qol).tw.
25.	(hye or hyes).tw.
26.	health$ year$ equivalent$.tw.
27.	health utilit$.tw.
28.	(hui or hui1 or hui2 or hui3).tw.
29.	disutilit$.tw.
30.	rosser.tw.

31.	(quality of wellbeing or quality of well being or qwb).tw.
32.	willingness to pay.tw.
33.	standard gamble$.tw.
34.	time trade off.tw.
35.	time tradeoff.tw.
36.	tto.tw.
37.	exp models, economic/ or *models, theoretical/ or *models, organizational/
38.	economic model$.tw.
39.	markov chains/
40.	markov$.tw.
41.	monte carlo method/
42.	monte carlo.tw.
43.	exp decision theory/
44.	(decision$ adj2 (tree$ or analy$ or model$)).tw.
45.	or/1-44
46.	(letter or editorial or comment).pt.
47.	45 not 46

Embase search terms

1.	exp economic aspect/
2.	cost$.ti.
3.	(cost$ adj2 (effective$ or utilit$ or benefit$ or minimi$)).ab.
4.	(economic$ or pharmacoeconomic$ or pharmaco-economic$).ti.
5.	(price$ or pricing$).tw.
6.	(financial or finance or finances or financed).tw.
7.	(fee or fees).tw.
8.	(value adj2 (money or monetary)).tw.
9.	quality adjusted life year/
10.	quality adjusted life.tw.
11.	(qaly$ or qald$ or qale$ or qtime$).tw.
12.	disability adjusted life.tw.
13.	daly$.tw.
14.	(sf36 or sf 36 or short form 36 or shortform 36 or sf thirtysix or sf thirty six or shortform thirtysix or shortform thirty six or short form thirtysix or short form thirty six).tw.
15.	(sf6 or sf 6 or short form 6 or shortform 6 or sf six or sfsix or shortform six or short form six).tw.
16.	(sf12 or sf 12 or short form 12 or shortform 12 or sf twelve or sftwelve or shortform twelve or short form twelve).tw.
17.	(sf16 or sf 16 or short form 16 or shortform 16 or sf sixteen or sfsixteen or shortform sixteen or short form sixteen).tw.
18.	(sf20 or sf 20 or short form 20 or shortform 20 or sf twenty or sftwenty or shortform twenty or short form twenty).tw.
19.	(euroqol or euro qol or eq5d or eq 5d).tw.
20.	(hql or hqol or h qol or hrqol or hr qol).tw.
21.	(hye or hyes).tw.
22.	health$ year$ equivalent$.tw.
23.	health utilit$.tw.

24.	(hui or hui1 or hui2 or hui3).tw.
25.	disutilit$.tw.
26.	rosser.tw.
27.	(quality of wellbeing or quality of well being or qwb).tw.
28.	willingness to pay.tw.
29.	standard gamble$.tw.
30.	(time trade off or time tradeoff or tto).tw.
31.	exp mathematical model/
32.	economic model$.tw.
33.	markov$.tw.
34.	monte carlo method/
35.	monte carlo.tw.
36.	decision theory/
37.	(decision$ adj2 (tree$ or analy$ or model$)).tw.
38.	or/1-37
39.	(comment or letter or editorial).pt.
40.	38 not 39

F.3 Searches by specific questions

F.3.1 Standard principles (patient information)

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Hand hygiene	Patient views, motivation			2002 to 18/04/2011

Patient views, motivation search terms

Medline search terms

1.	Patients/ or Inpatients/ or Outpatients/
2.	Caregivers/ or exp Family/ or exp Parents/ or exp Legal-Guardians/
3.	(patients or carer$ or famil$).tw.
4.	or/1-3
5.	Popular-Works-Publication-Type/ or exp Information-Services/ or Publications/ or Books/ or Pamphlets/ or Counseling/ or Directive-Counseling/
6.	4 and 5
7.	((patient or patients) adj3 (education or educate or educating or information or literature or leaflet$ or booklet$ or pamphlet$)).ti,ab.
8.	Patient-Education/ or Patient-Education-Handout-Publication-Type/
9.	or/6-8
10.	exp Consumer-Satisfaction/ or Personal-Satisfaction/ or exp Patient-Acceptance-Of-Health-Care/ or exp Consumer-Participation/ or exp Patient-Rights/ or Health Care Surveys/ or Questionnaires/ or Interview/ or Focus groups/

11.	(patient$ adj3 (view$ or opinion$ or awareness or tolerance or perception or persistenc$ or attitude$ or compliance or satisfaction or concern$ or belief$ or feeling$ or position or idea$ or preference$ or choice$)).tw.
12.	(Discomfort or comfort or inconvenience or bother$4 or trouble or fear$ or anxiety or anxious or worr$3).tw.
13.	or/10-12
14.	or/9,13
15.	Motivation/
16.	Health Knowledge, Attitudes, Practice/
17.	behavior/ or health behavior/
18.	Health Promotion/
19.	"Practice (Psychology)"/
20.	(motivat$ or barrier$ or behavio?r or incentive$ or disincentive$).ti,ab.
21.	or/15-20
22.	or/14,21

Embase search terms

1.	Consumer attitude/ or patient satisfaction/ or patient compliance/ or patient right/ or health survey/ or questionnaire/ or interview/
2.	(patient$ adj3 (view$ or opinion$ or awareness or tolerance or perception or persistenc$ or attitude$ or compliance or satisfaction or concern$ or belief$ or feeling$ or position or idea$ or preference$ or choice$)).tw.
3.	(Discomfort or comfort or inconvenience or bother$4 or trouble or fear$ or anxiety or anxious or embarrass$4).tw.
4.	or/1-3
5.	Patient/ or Hospital patient/ or Outpatient/
6.	Caregiver/ or exp Family/ or exp Parent/
7.	(patients or carer$ or famil$).tw.
8.	or/5-7
9.	Information Service/ or Information center/ or Publication/ or Book/ or Counseling/ or Directive counseling/
10.	8 and 9
11.	((patient or patients) adj3 (education or educate or educating or information or literature or leaflet$ or booklet$ or pamphlet$)).ti,ab.
12.	Patient information/ or Patient education/
13.	or/10-12
14.	or/4, 13
15.	behavior/ or motivation/
16.	health behavior/ or attitude to health/
17.	(motivat$ or barrier$ or behavio?r or incentive$ or disincentive$).ti,ab.
18.	"theory of planned behavior"/
19.	or/15-18
20.	or/14,19
21.	conference abstract.pt.
22.	20 not 21

Cinahl search terms

S1	mh Patients or mh Inpatients or mh Outpatients or mh Caregivers or mh Family+ or mh

	Parents+ or mh Guardianship, Legal or patients or carer* or famil*
S2	mh Information Services+ or mh Books+ or mh Pamphlets or mh Counseling
S3	S1 and S2
S4	patient n3 education or patient n3 educate or patient n3 educating or patient n3 information or patient n3 literature or patient n3 leaflet* or patient n3 booklet* or patient n3 pamphlet*
S5	patients n3 education or patients n3 educate or patients n3 educating or patients n3 information or patients n3 literature or patients n3 leaflet* or patients n3 booklet* or patients n3 pamphlet* or mh Patient Education+
S6	S3 or S4 or S5
S7	mh Consumer Satisfaction+ or mh Consumer Attitudes or mh Personal Satisfaction or mh Consumer Participation or mh Patient Rights+ or mh Questionnaires+ or mh Interviews+ or mh Focus groups or mh surveys
S8	patient* n3 view* or patient* n3 opinion* or patient* n3 awareness or patient* n3 tolerance or patient* n3 perception or patient* n3 persistenc* or patient* n3 attitude* or patient* n3 compliance or patient* n3 satisfaction or patient* n3 concern* or patient* n3 belief* or patient* n3 feeling*
S9	patient* n3 position or patient* n3 idea* or patient* n3 preference* or patient* n3 choice* or discomfort or comfort or inconvenience or bother* or trouble or fear* or anxiety or anxious
S10	embarrass*
S11	S7 or S8 or S9 or S10
S12	S6 or S11
S13	(MH "Case Studies") or PT case study or PT commentary or PT anecdote or PT editorial or PT letter
S14	S12 not S13
S15	(MH "Health Behavior") OR (MH "Behavior") OR (MH "Motivation")
S16	(MH "Health Knowledge")
S17	(MH "Health Promotion")
S18	(MH "Ajzen's Theory of Planned Behavior")
S19	motivat* or barrier* or behavior or behaviour or incentive* or disincentive*
S20	S15 or S16 or S17 or S18 or S19
S21	S14 or S20

Cochrane search terms

#1	MeSH descriptor Consumer Satisfaction explode all trees
#2	MeSH descriptor Personal Satisfaction, this term only
#3	MeSH descriptor Patient Acceptance of Health Care explode all trees
#4	MeSH descriptor Consumer Participation explode all trees
#5	MeSH descriptor Patient Rights explode all trees
#6	MeSH descriptor Health Care Surveys, this term only
#7	MeSH descriptor Questionnaires, this term only
#8	MeSH descriptor Focus Groups, this term only
#9	(patient* NEAR/3 (view* or opinion* or awareness or tolerance or perception or persistenc* or attitude* or compliance or satisfaction or concern* or belief* or feeling* or position or idea* or preference* or choice*)):ti,ab,kw
#10	(Discomfort or comfort or inconvenience or bother*4 or trouble or fear* or anxiety or anxious or worr*3):ti,ab,kw
#11	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10)
#12	MeSH descriptor Patients, this term only

#13	MeSH descriptor Inpatients, this term only
#14	MeSH descriptor Outpatients, this term only
#15	MeSH descriptor Caregivers, this term only
#16	MeSH descriptor Family explode all trees
#17	MeSH descriptor Parents explode all trees
#18	MeSH descriptor Legal Guardians explode all trees
#19	(patients or carer* or famil*):ti,ab,kw
#20	(#12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19)
#21	MeSH descriptor Information Services explode all trees
#22	MeSH descriptor Publications, this term only
#23	MeSH descriptor Books, this term only
#24	MeSH descriptor Pamphlets, this term only
#25	MeSH descriptor Counseling, this term only
#26	MeSH descriptor Directive Counseling, this term only
#27	(#21 OR #22 OR #23 OR #24 OR #25 OR #26)
#28	(#20 AND #27)
#29	((patient or patients) NEAR/3 (education or educate or educating or information or literature or leaflet* or booklet* or pamphlet*)):ti,ab,kw
#30	MeSH descriptor Patient Education as Topic, this term only
#31	(#28 OR #29 OR #30)
#32	(#11 OR #31)
#33	MeSH descriptor Motivation, this term only
#34	MeSH descriptor Health Knowledge, Attitudes, Practice, this term only
#35	MeSH descriptor Behavior, this term only
#36	MeSH descriptor Health Behavior, this term only
#37	MeSH descriptor Health Promotion, this term only
#38	MeSH descriptor Practice (Psychology), this term only
#39	(motivat* or barrier* or behavio*r or incentive* or disincentive*):ti,ab,kw
#40	(#33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39)
#41	(#32 OR #40)

PsychInfo search terms

1.	exp consumer satisfaction/ or exp client attitudes/ or client participation/ or exp client rights/ or treatment compliance/ or consumer surveys/ or exp questionnaires/ or interviews/ or expectations/
2.	(patient$ adj3 (view$ or opinion$ or awareness or tolerance or perception or persistenc$ or attitude$ or compliance or satisfaction or concern$ or belief$ or feeling$ or position or idea$ or preference$ or choice$ or expect$)).tw.
3.	(Discomfort or comfort or inconvenience or bother$4 or trouble or fear$ or anxiety or anxious or embarrass$4).tw.
4.	or/1-3
5.	exp patients/
6.	caregivers/ or exp family/ or exp parents/ or exp guardianship/
7.	(patients or carer$ or famil$).tw.
8.	or/5-7
9.	exp information services/ or exp printed communications media/ or reading materials/ or exp counseling/

10.	8 and 9
11.	((patient or patients) adj3 (education or educate or educating or information or literature or leaflet$ or booklet$ or pamphlet$)).ti,ab.
12.	client education/
13.	or/10-12
14.	or/4,13
15.	motivation/ or planned behavior/
16.	behavioral assessment/ or behavior/
17.	health behavior/
18.	(motivat$ or barrier$ or behavio?r or incentive$ or disincentive$).ti,ab.
19.	or/14-18
20.	or/14,19

F.3.2 Hand decontamination – when to decontaminate

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Hand hygiene	Guidelines, policies		Systematic reviews, RCTs, implementation terms (Medline and Embase only)	2002 to 18/04/2011

Guidelines, policies search terms

Medline search terms

1.	(world health organi?ation or five moments or 5 moments or IPS or infection prevention society or CDC or ((center$1 or centre$1) adj2 disease control) or Ayliffe).ti,ab.
2.	world health organization/
3.	(guideline$ or policy or policies).ti,ab.
4.	exp guideline/
5.	guidelines as topic/ or practice guidelines as topic/ or guideline adherence/
6.	or/1-5

Embase search terms

1.	(world health organi?ation or five moments or 5 moments or IPS or infection prevention society or CDC or ((center$1 or centre$1) adj2 disease control) or Ayliffe).ti,ab.
2.	world health organization/
3.	(guideline$ or policy or policies).ti,ab.
4.	practice guideline/
5.	or/1-4

Cinahl search terms

S1	(MH "World Health Organization")
S2	world health organi?ation or five moments or 5 moments or IPS or infection prevention

	society or CDC or center* n2 disease control or centre* n2 disease control or Ayliffe
S3	guideline* or policy or policies
S4	(MH "Guideline Adherence") OR (MH "Practice Guidelines")
S5	S1 or S2 or S3 or S4

Cochrane search terms

#1	(world health organi?ation or five moments or 5 moments or IPS or infection prevention society or CDC or ((center* or centre*) NEAR/2 disease control) or Ayliffe):ti,ab,kw
#2	MeSH descriptor World Health Organization, this term only
#3	(guideline* or policy or policies):ti,ab,kw
#4	MeSH descriptor Guidelines as Topic, this term only
#5	MeSH descriptor Practice Guidelines as Topic, this term only
#6	MeSH descriptor Guideline Adherence, this term only
#7	#1 or #2 or #3 or #4 or #5 or #6

Implementation search terms

Medline search terms

1.	Program Evaluation/
2.	(implement$ or validat$ or evaluat$ or impact$ or effect$).ti.
3.	or/1-2

Embase search terms

1.	(implement$ or validat$ or evaluat$ or impact$ or effect$).ti.

F.3.3 Hand decontamination – cleaning preparations

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Hand hygiene	Cleaning preparations		Systematic reviews, RCTs, observational studies (Medline and Embase only)	2002 to 18/04/2011

Cleaning preparation search terms

Medline search terms

1.	disinfectants/ or soaps/ or anti-infective agents, local/ or surface-active agents/
2.	((alcohol$ or alcohol-based or non-alcohol$ or non alcohol$ or antimicrob$ or antiseptic or antibacterial or detergent$ or sporicid$ or disinfect$) adj3 (wash$ or rub$ or gel$ or agent$ or sanitiz$ or sanitis$ or wipe$)).ti,ab.
3.	(soap$ or skin wipe$ or hand wipe$ or wet wipe$).ti,ab.
4.	or/1-3

Embase search terms

1.	topical antiinfective agent/
2.	soap/
3.	surfactant/
4.	((alcohol$ or alcohol-based or non-alcohol$ or non alcohol$ or antimicrob$ or antiseptic or antibacterial or detergent$ or sporicid$ or disinfect$) adj3 (wash$ or rub$ or gel$ or agent$ or sanitiz$ or sanitis$ or wipe$)).ti,ab.
5.	(soap$ or skin wipe$ or hand wipe$ or wet wipe$).ti,ab.
6.	or/1-5

Cinahl search terms

S1	(MH "Disinfectants") OR (MH "Antiinfective Agents, Local")
S2	(MH "Soaps")
S3	(MH "Surface-Active Agents")
S4	soap* or skin wipe* or hand wipe* or wet wipe*
S5	alcohol* n3 wash* or alcohol-based n3 wash* or non-alcohol* n3 wash* or non alcohol* n3 wash* or antimicrob* n3 wash* or antiseptic n3 wash* or antibacterial n3 wash* or detergent* n3 wash* or sporicid* n3 wash* or disinfect* n3 wash*
S6	alcohol* n3 rub* or alcohol-based n3 rub* or non-alcohol* n3 rub* or non alcohol* n3 rub* or antimicrob* n3 rub* or antiseptic n3 rub* or antibacterial n3 rub* or detergent* n3 rub* or sporicid* n3 rub* or disinfect* n3 rub*
S7	alcohol* n3 gel* or alcohol-based n3 gel* or non-alcohol* n3 gel* or non alcohol* n3 gel* or antimicrob* n3 gel* or antiseptic n3 gel* or antibacterial n3 gel* or detergent* n3 gel* or sporicid* n3 gel* or disinfect* n3 gel*
S8	alcohol* n3 agent* or alcohol-based n3 agent* or non-alcohol* n3 agent* or non alcohol* n3 agent* or antimicrob* n3 agent* or antiseptic n3 agent* or antibacterial n3 agent* or detergent* n3 agent* or sporicid* n3 agent* or disinfect* n3 agent*
S9	alcohol* n3 sanitiz* or alcohol-based n3 sanitiz* or non-alcohol* n3 sanitiz* or non alcohol* n3 sanitiz* or antimicrob* n3 sanitiz* or antiseptic n3 sanitiz* or antibacterial n3 sanitiz* or detergent* n3 sanitiz* or sporicid* n3 sanitiz* or disinfect* n3 sanitiz*
S10	alcohol* n3 sanitis* or alcohol-based n3 sanitis* or non-alcohol* n3 sanitis* or non alcohol* n3 sanitis* or antimicrob* n3 sanitis* or antiseptic n3 sanitis* or antibacterial n3 sanitis* or detergent* n3 sanitis* or sporicid* n3 sanitis* or disinfect* n3 sanitis*
S11	alcohol* n3 wipe* or alcohol-based n3 wipe* or non-alcohol* n3 wipe* or non alcohol* n3 wipe* or antimicrob* n3 wipe* or antiseptic n3 wipe* or antibacterial n3 wipe* or detergent* n3 wipe* or sporicid* n3 wipe* or disinfect* n3 wipe*
S12	S1 or S2 or S3 or S4 or S5 or S6 or S7 or S8 or S9 or S10 or S11

Cochrane search terms

#1	MeSH descriptor Disinfectants, this term only
#2	MeSH descriptor Soaps, this term only
#3	MeSH descriptor Anti-Infective Agents, Local, this term only
#4	MeSH descriptor Surface-Active Agents, this term only
#5	(soap* or skin wipe* or hand wipe* or wet wipe*):ti,ab,kw
#6	((alcohol* or alcohol-based or non-alcohol* or non alcohol* or antimicrob* or antiseptic or antibacterial or detergent* or sporicid* or disinfect*) NEAR/3 (wash* or rub* or gel* or agent* or sanitiz* or sanitis* or wipe*)):ti,ab,kw
#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)

F.3.4 Hand decontamination – wrist decontamination

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Hand hygiene	Wrists			2002 to 18/04/2011

Wrist search terms

Medline search terms

1.	Wrist/
2.	(wrist$ or forearm$).ti,ab.
3.	1 or 2

Embase search terms

1.	wrist/
2.	(wrist$ or forearm$).ti,ab.
3.	or/1-2

Cinahl search terms

S1	(MH "Wrist")
S2	wrist* or forearm*
S3	S1 or S2

Cochrane search terms

#1	MeSH descriptor Wrist, this term only
#2	(wrist* or forearm*):ti,ab,kw
#3	(#1 OR #2)

F.3.5 Hand decontamination – bare below the elbows

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Infection terms	Bare below the elbows			2002 to 18/04/2011

Medline search terms

1.	infection control/ or cross infection/ or universal precautions/ or disease transmission, infectious/ or equipment contamination/
2.	(infect$ or contaminat$ or decontaminat$ or disinfect$ or colonis$ or coloniz$).ti,ab.
3.	1 or 2

4.	(sleeve$ adj3 (short$ or long$ or roll$)).ti,ab.
5.	3 and 4
6.	(bare below adj2 elbow$).ti,ab.
7.	5 or 6

Embase search terms

1.	infection control/
2.	cross infection/
3.	exp disease transmission/
4.	(infect$ or contaminat$ or decontaminat$ or disinfect$ or colonis$ or coloniz$).ti,ab.
5.	or/1-4
6.	(sleeve$ adj3 (short$ or long$ or roll$)).ti,ab.
7.	5 and 6
8.	(bare below adj2 elbow$).ti,ab.
9.	7 or 8

Cinahl search terms

S1	(MH "Infection Control") OR (MH "Universal Precautions")
S2	(MH "Cross Infection") OR (MH "Microbial Contamination+")
S3	(MH "Disease Transmission+")
S4	(MH "Equipment Contamination")
S5	infect* or contaminat* or decontaminat* or disinfect* or colonis* or coloniz*
S6	S1 or S2 or S3 or S4 or S5
S7	sleeve* n3 short* or sleeve* n3 long* or sleeve* n3 roll*
S8	S6 and S7
S9	bare below n2 elbow*
S10	S8 or S9

Cochrane search terms

#1	(sleeve* NEAR/3 (short* or long* or roll*)):ti,ab,kw
#2	(bare below NEAR/2 elbow*):ti,ab,kw
#3	(#1 OR #2)

F.3.6 Personal protective equipment – legislation

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

No search was conducted for this question as it related to changes in legislation only.

F.3.7 Personal protective equipment - gloves

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Infection terms	Gloves		Systematic reviews, RCTs,	2002 to 18/04/2011

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
			observational studies (Medline and Embase only)	

Medline search terms

1.	infection control/ or cross infection/ or universal precautions/ or disease transmission, infectious/ or equipment contamination/
2.	(infect$ or colonis$ or coloniz$ or contaminat$).ti,ab.
3.	or/1-2
4.	exp Gloves, Protective/
5.	(glov$ adj3 (plastic or latex or vinyl or synthetic or nitrile or material$)).ti,ab.
6.	or/4-5
7.	3 and 6

Embase search terms

1.	infection control/ or cross infection/ or exp disease transmission/
2.	(infect$ or colonis$ or coloniz$ or contaminat$).ti,ab.
3.	or/1-2
4.	glove/
5.	surgical glove/
6.	(glov$ adj3 (plastic or latex or vinyl or synthetic or nitrile or material$)).ti,ab.
7.	or/4-6
8.	3 and 7

Cinahl search terms

S1	mh infection control or mh cross infection or mh universal precautions or mh equipment contamination or mh disease transmission+ or mh Microbial Contamination+ or infect* or colonis* or coloniz* or contaminat*
S2	(MH "Gloves")
S3	glov* n3 plastic or glov* n3 latex or glov* n3 vinyl or glov* n3 synthetic or glov* n3 nitrile or glov* n3 material* or glov* n3 polythene or glov* n3 powder*
S4	S2 or S3
S5	S1 and S4

Cochrane search terms

#1	MeSH descriptor Infection Control, this term only
#2	MeSH descriptor Cross Infection, this term only
#3	MeSH descriptor Universal Precautions, this term only
#4	MeSH descriptor Equipment Contamination, this term only
#5	MeSH descriptor Disease Transmission, Infectious, this term only
#6	(infect* or colonis* or coloniz* or contaminat*):ti,ab,kw
#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8	MeSH descriptor Gloves, Protective explode all trees
#9	(glov* NEAR/3 (plastic or latex or vinyl or synthetic or nitrile or material* or polythene or powder*)):ti,ab,kw
#10	(#8 OR #9)
#11	(#10 AND #7)

F.3.8 Personal protective equipment – aprons

What is the clinical and cost effectiveness of healthcare workers wearing plastic aprons or fluid repellent gowns vs. no aprons or gown, gloves only or standard uniform on blood borne viruses and bodily fluid decontamination?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Infection terms	Aprons, gowns		Systematic reviews, RCTs, observational studies (Medline and Embase only)	2002 to 18/04/2011

Medline search terms

1.	infection control/ or cross infection/ or universal precautions/ or equipment contamination/ or disease transmission, infectious/
2.	(infect$ or colonis$ or coloniz$ or contaminat$).ti,ab.
3.	or/1-2
4.	(gown$ or apron$ or overgown$ or covergown$ or coverall$).ti,ab.
5.	Protective Clothing/
6.	or/4-5
7.	3 and 6

Embase search terms

1.	infection control/ or cross infection/ or exp disease transmission/
2.	(infect$ or colonis$ or coloniz$ or contaminat$).ti,ab.
3.	or/1-2
4.	(gown$ or apron$ or overgown$ or covergown$ or coverall$).ti,ab.
5.	protective clothing/
6.	or/4-5
7.	3 and 6

Cinahl search terms

S1	mh infection control or mh cross infection or mh universal precautions or mh equipment contamination or mh disease transmission+ or mh Microbial Contamination+ or infect* or colonis* or coloniz* or contaminat*
S2	gown* or apron* or overgown* or covergown* or mh Protective Clothing
S3	S1 and S2

Cochrane search terms

#1	MeSH descriptor Infection Control, this term only
#2	MeSH descriptor Cross Infection, this term only
#3	MeSH descriptor Universal Precautions, this term only
#4	MeSH descriptor Equipment Contamination, this term only
#5	MeSH descriptor Disease Transmission, Infectious, this term only
#6	(infect* or colonis* or coloniz* or contaminat*):ti,ab,kw
#7	(#1 OR #2 OR #3 OR #4 OR #5 OR #6)
#8	(gown* or apron* or overgown* or covergown* or coverall*):ti,ab,kw

#9	MeSH descriptor Protective Clothing
#10	#8 or #9
#11	#7 and #10

F.3.9 Sharps – legislation

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

No search was conducted for this question as it related to changes in legislation only.

F.3.10 Sharps – safety devices

Searches for the following two clinical questions were run as one search.

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

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Infection/ needlestick terms	Safety devices		Systematic reviews, RCTs, observational studies (Medline and Embase only)	2002 to 18/04/2011

Medline search terms

1.	infection control/ or cross infection/ or universal precautions/ or equipment contamination/ or disease transmission, infectious/
2.	((needlestick or needle-stick or needle stick or accidental innoculation$) adj2 injur$).ti,ab.
3.	(infection$ adj2 (control or prevent$)).ti,ab.
4.	Needlestick Injuries/
5.	or/1-4
6.	(needle$ adj1 (retract$ or covered or capped or fixed or uncapped or guard$ or protect$ or removal)).ti,ab.
7.	(safe$ adj1 (needle$ or sharp$ or lancet$ or cannula$ or re-sheath$ or resheat$)).ti,ab.
8.	(needleless or needlefree or needle-free or ((needle stick or needle-stick or needlestick) adj prevent$)).ti,ab.
9.	or/6-8
10.	5 and 9

Embase search terms

1.	infection control/ or cross infection/ or exp disease transmission/
2.	((needlestick or needle-stick or needle stick or accidental innoculation$) adj2 injur$).ti,ab.
3.	(infection$ adj2 (control or prevent$)).ti,ab.
4.	needlestick injury/

5.	or/1-4
6.	(needle$ adj1 (retract$ or covered or capped or fixed or uncapped or guard$ or protect$ or removal)).ti,ab.
7.	(safe$ adj1 (needle$ or sharp$ or lancet$ or cannula$ or re-sheath$ or resheat$)).ti,ab.
8.	(needleless or needlefree or needle-free or ((needle stick or needle-stick or needlestick) adj prevent$)).ti,ab.
9.	or/6-8
10.	5 and 9

Cinahl search terms

S1	mh infection control or mh cross infection or mh universal precautions or mh equipment contamination or mh disease transmission, infectious or infection n2 control or infection n2 prevent* or mh Needlestick Injuries or needlestick n2 injur* or needle-stick n2 injur* or needle stick n2 injur* or accidental innoculation* n2 injur*
S2	needleless or needlefree or needle-free or needle stick n prevent* or needle-stick n prevent* or needlestick n prevent*
S3	safe* n1 needle* or safe* n1 sharp* or safe* n1 lancet* or safe* n1 cannula* or safe* n1 re-sheath* or safe* n1 resheat*
S4	needle* n1 retract* or needle* n1 covered or needle* n1 capped or needle* n1 fixed or needle* n1 uncapped or needle* n1 guard* or needle* n1 protect* or needle* n1 removal
S5	S2 or S3 or S4
S6	S1 and S5

Cochrane search terms

#1	MeSH descriptor Infection Control, this term only
#2	MeSH descriptor Cross Infection, this term only
#3	MeSH descriptor Universal Precautions, this term only
#4	MeSH descriptor Equipment Contamination, this term only
#5	MeSH descriptor Disease Transmission, Infectious, this term only
#6	MeSH descriptor Disease Transmission, Infectious, this term only
#7	(infection* NEAR/2 (control or prevent*)):ti,ab,kw
#8	MeSH descriptor Needlestick Injuries, this term only
#9	((needlestick or needle-stick or needle stick or accidental innoculation*) NEAR/2 injur*):ti,ab,kw
#10	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9)
#11	(needleless or needlefree or needle-free or ((needle stick or needle-stick or needlestick) NEAR prevent*)):ti,ab,kw
#12	(safe* NEAR (needle* or sharp* or lancet* or cannula* or re-sheath* or resheat*)):ti,ab,kw
#13	(needle8 NEAR (retract* or covered or capped or fixed or uncapped or guard* or protect* or removal)):ti,ab,kw
#14	(#11 OR #12 OR #13)
#15	(#10 AND #14)

F.3.11 Long term urinary catheters – catheter type

Searches for the following two clinical questions were run as one search.

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

What is the clinical and cost effectiveness of different types of long term urinary intermittent self catheters (uncoated, hydrophilic or gel reservoir) on urinary tract infections, bacteraemia, frequency of catheter change, encrustations and blockages, mortality, and patient preference?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Long term urinary catheters	Catheter types		Systematic reviews and RCTs (Medline and Embase only)	2002 to 18/04/2011

Catheter type search terms

Medline search terms

1.	(impregnat$ or silicon$ or latex or coat$ or silver or hydrogel or hydrophilic or uncoat$ or non coat$ or gel reservoir$).ti,ab.

Embase search terms

1.	(impregnat$ or silicon$ or latex or coat$ or silver or hydrogel or hydrophilic or uncoat$ or non coat$ or gel reservoir$).ti,ab.

Cinahl search terms

S1	impregnat* or silicon* or latex or coat* or silver or hydrogel or hydrophilic or uncoat* or noncoat* or gel reservoir*

Cochrane search terms

#1	(impregnat* or silicon* or latex or coat* or silver or hydrogel or hydrophilic or uncoat* or noncoat* or gel reservoir*):ti,ab,kw

F.3.12 Long term urinary catheters – single versus multi use

In patients performing intermittent catheterisation, what is the clinical and cost effectiveness of noncoated catheters reused multiple times compared to single use on urinary tract infections, bacteraemia, frequency of catheter change, encrustations and blockages, mortality, and patient preference?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Intermittent catheterisation	Single use catheters	Multiple use catheters		No date restrictions, search run up to 18/04/2011

Medline search terms

1.	Urinary Catheterization/
2.	(intermittent adj2 catheter$).ti,ab.
3.	or/1-2
4.	(sterile or "single use" or single-use).ti,ab.
5.	(clean or "multi use" or multi-use or "multiple use$" or reuse$).ti,ab.
6.	(("multi use" or multi-use or "multiple use$" or reuse$) adj2 catheter$).ti,ab.
7.	6 or (4 and 5)
8.	3 and 7

Embase search terms

1.	intermittent catheterization/
2.	(intermittent adj2 catheter$).ti,ab.
3.	(sterile or "single use" or single-use).ti,ab.
4.	(clean or "multi use" or multi-use or "multiple use$" or reuse$).ti,ab.
5.	(("multi use" or multi-use or "multiple use$" or reuse$) adj2 catheter$).ti,ab.
6.	5 or (3 and 4)
7.	or/1-2
8.	6 and 7

Cinahl search terms

S1	(MH "Urinary Catheterization, Intermittent")
S2	intermittent n2 catheter*
S3	S1 or S2
S4	sterile or single use or single-use
S5	clean or multi use or multi-use or multiple use* or reuse*
S6	reuse* n2 catheter* or multi use n2 catheter* or multi-use n2 catheter* or multiple use* n2 catheter*
S7	S4 and S5
S8	S6 or S7
S9	S3 and S8

Cochrane search terms

#1	MeSH descriptor Urinary Catheterization, this term only
#2	(intermittent NEAR/2 catheter*):ti,ab,kw
#3	(#1 OR #2)
#4	(sterile or "single use" or single-use):ti,ab,kw
#5	(clean or "multi use" or multi-use or "multiple use*" or reuse*):ti,ab,kw
#6	(#4 AND #5)
#7	(("multi use" or multi-use or "multiple use*" or reuse*) NEAR/2 catheter*):ti,ab,kw
#8	(#6 OR #7)
#9	(#3 AND #8)

F.3.13 Long term urinary catheters – bladder washout

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Long term urinary catheters	Bladder washout/irrigation/ instillation		Systematic reviews and RCTs (Medline and Embase only)	2002 to 18/04/2011

Bladder washout/irrigation/instillation search terms

Medline search terms

1.	therapeutic irrigation/
2.	((bladder adj2 wash$) or bath$ or irrigat$ or instillat$ or washout$ or lavage$ or bwo).ti,ab.
3.	or/1-2

Embase search terms

1.	bladder irrigation/ or bladder irrigator/
2.	((bladder adj2 wash$) or bath$ or irrigat$ or instillat$ or washout$ or lavage$ or bwo).ti,ab.
3.	or/1-2

Cinahl search terms

S1	bladder n2 wash* or bladder n2 bath* or irrigat* or instillat* or washout* or lavage* or bwo
S2	(MH "Irrigation") OR (MH "Urinary Bladder Irrigation")
S3	S1 or S2

Cochrane search terms

#1	MeSH descriptor Irrigation, this term only
#2	((bladder NEAR/2 (wash* or bath*)) or irrigat* or instillat* or washout* or lavage* or bwo):ti,ab,kw
#3	(#1 OR #2)

F.3.14 Long term urinary catheters – antibiotic prophylaxis

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Long term urinary catheters	Antibiotics		Systematic reviews and RCTs (Medline and Embase only)	2002 to 18/04/2011

Antibiotic search terms

Medline search terms

1.	exp Anti-Bacterial Agents/
2.	(antibiotic$ or antimicrobial$ or antibacterial$ or anti-bacterial$ or anti-microbial$).ti,ab.
3.	(penicillin$ or benzylpenicillin or phenoxymethylpenicillin or temocillin or flucloxacillin or ampicillin or amox?cillin or co-amoxiclav or co-fluampicil or ticarcillin or piperacillin or pivmecillinam or mecillinam$).ti,ab
4.	(cephalosporin$ or cefradine or cephradine or cefuroxime or cefotaxime or ceftazidime or ceftriaxone or ceftazidime or ceftriaxone or cefalexin or cephalexin or cefradine or cefadroxil or cefaclor or cefixime or cefpodoxime).ti,ab
5.	(carbapenem$ or imipenem or meropenem or doripenem or ertapenem or cilastatin or aztreonam).ti,ab
6.	(tetracycline$ or minocycline or oxytetracycline or doxycycline or demeclocycline or lymecycline or tigecycline).ti,ab

7.	(aminoglycoside$ or amikacin or gentamicin or neomycin or streptomycin or tobramycin).ti,ab
8.	(macrolide$ or erythromycin or azithromycin or clarithromycin or spiramycin or telithromycin or clindamycin).ti.ab
9.	(trimethoprim or metronidazole or tinidazole or methenamine or nitrofurantoin).ti,ab
10.	(quinolone$ or nalidixic acid or norfloxacin or ciprofloxacin or ofloxacin or levofloxacin or moxifloxacin).ti,ab
11.	or/1-10

Embase search terms

1.	exp antibiotic agent/
2.	(antibiotic$ or antimicrobial$ or antibacterial$ or anti-bacterial$ or anti-microbial$).ti,ab.
3.	(penicillin$ or benzylpenicillin or phenoxymethylpenicillin or temocillin or flucloxacillin or ampicillin or amox?cillin or co-amoxiclav or co-fluampicil or ticarcillin or piperacillin or pivmecillinam or mecillinam$).ti,ab.
4.	(cephalosporin$ or cefradine or cephradine or cefuroxime or cefotaxime or ceftazidime or ceftriaxone or ceftazidime or ceftriaxone or cefalexin or cephalexin or cefradine or cefadroxil or cefaclor or cefixime or cefpodoxime).ti,ab.
5.	(carbapenem$ or imipenem or meropenem or doripenem or ertapenem or cilastatin or aztreonam).ti,ab.
6.	(tetracycline$ or minocycline or oxytetracycline or doxycycline or demeclocycline or lymecycline or tigecycline).ti,ab.
7.	(aminoglycoside$ or amikacin or gentamicin or neomycin or streptomycin or tobramycin).ti,ab.
8.	(macrolide$ or erythromycin or azithromycin or clarithromycin or spiramycin or telithromycin or clindamycin).ti,ab.
9.	(trimethoprim or metronidazole or tinidazole or methenamine or nitrofurantoin).ti,ab.
10.	(quinolone$ or nalidixic acid or norfloxacin or ciprofloxacin or ofloxacin or levofloxacin or moxifloxacin).ti,ab.
11.	or/1-10

Cinahl search terms

S1	mh anti-bacterial agents+ or antibiotic* or antimicrobial* or antibacterial* or anti-bacterial* or anti-microbial*
S2	penicillin* or benzylpenicillin or phenoxymethylpenicillin or temocillin or flucloxacillin or ampicillin or amoxicillin or amoxycillin or co-amoxiclav or co-fluampicil or ticarcillin or piperacillin
S3	pivmecillinam or mecillinam* or cephalosporin* or cefradine or cephradine or cefuroxime or cefotaxime or ceftazidime or ceftriaxone or ceftazidime or ceftriaxone or cefalexin
S4	cephalexin or cefradine or cefadroxil or cefaclor or cefixime or cefpodoxime or carbapenem* or imipenem or meropenem or doripenem or ertapenem or cilastatin
S5	aztreonam or tetracycline* or minocycline or oxytetracycline or doxycycline or demeclocycline or lymecycline or tigecycline or aminoglycoside* or amikacin or gentamicin or neomycin
S6	streptomycin or tobramycin or macrolide* or erythromycin or azithromycin or clarithromycin or spiramycin or telithromycin or clindamycin or trimethoprim or metronidazole or tinidazole
S7	methenamine or nitrofurantoin or quinolone* or nalidixic acid or norfloxacin or ciprofloxacin or ofloxacin or levofloxacin or moxifloxacin
S8	S1 or S2 or S3 or S4 or S5 or S6 or S7

Cochrane search terms

#1	MeSH descriptor Anti-Bacterial Agents explode all trees
#2	(antibiotic* or antimicrobial* or antibacterial* or anti-bacterial* or anti-microbial*):ti,ab,kw
#3	(penicillin* or benzylpenicillin or phenoxymethylpenicillin or temocillin or flucloxacillin or

	ampicillin or amox?cillin or co-amoxiclav or co-fluampicil or ticarcillin or piperacillin or pivmecillinam or mecillinam*):ti,ab,kw
#4	(cephalosporin* or cefradine or cephradine or cefuroxime or cefotaxime or ceftazidime or ceftriaxone or ceftazidime or ceftriaxone or cefalexin or cephalexin or cefradine or cefadroxil or cefaclor or cefixime or cefpodoxime):ti,ab,kw
#5	(carbapenem* or imipenem or meropenem or doripenem or ertapenem or cilastatin or aztreonam):ti,ab,kw
#6	(tetracycline* or minocycline or oxytetracycline or doxycycline or demeclocycline or lymecycline or tigecycline):ti,ab,kw
#7	(aminoglycoside* or amikacin or gentamicin or neomycin or streptomycin or tobramycin):ti,ab,kw
#8	(macrolide* or erythromycin or azithromycin or clarithromycin or spiramycin or telithromycin or clindamycin):ti,ab,kw
#9	(trimethoprim or metronidazole or tinidazole or methenamine or nitrofurantoin):ti,ab,kw
#10	(quinolone* or nalidixic acid or norfloxacin or ciprofloxacin or ofloxacin or levofloxacin or moxifloxacin):ti,ab,kw
#11	(#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10)

F.3.15 Percutaneous endoscopic gastrostomy – syringes

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Percutaneous endoscopic gastrostomy	Syringes			2002 to 18/04/2011

Syringe search terms

Medline search terms

1.	(flush$ or syringe$).ti,ab.
2.	Syringes/
3.	or/1-2

Embase search terms

1.	(flush$ or syringe$).ti,ab.
2.	syringe/
3.	or/1-2

Cinahl search terms

S1	mh syringes or syringe* or flush*

Cochrane search terms

#1	(flush* or syringe*):ti,ab,kw
#2	MeSH descriptor Syringes, this term only
#3	(#1 OR #2)

F.3.16 Vascular access devices - dressings

Searches for the following two clinical questions were run as one search.

What is the clinical and cost effectiveness of dressings (transparent semi-permeable, impregnated or gauze and tape) covering peripherally or centrally inserted vascular access devices insertion sites that are bleeding or oozing on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and phlebitis?

What is the clinical and cost effectiveness of frequency of dressing change (from daily up to 7 days) on catheter tip colonisation, frequency of dressing change, infection related mortality, septicaemia, bacteraemia and phlebitis?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Vascular access devices	Dressings		Systematic reviews, RCTs, observational studies (Medline and Embase only)	For peripheral catheters no date restriction, for central catheters 2002 onwards. Search run up to 18/04/2011

Dressing search terms

Medline search terms

1.	Occlusive Dressings/
2.	(gauze$ or (dressing$ adj3 (occlusive or impregnat$ or plain or patch or clear or transparent or cannula$ or VAD or antimicrobial or semi permeable or semi-permeable or IV or catheter$ or line$ or vapo?r permeable or silver))).ti,ab.
3.	(tegaderm or biopatch or vecafix or dermafilm or polyskin or hydrofilm or activheal or mepore or bioclusive or opsite or c-view or easi-v or central gard or atrauman or urgotul or bactigras).ti,ab
4.	*bandages/
5.	or/1-4

Embase search terms

1.	foam dressing/ or gauze dressing/ or hydrocolloid dressing/ or hydrogel dressing/ or occlusive dressing/ or transparent dressing/
2.	(gauze$ or (dressing$ adj3 (occlusive or impregnat$ or plain or patch or clear or transparent or cannula$ or VAD or antimicrobial or semi permeable or semi-permeable or IV or catheter$ or line$ or vapo?r permeable or silver))).ti,ab.
3.	(tegaderm or biopatch or vecafix or dermafilm or polyskin or hydrofilm or activheal or mepore or bioclusive or opsite or c-view or easi-v or central gard or atrauman or urgotul or bactigras).ti,ab.
4.	or/1-3

Cinahl search terms

S1	((MH "Bandages and Dressings+")) or gauze* or dressing* n3 occlusive or dressing* n3 impregnat* or dressing* n3 plain or dressing* n3 patch or dressing* n3 clear or dressing* n3 transparent or dressing* n3 cannula* or dressing* n3 VAD or dressing* n3 antimicrobial or dressing* n3 semi permeable
S2	dressing* n3 semi-permeable or dressing* n3 IV or dressing* n3 catheter* or dressing* n3 line* or dressing* n3 vapor permeable or dressing* n3 vapour permeable or dressing* n3

	silver or tegaderm or biopatch or vecafix or dermafilm or polyskin
S3	hydrofilm or activheal or mepore or bioclusive or opsite or c-view or easi-v or central gard or atrauman or urgotul or bactigras
S4	S1 or S2 or S3

Cochrane search terms

#1	MeSH descriptor Occlusive Dressings
#2	MeSH descriptor Bandages
#3	(gauze* or (dressing* NEAR/3 (occlusive or impregnat* or plain or patch or clear or transparent or cannula* or VAD or antimicrobial or semi permeable or semi-permeable or IV or catheter* or line* or vapo?r permeable or silver))):ti,ab,kw
#4	(tegaderm or biopatch or vecafix or dermafilm or polyskin or hydrofilm or activheal or mepore or bioclusive or opsite or c-view or easi-v or central gard or atrauman or urgotul or bactigras):ti,ab,kw
#5	#1 or #2 or #3 or #4

F.3.17 Vascular access devices - decontamination

Searches for the following four clinical questions were run as one search.

What is the most clinical and cost effective product or solution for decontaminating VAD ports and hubs prior to access on catheter tip colonisation, infection related mortality, septicaemia, bacteraemia and frequency of line removal?

What is the most clinical and cost effective product or solution for decontamination of the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?

What is the most clinical and cost effective duration of application of decontamination product/solution to the skin prior to insertion of peripherally inserted VAD on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?

What is the most clinical and cost effective products or solution for skin decontamination when changing VAD dressings on catheter tip colonisation, infection related mortality, frequency of line removal, septicaemia, bacteraemia and phlebitis?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Vascular access devices	Decontamination		Systematic reviews, RCTs, observational studies (Medline and Embase only)	For peripheral catheters no date restriction, for central catheters 2002 onwards. Search run up to 18/04/2011

Decontamination search terms

Medline search terms

1.	(clean$ or disinfect$ or decontaminat$).ti,ab.
2.	disinfection/
3.	Chlorhexidine/

4.	Povidone-Iodine/
5.	iodine/
6.	(chlorhexidine or povidone iodine or providone iodine or alcohol$ or iodine or chd or pvp-i).ti,ab.
7.	(chloraPrep or sterets or hydrex or sani cloth).ti,ab.
8.	or/1-7

Embase search terms

1.	(clean$ or disinfect$ or decontaminat$).ti,ab.
2.	chlorhexidine/
3.	povidone iodine/
4.	2 propanol/
5.	(chlorhexidine or povidone iodine or providone iodine or alcohol$ or iodine or chd or pvp-i).ti,ab.
6.	(chloraPrep or sterets or hydrex or sani cloth).ti,ab.
7.	disinfection/
8.	or/1-7

Cinahl search terms

S1	clean* or disinfect* or decontaminat* or chlorhexidine or povidone iodine or povidone-iodine or providone iodine or providone-iodine or alcohol* or iodine or chd or pvp-i
S2	chloraPrep or sterets or hydrex or sani cloth or mh disinfection or mh Chlorhexidine or mh Povidone-Iodine or mh iodine
S3	S1 or S2

Cochrane search terms

#1	(clean* or disinfect* or decontaminat*):ti,ab,kw
#2	MeSH descriptor Disinfection
#3	MeSH descriptor Chlorhexidine
#4	MeSH descriptor Povidone-Iodine
#5	MeSH descriptor Iodine
#6	(chlorhexidine or povidone iodine or providone iodine or alcohol* or iodine or chd or pvp-i):ti,ab,kw
#7	(chloraPrep or sterets or hydrex or sani cloth):ti,ab,kw
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7

F.3.18 Vascular access devices – vials

What is the clinical and cost effectiveness of multi dose vials vs. single use vials for administrating infusions or drugs on preventing contamination of the infusate and healthcare associated infection?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Vascular access devices	Vials			No date restriction to 18/04/2011

Medline search terms

	((single dose or single-dose or multi dose or multi-dose or multidose or multiple dose) adj3 (vial$ or phial$)).ti,ab.

Embase search terms

	((single dose or single-dose or multi dose or multi-dose or multidose or multiple dose) adj3 (vial$ or phial$)).ti,ab.

Cinahl search terms

	single dose n3 vial* or single dose n3 phial* or single-dose n3 vial* or single-dose n3 phial* or multi dose n3 vial* or multi dose n3 phial* or multi-dose n3 vial* or multi-dose n3 phial* or multidose n3 vial* or multidose n3 phial* or multiple dose* n3 vial* or multiple dose* n3 phial*

Cochrane search terms

	((single dose or single-dose or multi dose or multi-dose or multidose or multiple dose) NEAR/3 (vial* or phial*)):ti,ab,kw

F.3.19 Asepsis

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Asepsis	Long term urinary catheters			2002 to 18/04/2011

What is the most clinically and cost effective technique (aseptic technique, non-touch, ANTT vs. a clean technique) when handling PEGs to reduce healthcare associated infections?

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Asepsis	Percutaneous endoscopic gastrostomy			2002 to 18/04/2011

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

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Asepsis	Vascular access devices			2002 to 18/04/2011

A further broad search was also run, looking for systematic reviews and RCTs on the topic of asepsis in any situation.

Search constructed by combining the columns in the following table using the AND Boolean operator

Population	Intervention / exposure	Comparison	Study filter used	Date parameters
Asepsis			Systematic reviews and RCTs (Medline and Embase only)	2002 to 18/04/2011

F.4 Economic searches

Economic searches were run in Medline and Embase by combining the hand hygiene, long term urinary catheters, vascular access devices and asepsis population search terms, and also the personal protective equipment and sharps search terms, with the economic filters. Search terms for the CRD and HEED databases are given below. Searches were run from 2002 to 18/04/2011.

Hand hygiene search terms

CRD search terms

#1	MeSH Handwashing EXPLODE 1
#2	handwash* OR hand AND wash* OR hand AND hygiene
#3	hand* NEAR clean*
#4	hand* NEAR disinfect*
#5	hand* NEAR decontaminat*
#6	hand* NEAR antisepsis
#7	hand* NEAR wash*
#8	#1 or #2 or #3 or #4 or #5 or #6 or #7

HEED search terms

1.	AX=handwash* OR 'hand hygiene'
2.	AX=clean* or disinfect* or decontaminat* or antisepsis or wash*
3.	AX=hand or hands
4.	CS=2 AND 3
5.	CS=1 OR 4

Personal protective equipment search terms

CRD search terms

#1	gown* OR apron* OR overgown* OR covergown* OR coverall*
#2	MeSH Protective Clothing EXPLODE 1 2 3
#3	glov*
#4	#1 or #2 or #3

HEED search terms

1.	AX=gown* OR apron* OR overgown* OR covergown* OR coverall*
2.	AX=glov*
3.	CS=1 OR 2

Sharps search terms

CRD search terms

#1	needlestick OR needle-stick OR needle AND stick OR accidental AND innoculation*
#2	MeSH Needlestick Injuries

#3	safe* NEAR needle* OR safe* NEAR sharp* OR safe* NEAR lancet* OR safe* NEAR cannula* OR safe* NEAR re-sheath* OR safe* NEAR resheat*
#4	needle* NEAR retract* OR needle* NEAR covered OR needle* NEAR capped OR needle* NEAR fixed OR needle* NEAR uncapped OR needle* NEAR guard* OR needle* NEAR protect* OR needle* NEAR removal
#5	needleless OR needlefree OR needle-free
#6	#1 or #2 or #3 or #4 or #5

HEED search terms

1.	AX=needlestick OR needle-stick OR 'needle stick'
2.	AX=accidental AND innoculation*
3.	AX=needleless or needlefree or needle-free
4.	AX=retract* or covered or capped or fixed or uncapped or guard* or protect* or removal
5.	AX=needle*
6.	CS=4 AND 5
7.	AX=sharp* or lancet* or cannula* or re-sheath* or resheat*
8.	AX=safe*
9.	CS=7 AND 8
10.	CS=1 OR 2 OR 3 OR 6 OR 9

Long term urinary catheter search terms

CRD search terms

#1	MeSH Urinary Catheterization
#2	urinary OR urethr* OR indwelling OR suprapubic OR bladder OR intermittent
#3	catheter*
#4	#2 and #3
#5	#1 or #4

HEED search terms

1.	AX=urinary OR urethr* OR indwelling OR suprapubic OR ureter* OR bladder OR intermittent*
2.	AX=catheter*
3.	CS=1 AND 2

Vascular access devices search terms

CRD search terms

#1	MeSH Catheters, Indwelling
#2	MeSH Catheterization, Central Venous
#3	MeSH Catheterization
#4	PICC OR PIC OR TPN OR midline OR mid-line
#5	venous OR intravenous OR vascular OR intravascular
#6	access OR device* OR catheter* OR line*
#7	#5 and #6
#8	venous-access OR intravenous-access OR vascular-access
#9	central* OR tunnel* OR non-tunnel* OR implanted
#10	catheter* OR line*
#11	#9 and #10
#12	MeSH Catheterization, Peripheral EXPLODE 1

#13	peripheral*
#14	catheter* OR line* OR cannula*
#15	#13 and #14
#16	#1 or #2 or #3 or #4 or #7 or #8 or #11 or #12 or #15

HEED search terms

1.	AX=(central* OR peripheral* OR tunneled OR tunnelled OR implanted) AND (catheter* OR line* OR cannula*)
2.	AX=catheter AND (hub* OR port* OR site*)
3.	AX=PICC OR PIC OR TPN OR midline OR mid-line
4.	AX=(venous OR intravenous OR vascular OR intravascular) AND (access OR device* OR catheter* OR line*)
5.	CS=1 OR 2 OR 3 OR 4

Appendix G: Clinical evidence tables

G.1 Standard principles

G.1.1 What information do patients, carers and healthcare personnel require to prevent healthcare associated infections in primary and community care settings?

Study	Burnett 2008 [54]
Aim	To determine whether or not patients who required assistance with personal hygiene were encouraged and provided with facilities to do so, and to gain an insight into HCW's perceptions towards patient hand hygiene.
Population	33 nurses and 22 patients (mean age 75 years) at an acute teaching hospital in Scotland.
Methods	Six observational sessions each lasting 4 hours were undertaken. Observation was conducted by two infection control nurses working in the same hospital. Survey questionnaire was completed by 33 nurses. Questionnaire contained ten structured questions. Interviews were carried out with 22 patients requiring hand hygiene assistance Study was conducted in two medical wards, two surgical wards and two orthopaedic wards. Interview schedule consisted of two questions requiring yes/no answers, five requiring Likert-type response and three open ended questions.
Themes with findings	Hand washing is effective in reducing infection: Patient interviews indicated that majority of the patients believed hand hygiene to be an important part of preventing HCAI (95%). However, 545 of patients interviewed did not think that staff viewed hand hygiene to be important. Accessibility of hand washing facilities 55% of the patients said that they had never been offered facilities to wash/clean their hands during their current time in hospital and 86% reported that they had not been offered facilities to wash/clean their hands that morning. Variation in preference for alcohol gels and hand rubs : 82% of patients felt they would like to have the use of hand wipes especially prior to mealtimes and after visiting the toilet and 9% each said that they would like to be offered alcohol hand rub and would prefer a basin of soap and water. 85% of the nurses agreed that hand wipes would be beneficial.
Limitations	The study was indirect to the review question in terms of population and setting. It used a self reported questionnaire and the results may have been over estimated. It might be subject to observer bias as participants may change their behaviour when aware of being observed. Small sample size and non-random sampling strategies may contribute to selection bias in addition to the study being conducted in an acute care setting.

Study	Curtis 2003 [89]
Aim	To pinpoint particular risk practices and to understand what motivated domestic hygiene behaviour. A secondary objective was to also develop the methodology for research into home hygiene.
Population	Mothers and children in Wirral, North-West England. Ten households recruited by word of mouth from amongst those attending two local GP clinics or via personal contact. Inclusion criteria: Households contained an infant aged below three months who had received a polio vaccine in the past two weeks, and a toddler under the age of three years
Methods	Structured observation, surface virology and microbiology, semi-structured interviews, projective interviews and a focus group discussion used to study hygiene practices of care-child couples in10 households Structured observation: Each house hold was visited by one of two observers on three separate days, with intervals of 1-15 days between visits. Observer sat for 3 hours in the lounge or kitchen while child cares were asked to carry on daily activities as normal. At each occurrence of nappy changing, the following information was noted: identity of individuals, time and location of changing, surface on which child was placed, condition of nappy (dry, wet or soiled), where the dirty nappy was placed and how it was disposed and when, how and how often hands were washed during and after nappy changing.
Themes with findings	<u>Disgust:</u> "They feel alright [after nappy changing] but I feel as if I need to go and wash them" "You just have to wash your hands after you've been to the loo" "When you've done , like the baby's nappies or whatever if it gets on your hands and you're walking down the road later, you can still smell it- even though you've washed your hands it's just...seems to have this incredible ability to keep the smell there" "During I'm preparing food-just because I don't particularly like the feel on my hands you know if you're sticky or whatever" ".whenever I've had a cigarette outside, I'll come in and...I wash my hands" " if you've been into the garden touching anything out there, always wash your hands" <u>Susceptibility to infection:</u> "if you go the loo if you have diarrhoea for example and you go to the loo and don't wash your hands and then start eating an apple or something and you would have thought you'd be more likely to get worse or something" "...eliminating some of the bacteria that are going to be around...including E.Coli, Salmonella...the big ones that everyone knows about are so hyped up that you can't help but try and counteract those risks can you-I can't" "Because, like germs and bacteria left on your hands and then you put like your fingers in your mouth you could transmit all different germs" <u>Responsibility:</u> "Just a bit frightened of more germs going about than anything because they have got no immune system really, have they, when they are under two"

Study	Curtis 2003 [89]
	"I found I washed my hands more than I would have...before I had the babies" " ..to get rid of the smell and the odours and anything that might be kind of lingering- because it's not good for him" "You seem to wash your hands more with having the baby" "Since having him I wash my hands all the time"
Limitations	This study was conducted in child-carer couples and the findings may only be indirectly applicable to the population defined in the review question. Also, small sample size and non-random sampling methods reduce the generisability of the findings. Another limitation of this study was that it assumed that that all viruses detected was excreted by the vaccinated infants in faeces, though nasopharyngeal excretion is technically possible, as is infection and excretion by other household members.

Study	Curtis 2009 (Systematic Review) [90]
Aim	To elucidate factors associated with risky hygiene behaviour and provide insights needed to develop strategies for changing hand washing behaviour.
Population	Mothers and child carers across 11 developing countries.
Methods	The review collected the results of 13 formative research studies conducted in 11 developing counties. The studies were carried out for the purposes of designing large scale or national hand washing promotion programmes or child carers in domestic settings. The studies used structured observations, focus group discussions, interviews and elicitation of information from key informants as tools for qualitative data collection. Research contractors were recruited to carry out the fieldwork in every country and they developed and pre-tested their own versions of the study instruments. Data, consisting of verbatim transcriptions, was translated into English or French and then analysed thematically to identify tractable factors that positively influenced hand washing behaviour
Themes with findings	<u>Disgust:</u> "I don't want the scent of that thing [faeces] to remain on my hands."(Ghana) "The dirty things are cough, what women have-periods, rotten items or dead items."(Kerala, India) "If they did not wash hands, when they next ate, they would be eating the microbes from their bottom" [this would be] "like eating faeces and would be disgusting" (Kyrgyzstan) "I feel very bad if I come out of the toilet and I do not wash my hands. I feel like am just smelling like toilet"(Kenya) "My hands stink after the toilet so my friends will boo at me" (Madagascar) "After eating foods you can't move with dirty hands. I have got to wash my hands with soap after eating fish or any other oily foods" (Uganda) <u>Responsibility:</u> "Because I am a nursing mother, I always feel good when I touch my child with clean hands"(Ghana) "We do everything for the health of our children. We have to bathe them, wash their hands and legs, we have to give them food, look after them when they are sick"(Kerala, India) "My children are my pride and joy. I wash my hands to protect them"(Kenya) <u>Susceptibility to infection:</u> "If I did not wash my hands I would get cholera and diarrhoea for the children, many people do it because of Cholera" (Uganda) "I wash my hands before carrying a baby so that I don't infect the child with any disease"(Ghana)
Limitations	The studies were conducted in developing country settings and therefore have limited applicability in terms of population and setting to this review question. The review itself was based on summary reports and not on original data and this may have led to filtration by report authors leading to loss of insight. Studies by themselves were unequal in design and quality. The review in based upon a conceptual framework and it is difficult to draw statistical links between brain factors and risk behaviour.

Study	Davis 2008 [93]
Aim	To investigate: surgical patients' willingness to question healthcare staff about their treatment differences between patients' willingness to ask factual versus challenging questions related to the quality and safety of their healthcare patient characteristics that could affect patients' willingness to ask safety related questions the impact of doctors' instructions on patients' willingness to ask safety related questions
Population	80 patients from four surgical wards in an inner city London teaching hospital; 101 patients were approached and 80 agreed to participate. Inclusion criteria: age above 18 years, spoke English, able and willing to give informed consent to participate in the study
Methods	Sampling was done based on convenience. Patients were recruited post-operatively over a three month period A "Patient Willingness to Ask Safety Questions Survey"(PWASQS) was developed comprising 28 questions Survey assessed patients' willingness to ask healthcare staff questions that current safety initiatives (mainly from UK and US) ask patients to ask Researcher went through all the questions with the patient Patients had to answer on a 4-point scale how willing they would be to ask each question in the PWASQS. Scores ranged from 1 to 4; the higher the score, the more willing the patient was to ask the question
Themes with findings	<u>Employment status of HCW:</u> Patients reported that they were more likely to ask nurses whether they had washed their hands [2.13±0.91 (mean score ± SD); 1.94to 2.35 (95% CI)] as compared to doctors [2.03±0.87 (mean score ± SD); 1.84to 2.24 (95% CI)] <u>Encouragement from HCW:</u> Patients reported that they were more likely to ask both nurses and doctors whether they had washed their hands if they had been instructed by a doctor to do so; Nurses [3.05±1.01 (mean score ± SD); 2.81 to 3.27(95% CI)] Doctors[3.04±0.95 (mean score ± SD); 2.81 to 3.24(95% CI)]
Limitations	Study was conducted in an acute care setting on a small sample of patients and the findings may not be generalisable to the population. Differences may exist in patients' responses and actual behaviour and conclusions drawn have to be interpreted with caution. There is no mention of piloting or validation of the questionnaire and verification of the results after analysis. As it is a cross-sectional study, no causality can be established and any effects of the strength of association may be under or over estimated.

Study	Duncan 2007 [111]
Aim	To explore patient opinion about asking healthcare professionals to wash their hands prior to a clinical procedure and to ascertain if MRSA status and access to patient information about infection control would influence anxiety about asking.
Population	224 inpatients admitted to an acute NHS Trust Hospital generating a stratified sample of MRSA and non-MRSA patients to be sampled randomly.
Methods	Semi-structured questionnaire designed for use in a descriptive survey. Questionnaire had a set of close ended questions and small number of optional open ended questions. During analysis, co-relation was investigated using Kendall's Tau-b analysis
Findings	Hand washing is effective in reducing infection: Knowledge of MRSA was measured by asking patients about whether it was possible to have MRSA and be well, how is MRSA spread and what is the most effective way to reduce the spread of MRSA. 83.4% identified that is spread predominantly from hand to hand and 99% of respondents said that hand washing was the most effective way to reduce the spread of MRSA. Perceived need for more information regarding hand hygiene: 74.7% of respondents said that they had received no information upon admission.57.4% of respondents said that there was not enough information about hand hygiene and MRSA in the hospital. Comfortable in asking HCW to wash hands when : Prior knowledge of infection/prior admissions There was a negative co-relation between number of previous hospital admissions and anxiety over asking hospital staff to wash their hands indicating patients were more anxious about asking hospital staff to wash their hands if they had fewer admissions There was a weak positive co-relation between history of MRSA infection and anxiety over asking staff to wash their hands indicating patients would be more willing to participate in program to ask health personnel to wash their hands if they had a history of MRSA infection There was a weak positive co-relation between knowledge of MRSA and anxiety over asking staff to wash their hands indicating patients felt more anxious about asking staff to wash their hands despite having knowledge of MRSA There was a strong negative co-relation between availability of patient information on hand washing and MRSA upon admission to hospital and anxiety over asking staff to wash their hands indicating that patients felt more anxious about asking staff to wash their hands if there was less information available on admission. Encouragement from HCW There was a weak negative co-relation between staff wearing a badge saying 'It's OK to ask' and anxiety over asking staff to wash their hands indicating that patients would feel slightly less anxious about asking staff to wash their hands if they wore a badge saying 'It's OK to ask'
Limitations	The study was indirect evidence in terms of population and setting to the review question. As it was a cross sectional survey, any effects noted may be over/ under estimated. Sampling was a convenience based and may have led to selection bias. The study explores patients' perceptions and any inferences regarding actual behaviour should be drawn with caution.

Study	Duncanson 2005 [113]
Aim	To explore patients opinions on being asked to participate in a campaign to improve staff compliance with hand washing and to identify factors that may influence the likelihood of patients asking staff to wash their hands
Population	200 patients about to be discharged from an acute NHS Trust agreed to participate in the survey. 150 completed both the questionnaires 970 men and 80 women. Participants had been in hospital for an average of seven days.
Methods	Descriptive survey using two questionnaires First questionnaire was developed and piloted over five month period to collect information about all factors (except individual personality) using informal focus groups, interviews and feedback from previous patients Second questionnaire was the Neuroticism Extraversion Openness five Factor Inventory (NEO FFI) and was used to explore five aspects of personality of each participant viz extraversion, agreeableness, conscientiousness, neuroticism and openness. The research protocol and questionnaires were then piloted on ten patients Survey took place before the 'cleanyourhands campaign' was launched nationally Factors investigated were previous experience while in hospital (including number of previous admissions, history of hospital acquired infection and experience of being nursed in isolation), individual characteristics and personality and feelings about asking different groups of staff to wash their hands before providing direct patient care Data was collected over a six week period. Patients could complete the questionnaires on their last day of hospitalisation or take them home Different statistical tests were used for the analysis of the data
Themes with findings	Patient participation in improving staff compliance with hand hygiene: 79% of patients felt that patients should be involved in helping healthcare staff improve hand hygiene in hospitals Patients in the younger age group (mean age 42) were most likely to ask a surgeon to wash their hands while those in the older age group were most likely not to (mean age 60) Comfortable in asking HCW to wash hands: Employment status of HCW: Student nurses, trained nurses, venepuncturists and domestics were more likely to be asked to wash their hands; Surgeons, junior doctors, physiotherapists and porters were most likely never to be asked to wash their hands Encouragement from HCW: At least 50% of participants found the idea of staff wearing badges saying it was OK, letters from their surgeon or ward manager to be encouraging to be able to ask staff to wash their hands Posters/Signs: At least 50% of patients found the idea of posters on wards telling them to ask staff or that it was OK to ask encouraging to be able to ask staff to wash their hands Similar behaviour from other patients: Approximately 65% of the patients felt that they would be encouraged to ask staff to wash their hands if they saw other patients doing the same Practical situations: 78% of patients reported wanting to be involved in helping staff improve hand hygiene when presented with practical situations such as dealing with wound dressings or invasive devices

Study	Duncanson 2005 [113]
Limitations	The study was conducted in an acute care setting on patients on the verge of discharge and therefore is indirect to the population and setting relevant to the clinical question. Also, it explores the perceptions of patients and this may be different from what patients may actually do. A small sample size and non-random methods of sampling also greatly limit the generalisability of the findings.

Study	Kaltenthaler 1996 [211]
Aim	To provide a profile of hygiene behaviours associated with diarrhoea and to explore traditional areas ideas regarding causes of diarrhoea
Population	Twelve families from two villages in north eastern rural Botswana. Families were chose to include those with young children and people from different socio-economic backgrounds.
Methods	Semi-structured observations were carried out on each family lasting from 30 minutes to three hours and activities of all family members were recorded by the researcher In-depth interviews were conducted with 12 caregivers on the third observation visit by the researcher and the Family Welfare Educator and included questions regarding hand washing behaviour and what makes hands “dirty” Seven key informant interviews were also conducted by the researcher with Family Welfare Educators, health facility nurses, traditional healer, paediatrician and regional health inspector on perceived causes , treatment and prevention of diarrhoea Two focus group discussion were held covering ideas regarding hand washing and diarrhoea Field notes from all of the above were transcribed into sets of information on index cards and then grouped into categories of related sets of information Recurring themes were identified and summarized by the researcher with assistance from the Family Welfare Educators
Themes with findings	<u>Disgust:</u> Hand washing was performed to remove contamination or “dirt” Hand washing was also done for comfort reasons , like when when hands were sticky, uncomfortable or smelly Perceived sources of dirt were human and animal faeces, clothes-washing water and dish-washing water
Limitations	The study was conducted in two villages in Botswana and is indirect in terms of population and setting to the clinical question. No information was provided on whether diarrhoea was perceived to be preventable with hand washing.

Study	Longtin 2009 [271]
Aim	To assess patients' perceptions of a patient-participation program to improve healthcare worker's compliance with hand hygiene
Population	194 patients admitted to different departments at the University of Geneva hospitals, Switzerland, a primary and tertiary health care facility. Exclusion criteria: Extremely ill patients Presence of cognitive or hearing impairment Did not speak French
Methods	Respondents were interviewed at bedside by infection control nurses and medical students trained in interviewing techniques Questionnaire consisted of 40 open- or close-ended questions Responses consisted of short answers, 5-or 10-point Likert scale rankings, or multiple choice. Interviews took approximately 20 minutes to complete Respondents were asked about their knowledge of HCAI, knowledge of hand hygiene and infection control strategies, perception of HCW compliance with hand hygiene and their beliefs on patient participation in the care process
Themes with findings	Hand washing is effective in reducing infection: Hand hygiene was identified by 39.2% of respondents to be an important preventive measure for HCAI HCW implemented hand hygiene: Two-third of patients believed that HCW should perform hand hygiene before shaking hands with a patient 84.5% reported that nurses and 66.5% thought that doctors cleanse their hands "most of the time" Patient participation in improving staff compliance with hand hygiene: 40% felt that patients should remind HCW to clean their hands and 29.5% felt that this would help prevent HCAI Patients felt that they would not feel comfortable in asking nurses (76.3%) or physicians (77.3%) to wash their hands Comfortable in asking HCW to wash hands: Encouragement from HCW: An explicit invitation from a HCW significantly increased the intention to ask a physician (from 29.9% to 77.8% of respondents; p<.001) and the intention to ask a nurse (from 34.0% to 82.5%; p<.001) to perform hand hygiene Employment status of HCW: Despite an explicit authorization, the intention to ask a physician remained lower than the intention to ask a nurse (77.8% vs 82.5%; p=.04)
Limitations	Study was conducted at a tertiary hospital and thus findings may not be applicable in other settings. Interviews were conducted by HCW and this may have influenced responses towards being more socially acceptable. The study was conducted prior to introduction of any patient participation campaigns and thus the responses may not be consistent at a later time. A convenience-based method of sampling was used and this may have led to a selection bias. There is no mention of triangulation of the analysis and a possible interpreter bias may be present.

Study	Luszczynska 2007 [276]
Aim	To evaluate the frequency of asking medical personnel about hand washing among older and younger patients with and without MRSA infection and to evaluate the role of perceived behaviour control (PBC) and other variables in predicting intention to perform MRSA error prevention behaviour.
Population	171 patients who approached Patients Association in UK or MRSA Support, a UK charity organisation providing support for those interested in or affected by MRSA. Mean age of participants was 61.89 years; All participants had been hospitalised at least once prior to data collection. Patients included both who had a diagnosis of MRSA infection (n=101) and those who did not have a diagnosis.
Methods	Questionnaire based survey reviewing MRSA protective behaviour including actually asking medical staff to wash their hands, intention to ask hospital staff to wash their hands, attitudes towards asking staff about hand washing and perceived behavioural control regarding the same. Data collected was analysed by fitting it in a model with pre specified predictors of intention and correlation between variables was observed
Themes with findings	Patient participation in improving staff compliance with hand hygiene: 61.4% of participants did not try to ask a medical personnel to wash their hands even once since their last stay in hospital 56.7% of participants had never asked medical staff to wash their hands 6 months prior to the study Comfortable in asking HCW to wash hands: Prior knowledge of infection/prior admissions: Patients with MRSA tried to ask medical personnel to wash their hands since their last stay in hospital more frequently than those without MRSA. Similarly, within 6 months prior to data collection patients with MRSA asked sometimes about hand washing, where as patients without MRSA asked about it rarely. Knowledge predicted more frequent behaviour among patients without MRSA infections (both younger and older); Covariance between intention to ask medical staff about hand washing and asking about hand washing was 0.36 ($p<0.001$) Covariance between PBC that is, perceptions of their ability to perform the behaviour and asking about hand washing was 0.29 ($p<0.001$) Covariance between knowledge and asking about hand washing was 0.06
Limitations	The study was limited by a small sample size. Data was collected only from individuals who contacted the organisations and this limits the generizability of the findings. Study also did not control for patients' education which is an important confounding factor.

Study	McGuckin 1999 [288]
Aim	To study the effect of patient hand washing education on staff compliance with handwashing
Population	441 patients in general medical-surgical wards in four community hospitals in USA with an average length of stay of 5.3 days were enrolled in the study. 276 completed telephone interviews two weeks after discharge and were included in the analysis. 165 were lost to follow up due to nursing home admissions, deaths or incorrect telephone numbers.
Methods	Prospective 6 week intervention/control study was conducted; Patients determined to be responsive (if alert and responded in a coherent manner)were approached by researchers 24 hours after admission to participate in the "Partners In Your Care" hand washing intervention program. Patients were visited by a health educator to discuss the importance of hand washing by in preventing nosocomial infections. A patient education brochure describing the who, why, how, when and where of hand washing was distributed. Patients were asked to ask health care workers who had direct contact with them "Did you wash your hands?" and were also given reminders to stick to their hospital gowns. Two weeks after discharge, all enrolled patients were contacted by a member of the team for a telephone interview.
Themes with findings	Hand washing is effective in reducing infection: Of the 276 patients contacted for interview, 262 (95%) realised that patients get infections in hospitals and knew that hand washing was important Patient participation in improving staff compliance with hand hygiene: 107 (68%) of patients responded that they were comfortable asking the health care worker whether they had washed their hands. Comfortable in asking HCW to wash hands: Prior knowledge: 157 (57%) asked health care workers whether they had washed their hands after reading brochure Employment status of HCW: Of the patients who asked, 141 (90%) asked nurses and 50 (32%) asked physicians whether they had washed their hands
Limitations	The patients may have agreed to wash their hands as they knew they were under observation (observer bias). Study was conducted among inpatients in an acute care hospital and may not be generalisable to patients accessing primary health care services. The study also suffered from a high loss to follow up and those lost to follow up may have responded differently.

Study	McLaughlin 2008 [292]
Aim	To assess the the knowledge and perception of methicillin resistant Staphylococcus aureus (MRSA) among the general public and a group of hospital visitors
Population	N: 545 Participants were approached at five different public places (shopping centres) in a hospital catchment area in Dublin, Ireland. Also hospital visitors in front hallway of the hospital were asked to participate. Inclusion criteria: >16 years of age Had sufficient language skills to complete the questionnaire
Methods	Questionnaire of 35 questions divided into four broad categories: baseline data, factors thought to be involved in transmission of MRSA, treatment of MRSA and perceived consequence of MRSA. Trained research assistants approached potential participants and asked them to complete the questionnaire. Data was collected over a three week period.
Themes with findings	Hand washing is effective in reducing infection: Majority of the groups thought that MRSA transmission could be reduced by hand washing (81.2% of public, 86.1% of visitors and 92% of those who had had MRSA). Responsibility: 92% of participants who had MRSA were worried about passing it to their families, and 94.8% of visitors and 90% of the public felt the same...
Limitations	The study was conducted at a time when MRSA was initially scrutinised by the media quite extensively and the general population had been made aware of a life threatening “bug”. The effects may not be sustainable over the years and sensitisation of the population needs to be taken into account while applying the findings.

Study	Morrison 2009 [310]
Aim	To examine perceptions of influenza and in particular the anticipated likelihood of implementing a variety of infection control behaviours in a Western culture with no recent epidemic experience to inform the development of a website-based infection control intervention to modify respiratory infection transmission within the home, in both pandemic and non-pandemic contexts.
Population	31 participants (18 women and 13 men) aged 17 to 68 years from southern England (general population). Inclusion criteria: Currently living with at least one person Ability to speak fluent English
Methods	Recruitment to the study was done using advertisements (paper and online) and snowballing techniques Purposive sampling methods were used to ensure a diverse sample Design: A total of one interview and 8 focus groups were conducted with each group containing two to six participants. Semi structured focus groups lasting between one to one and a half hours were conducted by the first author. Focus group schedule was used to guide the discussion and a pilot interview was conducted first. Participants were invited to discuss their thoughts about how colds and flu were caught and spread between people and the use of hand washing, social distancing and cough hygiene as measures to reduce the spread of infections The discussions were audio recorded and transcribed verbatim Inductive thematic analysis incorporating grounded theory techniques was used to identify recurring patterns within the data. Study enrolment ceased when saturation had been achieved Analysis included familiarisation with the data, in-vivo coding, organisation of lower level codes into potential themes and use of the coding framework to interpret data to identify key influences on participants' likely adherence to infection control measures.
Themes with findings	<u>Hand washing is effective in reducing infection:</u> Participants recognised that infections were transmitted by touching an infected person or contaminated object Positive attitudes were expressed towards hand washing and the belief that it was an effective prevention measure However, over half of the participants questioned the effectiveness of infection control measures including hand washing, believing that transmission of infection, particularly pandemics, could not be controlled. <u>Responsibility:</u> "Well yeah, obviously if you picked up a disease and you're fighting it and nearly dying you're not gonna want to pass it on to your little sister or your younger brother or your mum or anyone are you?" F6 male, age 23 "Be more aware of other people and how they might get infected by you instead of relying on other people to protect themselves from you" F9 male age 19 "It's really important to stay safe as you won't be able to care for them if you get ill"F2 female, age 24 Although participants were mainly motivated to protect the health of family and loved ones, they also expressed a wider sense of responsibility to protect the health of any 'other' in society at risk of infection

Study	Morrison 2009 [310]
	Selfish attitudes were prevalent in the context of non-pandemic influenza, suggesting that it was the responsibility of others to implement the behaviours Reminders: Many participants stated that even if they did wish to implement the infection control measures, they would most likely forget. Reminders such as hand washing timers to ensure that hands were washed for an adequate length of time, adverts, posters or campaigns to remind people would address this issue. Not many participants were aware of behaviours recommended to prevent the spread of colds and/or influenza; "No one's ever told you when, not even your doctor's told you when you get a cold you should wash your hands a lot more than you usually do" F6 male, age 23 Accessibility of hand washing facilities: Practical difficulties such as access to required facilities represented one of the most commonly cited barriers to implementation of infection control measures, including hand washing
Limitations	Sample size may not have been large enough to make generalisations. Focus group discussion yield responses from groups and individual responses may have been significantly different. Study was survey based on a hypothetical question regarding what participants would do in the event of an epidemic and actual behaviour may differ significantly.

Study	Park 2010 [348]
Aim	To assess the perceptions, motivating factors and behaviours associated with the use of hand washing to prevent H1N1 influenza transmission during the peak pandemic period in Korea
Population	N (enrolled): 11,085 students (M: 8485, F: 2600) at a public university campus in Suwon, Korea, between December 1 and 8, 2009. Inclusion criteria: Current enrolment as a student of the university Willingness to participate in the research study N (completed the questionnaire): 945 (M: 738,F: 204)
Methods	A cross-sectional survey questionnaire was used Questionnaire was designed to assess recent hand-washing behaviours, changes in hand-washing behaviours, information encountered regarding hand-washing, perceived effectiveness of hand-washing in preventing infection with H1N1 influenza, perceived severity of H1N1 influenza, perceived susceptibility to H1N1 influenza infection, and recent flu like symptoms Questionnaire was validated by piloting the questionnaire prior to the survey
Themes with findings	Hand washing is effective in reducing infection: 95.7% of male and 96.1% of female participants perceived hand-washing as an effective measure to prevent H1N1 infection. Hand-washing frequency was positively correlated with perceived effectiveness of hand-washing (p=0.002) Susceptibility to infection: 59.5% of participants rated their personal susceptibility to H1N1 influenza as “low” or “somewhat low” and hand-washing frequency was positively co-related with perceived of infection(p=0.001).
Limitations	Study was conducted during the H1N1 outbreak situation and this would have influenced attitudes and behaviour patterns during that time. Also, social and cultural patterns and attitudes to hygiene may be different in this setting which may decrease the applicability of this study to this review.

Study	Pieper 2007 [366]
Aim	To examine patients' wound care knowledge and concerns prior to discharge from an acute care hospital
Population	76 patients (17 men and 59 women) scheduled for discharge home from a large urban acute care hospital. (Mean age: 48±13). Inclusion criteria: Patient started feeling well enough to participate and showed no overt signs of altered mental status Presence of an acute or chronic wound Ability to understand and respond in English Exclusion criteria: Patients discharged to a setting other than home Patients who did not have a wound Patients who verbalized feeling ill or whose health status was poor by physical assessment
Methods	Patients meeting the study criteria were identified by advanced practice nurses on their wards Questionnaire was administered to patient by a trained research assistant after obtaining consent. Questionnaire had the following sections: demographic, wound pain, discharge concerns, beliefs about wound and their care, literacy and learning and wound care. Completion of questionnaire took approximately 45 minutes. Participants were asked who taught them about wound care in hospital and where or to who would they go for wound care information when they were home.
Findings	In the section about knowledge about wounds and their care, patients reported the following: Hand washing is effective in reducing infection: 98.7% correctly reported that hands should be washed before the dressing is changed
Limitations	Study was conducted on patients ready to be discharged after stay in the hospital and this may affect the nature of their responses due to an increased level of sensitisation/ knowledge/anxiety. A self reported questionnaire was used and responses may not reflect actual practice. Study had a small sample size.

Study	Pittet 2011[373]
Aim	To understand what acute hospitals are doing about empowering patients to ask HCWs whether they have washed their hands, to find out whether the coordinators supported the proposal to give patients a hand rub and to gauge the degree of local support for greater patient involvement
Population	530 members of the public in England (public opinion survey) and 222 inpatients in surgical/medical wards and discharge lounges in five acute hospitals in UK (inpatient survey) Inclusion criteria: Patients were conscious and willing to participate in the survey
Methods	Survey carried out by the National Patient Safety Agency (NPSA) between December 2007 and March 2008 three years after the introduction of the initial 'cleanyourhands'campaign Public opinion survey: Telephone survey; sample recruited on a national basis using random digit dialling; data was weighted to be nationally representative and included a sample of 30 Muslim respondents to enable the NPSA to ascertain any differences in attitude between religious faiths Inpatient survey: Face-to-face interviews with inpatients in medical and surgical wards and discharge lounges; questions were adapted from the public opinion survey; this survey was designed by the NPSA with support from five participating hospitals. Data from questionnaires was collated and analysed using available statistical tools and summary measures were calculated and presented as percentages.
Findings	Variation in preference for alcohol gels and hand rubs : 85% of inpatient respondents said they would feel comfortable being given a bottle a hand rub and would use it for themselves. 53% reported they would ask visitors to use it and 14% reported they would ask HCWs to use it. Reminders: 59% of inpatients said they would like to receive information on hand hygiene and the use of hand rub on arrival at hospital a d 31% indicated a preference for HCWs to tell them about it Patient participation in improving staff compliance with hand hygiene: 94% of inpatient respondents said they had not asked their nurse or doctor to clean their hands. 53% assumed that the HCWs would have already cleaned their hands and trusted them to do so. Comfortable in asking HCW to wash hands: Employment status of HCW: Around 50% of respondents were not very likely (28%) or not at all likely (23%) to ask a nurse to clean their hands. Around 57% reported the same for doctors. Respondents reported that they were more likely to ask a nurse or doctor to clean their hands if they were given a bottle of hand rub by the hospital. (Public opinion survey)
Limitations	Validation and piloting of questionnaire was not reported. Study was a cross-sectional survey and responses may differ from actual practice.

Study	Rubin 2009 [409]
Aim	To assess the associations between perceptions and anxiety about swine flu and behaviour change relating to swine flu
Population	1000 residents (general public) of England, Scotland and Wales. Inclusion criteria: 18 years or older able to speak English Had heard of swine flu
Methods	Telephonic survey using random digit dialling Interview conducted over the phone lasting 20 minutes Participants were asked nine questions about recent behaviours; six of these behaviours were avoidance behaviours and three were recommended behaviours (including hand washing with soap and water) that is increased cleaning or disinfecting of surfaces, washing hands with soap and water more often than usual and discussing with a friend or family member what to do if either person caught swine flu. Items were assessed on whether participants believed that a specific action reduced their risk of catching swine flu, with possible response options being strongly agree (scored as 5) to strongly disagree (scored as 1) Binary logistic regression analysis was used to calculate univariate associations between perception variables and whether participants had engaged in avoidance or recommended behaviours.
Themes with findings	<u>Hand washing is effective in reducing infection:</u> 56.9% of participants strongly agreed and a further 30.9% tended to agree that washing their hands reduced their risk of catching swine flu. 28.1% of participants reported actually washing their hands more than usual because of swine flu There was a significant univariate association between perceived efficacy of washing hands regularly with soap and water and actually washing hands more regularly (odds ratio 1.8. 95% CI 1.5 to 2.2) <u>Susceptibility to infection:</u> There was a strong association between perceived susceptibility to infection and adopting one of the recommended behaviours (Adjusted OR 1.5, 95% CI 1.3 to 1.8) <u>Severity of infection:</u> There was a significant association between perceived severity of infection and adopting one of the recommended behaviours (Adjusted OR 1.4, 955 CI 1.2 to 1.7)
Limitations	Study was conducted during the swine flu outbreak (May 2009) and hand washing behaviour at other times may follow different trends. It was a cross sectional survey and therefore causality cannot be established, strength of associations may have been under/over estimated

Study	Schmidt 2009 [424]
Aim	To establish the current need for enhanced hand hygiene interventions, identify barriers to their implementation and to test their acceptability and feasibility.
Population	Children (from various ethnic backgrounds) from four classes in primary schools in East London. Class grades included year 1 (one class), year 2(two classes) and year 6(one class).
Methods	Key informant interviews with head teachers, teachers and school nurses regarding current activities, perceived importance of hygiene activities for children in relation to other educational activities, motivations for implementing hygiene activities and perceived barriers and constraints to implementing them Semi structured interviews, essay questions and group discussions with children including questions on illness perception and hygiene behaviour Testing of staff and children's acceptability of three different hygiene products for organised hand hygiene in the classroom: liquid soap, alcohol based hand sanitiser (liquid and gel) Interviews with children were recorded and transcribed. Thematic analysis was conducted and grouping was done according to themes.
Themes with findings	<u>Disgust:</u> 'Cleanliness, so there's no bits on your hands and you're not muddy or dirty or anything' (Year 6 child) 'Because when you do dirty stuff like handstands you might get your hands dirty' (Year 1 child) 'After toilet'(Year 1 child) 'if you have played in the garden or touched soil..'(Year 6 child) 'After touching a bin..' (Year 6 child) <u>Susceptibility to infection:</u> 'So I don't get ill' (Year 2 child) 'Because if you don't you will get germs and you will start to be ill'(Year 1 child) 'Hygiene, you always have germs on your hands so when you eat without washing your hands all those germs go into your body' (Year 6 child) Variation in preference for alcohol gels and hand rubs : Rinse free alcohol gel was generally well received by children and teachers alike; Liquid alcohol based sanitiser was regarded as much less suitable by teachers and children because of its strong smell and the fact that it dripped on the ground
Limitations	Small sample size limits the generalisability of the findings. Behaviour and responses may have been altered due to the presence of the researchers (observer bias).

Study	Scott 2007 [426]
Aim	To determine the level of knowledge about hand hygiene and to elicit information on the barriers to good hand hygiene practices on campus
Population	4600 graduate and undergraduate students, predominantly female, living in residence halls on campus, in Boston, USA.
Methods	Online questionnaire delivered campus wide via email using an Internet survey tool. Self administered and anonymous survey. 994 survey responses received in 4 weeks and these were analysed
Themes with findings	Prevention of infection: 87% of respondents felt that hand washing was very important after touching infected skin and 60% actually washed their hands after touching infected skin 79% of respondents felt that hand washing was very important after coughing/sneezing and 195 actually washed their hands after coughing or sneezing
Limitations	Online survey with low response rate (18%). Students' education levels could be a confounding factor for the responses.

Study	Stoner 2007 [452]
Aim	To investigate specific perceptions and preferences of parents regarding hand hygiene by their child's doctor, highlighting areas that may yield to educational interventions.
Population	100 HCWs and 99 parents of children presenting to accident and emergency department of Columbus Children's hospital, Ohio, USA.
Methods	Questionnaire based study which reviewed parents' preferences regarding hand cleansers and hand hygiene practices used by doctors taking care of their children. Similar questionnaires were distributed to HCWs Responses between the two groups (HCW and parents) and within the HCW group were compared using Pearson chi-square and Fisher's exact tests
Themes with findings	Variation in preference for alcohol gels and hand rubs : 14.1% of parents felt that alcohol hand rub was a better method for cleaning hands as compared to 54.3% of parents who felt that hand washing with soap and water was a better method for cleaning hands.
Limitations	The study provides indirect evidence in terms of population and setting to this review question. It is likely that responses of the parents might have been influenced by the knowledge that the HCW were caring for their children at that point in time. The study had a small sample size and responses from self reported questionnaires may not reflect actual practice.

Study	Tanner 2011[458]
Aim	To explore patients' satisfaction with various hand hygiene products and identify the most popular one
Population	200 patients from eight wards at the Leicester Royal Infirmary. Wards included surgical, medical and orthopaedic patients. Thirty patients were unable to use the bile sink as they had no plug sockets by their bedside and therefore results were presented for the rest 170 patients. Exclusion criteria: Patients in isolation rooms Patients with cognitive impairment
Methods	Survey was first piloted with 10 patients and its initial results were included in the main findings Face-to face interviews were conducted with all the participants by a researcher at the bedside over a two month period. During interviews, patients were asked to try each product once and rate them on a numerical scale of 1 to 5 with 5 being the best. Patients were also asked which was their favourite product and asked to comment on any/all of the products. Interview questions ad a=sheets were also available in different languages (Gujarati, Hindi and Punjabi). Data was recorded on an interview sheet by the researcher The data was then entered into an Access database by a second researcher and statistical tests were carried out to determine which product achieved highest mean satisfaction rating and was preferred overall
Themes with findings	<u>Variation in preference for alcohol gels and hand rubs :</u> Alcohol foams had the highest mean satisfaction score (3.92), followed by wet cloth with antiseptic (3.76), followed by alcohol wipes (3.48), followed by a bowl of soapy water (3.28) and followed by a mobile sink (3.15) Of the people who did evaluate the mobile sinks, this shared first place as the most preferred option along with alcohol foam for Muslim and Hindu patients.
Limitations	Study reported that two of the products (alcohol wipes and mobile sink) had design flaws that limited their usability. This has an effect on the satisfaction scores and therefore results presented may be biased. Verification of findings (triangulation, cross-checking) is not reported. The study reports the use of specific products in each category (for example, Cutan Foam Hand Sanitizer for alcohol foam and Purell Sanitizing Hand wipe) and responses may be different to other products. Also, it is difficult to determine preferences on the basis of single use of a product and the results are less reliable than would have been if preferences were determined after use of products over time.

Study	Waterman 2006 [493]
Aim	To determine how comfortable hospitalized patients were in taking error prevention actions, how often they engaged in these actions and whether error prevention affected their hospitalization satisfaction.
Population	2078 adult patients discharged from 11 hospitals in the Midwest, USA. Patients were stratified by hospital and randomly selected for interviews.
Methods	Telephonic interviews were conducted with all the patients utilising an established patient satisfaction measurement system. Questionnaire was designed by patient safety researchers and staff Error prevention behaviours were divided into two sets and each patient answered questions only from one set (done to minimise respondent burden) First set included questions on asking friends and family to assist in error detection, asking doctors about medical care, asking a medication's purpose and confirming their identity; Second set included questions on asking doctors and nurses whether they had washed their hands before patient contact and helping mark a surgical site (1044 patients answered this questionnaire) In the analysis, association between performing each error prevention behaviour and age, race, gender, length of stay, payer type, emergency room admission, intensive care unit stay and comfort with error prevention was evaluated.
Themes with findings	<u>Patient participation in improving staff compliance with hand hygiene:</u> 46% of patients were very comfortable asking medical professionals about hand washing as opposed to 89% who were very comfortable asking general medical questions When hospitalised, only 5% of patients had asked about hand washing On multivariate analysis, very comfortable patients were found to be more likely to ask staff whether they had washed their hands as compared patient with other comfort levels [6.3 (1.4 to 28.2)]
Limitations	Study only took into account patient reports after discharge and did not use chart reviews or incident forms to confirm if errors had actually occurred (Reporting bias may be present). Patients may still have been on follow and this may have influenced responses. Selection of patients to receive either of the two questionnaires in unclear.

Study	Yardley 2011[522,522]
Aim	To test the assumption that hand washing would be viewed as the most feasible preventive behaviour and specific beliefs about hand washing identified from literature search would be related to hand washing intentions and behaviour.
Population	The study was conducted in the University of Southampton, UK. Interviews: 13 participants (three men and ten women) were interviewed in their own home or at the university. Questionnaire study: 176 people completed a survey; 129 (51 men and 75 women) were included in the analysis; 47 were excluded as failed to complete measures of intention for all four behaviours.
Methods	Interviews: Participants were shown paper based materials and were asked to think aloud and give their reactions to each page about proposed website materials and what would be the good and bad aspects of following the intervention advice. An inductive thematic analysis was used to categorize the data. Data was coded using manifest coding categories that were grounded in the text. The interpretation of this coded data included consideration of whether statements were made spontaneously or in response to paper based or web based intervention materials. Questionnaire based study: Questions regarding each behaviour were prefaced by a precise definition of the behaviour. The questions related to frequency of the behaviour and behavioural beliefs. Further, perceived behaviour control was assessed by two items, measuring self-efficacy and perceived control.
Themes with findings	<u>Hand washing is effective in reducing infection:</u> Respondents were unaware of the potential of hand washing in reducing their personal risk of colds/flu and were sceptical about its effectiveness. <u>Disgust:</u> Respondents reported that hand washing was learned in childhood and prompted by dirt, toilets, preparing food and getting dirty <u>Responsibility:</u> Respondents reported that hand washing was also prompted by the sense of wanting to protect others. <u>Variation in preference for alcohol gels and hand rubs :</u> Respondents felt that hand gels were useful outside the home; they were convenient, however, they were not a replacement for hand washing as it would not remove dirt.
Limitations	Validation and piloting of questionnaires not reported. No mention of verification of results or triangulation. Small sample size for interviews. Questionnaire based study which may not accurately depict actual practice.

G.2 Hand decontamination

G.2.1 When to wash hands

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Allegranzi 2010 [14] Study design: Cohort (prospective, before and after comparison) Setting: University Hospital, Bamko, Mali Duration of follow-up: 14 months	Population: Healthcare workers in University Hospital, Bamko, Mali Inclusion criteria: The strategy was implemented in 13 wards Exclusion criteria: Participants: 224 healthcare workers	Implementation of the WHO hand hygiene improvement strategy. The intervention included educational posters (hand hygiene indications, technique), 3-hour education sessions and key educational messages promoting hand rubbing as the gold standard for HH and the '5 moments for hand hygiene' concept. The WHO knowledge questionnaire was administered before and after each session. All participating HCW were given a 100ml pocket sized alcohol rub and trained how to use it. Group 1: Before guideline 4 months of preparation followed by 4 months of baseline evaluation. Group 2: After guideline 6 months of implementation and 2 months of follow up evaluation. As stated above, with the introduction of alcohol rub	Hand hygienedecontamination compliance Overall	Group 1: 155/1932 (8.0%) Group 2: 358/1639 (21.8%) p value: p < 0.001	Funding: WHO, University of Geneva Hospitals, and the Swiss Society of Public Health Administration and Hospital Pharmacists. Limitations: Low income African country, therefore applicability issues to UK NHS. Study stated that HCAI was not intended as an outcome due to lack of power from the small sample size. Additional outcomes: Hand decontamination compliance split by professional category, medical specialty. HCW perception of strategy. Other HCAIs were
			Hand decontamination compliance	Before patient contact Group 1: 23/503 (5.2%) Group 2: 91/439 (20.7%) p value: p < 0.001 Before aseptic task Group 1: 11/425 (2.6%) Group 2: 34/230 (14.8%) p value: p < 0.001 After body fluid exposure risk Group 1: 34/215 (15.8%) Group 2: 94/229 (12.6%) p value: p < 0.001 After patient contact Group 1: 91/559 (16.3%) Group 2: 201/505 (39.8%) p value: p < 0.001 After contact with patient surroundings Group 1: 15/457 (3.3%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		(locally produced, as per WHO instructions)		Group 2: 15/410 (3.7%) p value: 0.831	surgical site infections and pneumonia.
			Healthcare associated infections Overall	Group 1: 25/134 (18.7%) Group 2: 22/144 (15.3%) p value: 0.453	
			Healthcare associated infections	Urinary tract infections Group1: 8 Group 2: 10 Primary bloodstream infections Group1: 3 Group 2: 1	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Aragon 2005 [22] Study design: Cohort (retrospective comparison) Setting: USA Duration of follow-up: 1 year	Population: Vascular and thoracic surgery unit Inclusion criteria: All healthcare workers Exclusion criteria: None stated	Aim is to increase knowledge and importance of infection prevention, increase HCW compliance with hand decontamination and isolation procedures, increase the use of alcohol-based products for hand decontamination. Implementing CDC practice guideline (2002) Performance improvement plan, surveillance of at least 30 observation opportunities (one third isolation precaution). House-wide education on planned topics (hand decontamination, isolation precautions, patient education, preventing antibiotic resistant infections). These sessions were adapted from CDC material (www.cdc.gov/handhygiene/) Posters placed on individual units (monthly change outs). Measurement of alcohol foam usage hospital wide. Measurement of rate of hospital acquired infections with antibiotic resistant organisms. Group1: Before guideline Group 2: After guideline	Hand decontamination compliance, before patient care (via surveillance Q. Hand decontamination before interacting with the patient/ environment. Yes/No)	Group 1: 761 (30%) Group 2: 6 months: 730 (36%) 1 year: 696 (41%) p value: <0.05	Funding: Not stated Limitations: Unclear as to the exact population of patients and HCW were involved in the study. Limited figures given at baseline e.g. numbers of infections. Additional outcomes: Compliance with gowns, masks and gloves, use of alcohol foam soap (which increases at 6 months them dips at 1 year). Notes: Hand decontamination – hand washing with antibacterial soap and water for no less than 15 seconds or use of sufficient alcohol foam; Interacting with the patients' environment – enters room and touches anything in the room, including the patient.
			Hand decontamination compliance, after patient care (via surveillance Q. Hand decontamination after interacting with the patient/ environment. Yes/No)	Group 1: 784 (71%) Group 2: 6 months: 732 (75%) 1 year: 707 (74%) p value: <0.05	
			Nosocomial MRSA	Group 2: 6 months: -17% 1 year: -4%	
			Nosocomial VRE (vancomycin-resistant enterococcus)	Group 2: 6 months: -13% 1 year: +12.5%	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Larson 2007 [252] Study design: Cohort (retrospective comparison) Setting: ICUs from 40 hospitals, USA Duration of follow-up: 2 years (1 year prior to implementation and 1 year after)	Population: Hospitals that were members of the National Nosocomial Infections Surveillance (NNIS) System. Inclusion criteria: Being a NNIS hospital or using NNIS methods and definitions for at least 3 years prior to the study, providing HAI (hospital acquired infection) data from 1 or more intensive care units (ICU), and not using alcohol products for hand decontamination prior to publication of the hand decontamination guideline Exclusion criteria: 40 hospitals were recruited via letter and email. Mean of 417 active beds, 10% had 100 – 199 beds, 40% had 200 – 399 beds and 50% having ≥500 beds.	Site visits were made to each hospital, beginning 1 year following release of the guideline (CDC guideline, 2002). Prior to this each hospital initiated their educational and other efforts to implement the guideline. During the 2 day visit the study project director collected information from the director of the infection control department regarding changes in hand decontamination policies and procedures before and after publication of the guideline; obtained documentation regarding staff education, infection control policies and procedures, product usage, and multidisciplinary meetings regarding rates of HAIs within the ICUs studied. The project director also made rounds in one or more ICUs in each hospital to record the proportion of ICU rooms and areas in which alcohol hand decontamination products were available, to directly observe staff and administer a survey regarding hand decontamination awareness. Group1: Before guideline Group 2: After guideline	Central line associated blood stream infection (rates per 1000 device days)	Group 1: 5.54 Group 2: 4.76 p value: <0.001	Funding: Supported by The National Institutes of Health, National Institute of Nursing Research, Impact of hand decontamination guideline on infection costs. Limitations: Hand decontamination compliance not given before guideline implementation. Survey of hand decontamination compliance, rather than direct observation. Additional outcomes: Staff awareness of the guideline, guideline implementation score (scale of 0-12 with a median of 10.5 achieved), ventilator associated pneumonia, surgical site infection.
			Catheter associated urinary tract infection (rates per 1000 device days)	Group 1: 2.90 Group 2: 3.02 p value: .033	
			Hand decontamination compliance	Group 1: Group 2: 56.6% No data given pre guideline implementation.	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rosenthal 2005 [408] Study design: Cohort (prospective, before and after comparison) Setting: Intensive care units of a tertiary care hospital, Argentina Duration of follow-up: 21 months	Population: The study was conducted in 2 ICUs of a private, 180-bed tertiary care teaching hospital in Buenos Aires. Inclusion criteria: The infection control team composed of a medical doctor, an infection control nurse, and personnel support. Handwashing facilities are available, with 3 sinks in each ICU with 4% chlorhexidine handwash dispensers and paper towels. Exclusion criteria: None stated	A comprehensive infection control manual was distributed to HCWs. The Association for Professionals in Infection Control (APIC) hand hygiene guideline was used as an educational tool for this study Interventions to improve hand decontamination compliance were educational monthly meetings, posters, focussed education of all HCWs, educational group sessions once a week. Each participant was given was given an infection control manual and the APIC guideline was used as an educational tool to reinforce classroom teaching. Feedback was frequently given regarding hand decontamination and infection rates. Group 1: Before guideline Baseline handwashing compliance, over 4 months. Group 2: After guideline Intervention period, 17 months	Hand decontamination compliance (collected by a trained infection control practitioner; who covertly observed handwashing technique of HCW at random times, including all shifts, for 30 minute intervals during each phase of the study.)	Group 1: 268/1160 (23.1%) Group 2: 2056/3187 (64.5%) p value: <0.0001	Funding: No external funding was provided. Limitations: Authors note that other CVC and urinary catheter specific infection control interventions were also being conducted simultaneously. Additional outcomes: Ventilator associated pneumonia. Hand hygiene compliance also split by male/female HCW, job role, and time of day. CVC blood stream infections, catheter associated UTI. Notes: Attendance to educational classes was voluntary, supported by the administrator, and monitored.
			Nosocomial infections per 1000 bed days (Nosocomial infections were identified by a trained infection control nurse in the ICUs according to the adapted standard definitions of CDC.)	Group 1: 47.55 Group 2: 27.93 p value: 0.0001	

G.2.2 Cleaning preparation

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Girou 2002[154] Study design: RCT Setting: Intensive care, France Duration of follow-up: Divided into sessions of 2-3h.	Population: Healthcare workers Inclusion criteria: Healthcare workers Exclusion criteria: Patients assigned to the hand rubbing group whose hands became visibly soiled (such as with body fluids). They then had to wash their hands with a standard antiseptic soap, and the session was ended. All patients N: 23 Drop outs: Group 1 N: 11 Age (mean): No. patient care activities: 55 No. (%) activities when gloves were worn: 46 (83) Proportion compliance with hand decontamination: 64	All participants had been previously instructed in the use of alcohol based solution when the hospital-wide handrubbing policy was launched. A written protocol was available in each unit and no additional information was provided to participants before the study started. Patient care activities were monitored during daily sessions of 2-3 hours until a predetermined number of eligible activities had been performed. One session comprised 5 patient care activities that required hand decontamination before and after (direct contact with the skin of a patient before invasive care, after interruption of care, and after contact with any part of the patient that was colonised with multiresistant bacteria), which corresponded to 10 hand samplings. Group 1 Hand washing with medicated soap (chlorhexidine gluconate 4%; Hibiscrub, Zeneca Pharma.)	Median reduction bacterial contamination (imprint of finger prints and palm from dominant hand onto agar plates that contained neutralisers, incubated and CFUs counted. >300 CFUs were considered confluent)	Group1: 58% (-58-74) Group 2: 83% (78-92) p value: 0.012	Funding: Bode SA, Hamberg, Germany. Limitations: Finger print technique rather than glove juice technique, which recover bacterial burden for whole hand. Additional outcomes: (list additional outcomes reported in paper but not recorded in this table)
			Bacterial counts CFUs, mean (SD)	Before Group1: 232 (331) Group 2: 271 (372) After Group1: 69 (106) Group 2: 35 (59)	
			Median % reduction (IQR)	Group1: 73 (25-93) Group 2: 86 (70-96)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 2 N: 12 No. patient care activities: 59 No (%) activities when gloves were worn: 51 (86) Proportion compliance with hand decontamination: 71	Group 2 Hand rubbing with a waterless alcohol based solution (45% 2-propanol, 30% 1-propanol, 0.2% mecetronium ethyl sulphate, average 3-5 ml; Sterilium, Bode Chemie, Hamberg, Germany)			

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Larson 2001[250] Study design: RCT Setting: Critical care units, USA Duration of follow-up: 4 weeks	Population: 2 critical care units (medical and surgical) in a metropolitan academic health centre in Manhattan, USA. Staff members (physicians, nurses, housekeepers, respiratory therapists) working full time in an ICU. Inclusion criteria: Working full time (>30hrs/wk) in the medical or surgical ICU of a large medical centre in northern Manhattan, were aged 18-65, were free from known allergies to study products, were not currently receiving topical or	Group 1 CHG 2% chlorhexidine gluconate containing traditional antiseptic wash (Foam Care, Ballard, Draper, UT) Group 2 ALC Waterless handrub containing 61% ethanol with emollients (Avagard, 3M Health Care, St Paul, MN) Reliability and validity of diary recordings were assessed by daily visits to participants on each shift as unexpected	Frequency of hand washing (from diary of recording, handwashes per shift) Group 2 only washed their hands once soiled.	Group 1: 16.7 (9.4) Group 2: 6.1 (10.2) p value: 0.001	Funding: Supported (in part) by 3M Healthcare. Limitations: Significant difference between CFUs at Baseline (higher for ALC) 5.03 compared to 4.42 p = 0.01 Additional outcomes: Assessment of skin condition, visual skin scaling, hand skin assessment form, participant preference)
			ALC applications/shift (from diary of recordings)	Group 1: NA Group 2: 17.7 (9.8) p value: N/A	
			Log 10 CFU difference from baseline (paired t test)	4 weeks Group1: +0.24 p = 0.18 Group 2: -0.31p = 0.12 2 weeks Group1: +0.09 p = 0.59 Group 2: -0.46 p = 0.04	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	systemic steroids or antibiotics, and had no diagnosed current dermatologic conditions such a psoriasis. If subjects had a latex allergy but refrained from using latex gloves during the study they were eligible. <u>Exclusion criteria:</u> See above All patients N: 50 Drop outs: 2 Group 1 N: 24 Age (mean): 40.6 (6.95) Group 2 N: 26 Age (mean): 40.5 (7.28)	intervals, including random inspection of diary cards in progress. Hands were sampled using the glove juice method.	Log 10 CFU (mean, SD) (analysis of covariance)	4 weeks Group1: 4.64 (0.83) Group 2: 4.72 (0.97) p = 0.4 2 weeks Group1: 4.5 (0.78) Group 2: 4.59 (0.97) p = 0.2	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lucet 2002[274] Study design: RCT – crossover design Setting: 7 wards of the Bichat-Claude Bernard hospital, France Duration of follow-up: 1 week	Population: Two medical ICUs, surgical ICU, cardiac surgical ICU, surgical recovery unit, two medical units. Inclusion criteria: 5-7 volunteers from each unit were asked to participate (at least one doctor, nurse assistant and two nurses in each service). Exclusion criteria: N/R All patients N: 43 Male/female: 14/29 Mean age: 35.5 All HCWs performed each hand decontamination procedure.	Each volunteer performed 6 hand decontamination techniques in random order immediately after a healthcare procedure. The hand decontamination technique was standardised in terms of volume of product used, method for drying hands with a towel and absence of hand recontamination after drying. Group 1 Handwashing with unmedicated soap (10 or 30 seconds) Group 2 Handwashing with antiseptic soap (Hibiscrub or Betadine) (10 , 30 or 60 seconds) Group 3 Handrubbing with an alcohol based disinfectant (Sterilium) containing 2-propanol 45%, 1-propanol 30%,	Log 10 CFU (5 finger tips of dominant hand pressed on a trypticase-soy agar for 15s). Before. Log 10 CFU (5 finger tips of dominant hand pressed on a trypticase-soy agar for 15s). After	Group 1: 1.40 ±0.70 Group 2: 1.46 ±0.64 Group 3: 1.53 ±0.74 Group 1: 0.89 ±0.54 Group 2: 0.33 ±0.45 Group 3: 0.13 ±0.22 Reduction = statistically significant for all hand decontamination procedures	Funding: This study was supported by a grant from Rivadis (Thours, France) and Bode Chemie (Hamburg, Germany). Limitations: Crossover design Additional outcomes: Notes Also report Handwashing with unmedicated soap (for 10 seconds) and handwashing with antiseptic soap for 10 and 60 seconds.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Winnefeld 2000[507] Study design: RCT Setting: 12 medical and 4 surgical departments, Marseille, France Duration of follow-up: 8 days	Population: Nurses and nursing assistants Inclusion criteria: Nurses and nursing assistants in 12 medical and 4 surgical departments, Marseille, France. Exclusion criteria: None stated. All patients N: 52 Age (mean): Male/female: 2/49 Drop outs: 1 Group 1 N: 26 Age (mean): Drop outs: Mean no. of daily hand decontamination procedures: 10.11± 3.44 Group 2 N: 25 Age (mean): Drop outs: Mean no. of daily hand decontamination procedures:	The type of washing facilities available to staff were the same in every department. The 2 agents were used according to their standard practice and the instructions they regularly received in their continuing education. Group 1 Alcohol-based antiseptic hand rinse (Sterilium, Rivadis, Thouars, France, containing 2-propanol 45%, 1-propanol 30%, ethylhexadecyl dimethylammonium ethyl sulphate 0.2%, moisturizers and degreasers). 3 – 5ml of Sterilium is spread on both hands (covering all surfaces) and allowed to dry on the skin without rinsing. Group 2 Hand wash with a non-antiseptic soap (Savodoux, Paragerm, Carros, France, containing glycerine, carbamide, TEA lauryl sulphate, cocobetaine,	Colony forming units (CFU) (Sterile bag technique, Larson) Mean log change	Group1: -0.342 Group 2: +0.122 p value: 0.004	Funding: Not stated Limitations: Additional outcomes: Skin assessment (Larson score, Sauermann score, skin sensation). Notes:

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	10.24 ±4.47	cocamide DEA, allantoin, perfume and CI45410) Hands should be rubbed together for at least 10 s, rinsed under a stream of water, and then dried with a paper towel.			

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Zaragoza 1999[528] Study design: RCT – crossover design Setting: University of	Population: 4 randomly selected wards (2 medical and 2 surgical) and 3 intensive care units. Inclusion criteria: Eligible HCWs included all permanent and temporary faculty, house staff physicians, nurses and other HCWs). Exclusion criteria:	Group 1 regular hand washing with liquid soap. Group 2 Alcohol-based antiseptic hand rinse (Sterilium) containing 2-propanol 45%, 1-propanol 30%, ethylhexadecyl dimethylammonium ethyl sulphate 0.2%, moisturizers and	Mean colony forming units (CFU) (Hand printing onto blood-agar plates)	Before handwashing procedure on 1st study day Group 1: 82 (±75) Group 2: 75 (±39) p value: 0.562 Immediately after handwashing procedure Group 1: 42 (±39) Group 2: 9(±11) p value: <0.0001	Funding: Partially supported by a research grant from Beiersdorf SA Limitations: Small sample size, crossover design. Additional outcomes: Additional sample taken at 10 to 30 mins after handwashing,

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Barcelona Hospital Clinic, 850 bed tertiary care referral hospital. <u>Duration of follow-up:</u> 15 days	None stated. All patients – paired data used N: 43 Age (mean): N/R Male/female: N/R Drop outs: 7 excluded from final analysis because they were only available for one of the procedures evaluated.	degreasers). The protocol for alcoholic solution use includes directions for handwashing (soap and water) before the use of alcoholic solution whenever there is visible dirtiness. All HCWs were instructed in the use the alcoholic solution by personal training at the bedside (research nurse), and a written protocol was available at each unit.	Percentage reduction in CFU count	Group 1: 49.6 p value: 0.002 Group 2: 88.2 p value: <0.0001	while HCW was performing regular tasks in the ward or ICU. Notes:

G.2.3 Bare below the elbow

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Farrington 2010[129] Study design: RCT Setting: Cornwall UK Duration of follow-up: NA	Population group: Doctors and medical students Inclusion & exclusion criteria: Not reported All population N: 157 Age (mean): Not reported Drop outs: 8 did not take part: 4 declined to participate, 4 on annual leave Group 1 N: Not reported Group 2 N: Not reported No other information about participants reported, except that the participants included doctors and medical students were from a range of specialities and seniority. Paper reported that "there were no significant differences in baseline demographics" between the two comparison groups	Group 1 Bare below the elbows group No sleeves, watches or hand jewellery below the elbows, except a simple wedding band Group 2 Non bare below the elbows groups Using a white coat, with the sleeves tailored to the level of the carpometacaral joint of the thumb for each participant. Allowed to wear hand/wrist jewellery if this is reflective of the participants usual clinical wear before the BBE policy Hand washing technique for all participants: Participants were asked to wash hands with an alcohol based preparation that fluoresced under UV light. To reflect everyday clinical practice, there were no limitations on the amount of preparation applied, time spent or technique used by participants. Areas not fluorescing under the UV light (and therefore not covered by preparation) were recorded	Compliance: Percentage of the areas of the hands (wrist plus palm) missed	Group 1: 9.3 ± 9.2 Group 2: 11.1 ± 7.2 *Mean difference: -1.80 (95% CI: -4.46, 0.86) p value: 0.18	Funding: None Limitations: No information about randomisation allocation and concealment The participants were observed, and this could have changed their performance (Hawthorne effect) Unclear reporting – number of patient rescruited/analysed in each arm not reported Only doctors and medical students were involved, no other HCP Notes: Personal correspondence to authors, N=73 in the BBE group, 76 in the control group *Mean differences and P values calculated by NCGC using Review Manager 5.0, based on the number of participants provided by the authors.
			Compliance: Percentage of the areas of the wrists missed	Group 1: 38.9±38.7 Group 2: 52.8 ±27.9 *Mean difference: 13.9 (95% CI 24.77 to - 3.03) p value: 0.01	
			Compliance: Percentage of the areas of the palms missed	Group 1: 7.2± 7.1 Group 2: 8.2±6.4 *Mean difference: -1.00 [-3.17, 1.17] p value: 0.37	
			Colony forming units (CFUs)	Not reported	
			Cross infection of C. *Difficille*	Not reported	
			Removal of physical contamination (bodily fluids and dirt)	Not reported	
			Removal of transient organisms	Not reported	
			Cross infection of MRSA	Not reported	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		onto standard hand diagrams, using a previously validated technology.			

G.3 PPE

G.3.1 Gloves

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Murray 2001[312] Study design: Crossover trial Setting: UK Duration of follow-up: Not stated (during 1999)	Patient group: Dentists in general practice Inclusion criteria: Dentists in general practice who were members of the PREP panel, a group of General Dental Practitioners who undertake research projects within their dental practice. Exclusion criteria: Not stated. All N: 5 Group 1 N: 5 (1000 gloves used) Group 2 N: 5 (1020 gloves used)	Each dentist received ~ 400 gloves of the correct size, 200 latex and 200 nitrile. Participants were asked to wear one pair of gloves per patient on successive patients unless the patient's medical history precluded the wearing of latex gloves. Following treatment, their gloved hands were washed using a solution of Hibiscrub (ICI Pharmaceuticals, Macclesfield, Cheshire), the gloves were removed and placed in a labelled bag. Group 1 Non-powered latex gloves (Dermaclean: Ansell UK, London) Group 2	Punctures (Water inflation method) Length of time worn (mins)	Group 1: 513 Group 2: 157 Group 1: 9739 Group 2: 9098	Funding: Not stated Limitations: No randomisation, allocation or concealment Additional outcomes: Glove time worn and puncture rate by operator and glove type. Position of punctures. Notes: All dentists were right handed.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		Non-powdered nitrile gloves (Nitratex: Ansell UK, London)			

G.3.2 Aprons and gowns

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Callaghan 2002 [57] Study design: Comparative Study (not randomised) Setting: 2 UK hospital wards treating immunocompromised patients (renal dialysis and haematology) Duration of follow-up: To end of shift	Patient group: Nurses working in 2 renal dialysis and haematology hospital wards. Inclusion criteria: None stated Exclusion criteria: None stated All participants No information is provided about the number of staff involved, the comparability of the tasks they were undertaking and how many patients were in each ward.	Group 1 Nurses not wearing plastic aprons for any activity Group 2 Nurses routinely wearing plastic aprons.	Uniform contamination: Mean colony count	Group 1: 44.80- Group 2: 59.40	Funding: No funding sources Limitations: Poorly reported method in paper Observational study and so open to bias. Little information provided about baseline characteristics of two test settings. Healthcare workers knew they were being observed and so this may have influenced results Additional outcomes: Colony count on aprons at beginning, middle and end of shift. Self reported uniform laundering information.
			Apron contamination: Mean colony count	Group 1: N/A Group 2: 24.70	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
					Notes: Reported in CG02

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Gaspard 2009 [143] Study design: Observational Study Setting: 3 long term care facilities in France Duration of follow-up: To end of shift	Patient group: Nurses and care assistants working in 3 long term care facilities. Inclusion criteria: None stated Exclusion criteria: None stated All patients N: Age (mean): Drop outs: Group 1 N: Age (mean): Drop outs: Group 2 N: Age (mean): Drop outs:	Group 1 Care assistants not wearing plastic aprons for any activity Group 2 Care assistants wearing plastic aprons for washing and changing Group 3 Care assistants wearing plastic aprons for washing, changing and meal assistance. Group 4 Nurses not wearing plastic aprons for any activity Group 5 Nurses wearing plastic aprons for dressing	'Total compliance' with indications for plastic apron use:	Group1: - Group 2: 35/43 (81.4%) Group 3: 76/80 (95.0%) Group 4: - Group 5: 13/22 (59.1%) Group 6: 10/20 (50.0%)	Funding: No funding sources Limitations: Poorly reported method in paper Observational study and so open to bias. Results are presented by care facility Healthcare workers knew they were being observed and so this may have influenced results Additional outcomes: Number of care assistants and nurses changing their uniform at the start of the work shift. Notes: Paper also reports the number of MRSA positive
			MRSA positive clothing at the 'waist zone'.	Group1: 5/16 (31.2%) Group 2: 15/43 (34.9%) Group 3: 7/80 (8.7%) Group 4: 7/16 (43.7%) Group 5: 7/22 (31.8%) Group 6: 2/20 (10.0%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		Group 6 Nurses wearing plastic aprons for dressing and biological sampling.			clothing around pockets relating to part of the trial looking at education about pocket contents. Results are not presented here.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Srinivasan 2002 [447] Study design: Observational Study Setting: Medical intensive care unit in US Duration of follow-up: Until discharge or acquisition of Vancomycin Resistant	Patient group: Patients without VRE on admission to ICU Inclusion criteria: All admissions to the MICU whose admission perirectal culture did not grow VRE, but who then had a subsequent perirectal culture that did grow VRE.. Exclusion criteria: Patients whose admission perirectal culture did not grow VRE and who did not have a follow-up culture. Patients who had no perirectal cultures performed. All patients N: 100 Group 1 N: 49 Age (mean): 54.6 ± 16.2 Male (%): 51.0 Caucasian (%): 51.0 Drop outs: No data provided	Group 1 Isolation procedure included wearing gowns and gloves. (01/08/98 – 31/10/98) Group 2 Isolation procedure included wearing gloves only. Gowns were only worn when indicated by universal precaution guidelines or hospital policy. (01/11/98 – 31/01/99)	VRE acquisition: (patients with negative cultures on admission but with a positive culture during stay)	Group1: 11/49 (22%) Group 2: 21/51 (41%) Relative risk*: 0.414 95% CI*: 0.175 – 0.980 p value*: 0.055	Funding: No funding sources mentioned Limitations: No discussion of any other changes occurring over time period of study which may have influenced results. Study conducted in ICU, not primary or community care Healthcare workers may have influenced results as they knew they were being observed. Cluster design may have overestimated effect.
			Acquisition Rate (number of incidence cases per 100 patient-days at risk):	Group1: 1.8 Group 2: 3.78 Incidence rate ratios: 0.52 95% CI: 0.27 – 1.05 p value: 0.05	
			VRE acquisition (hazard ratio calculated using a multivariate proportional hazards model adjusting for length of stay).	Hazard ratio: 2.5 95% CI: 1.2 – 5.3 p value: 0.02	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Enterococci (VRE)	Group 2 N: 51 Age (mean): 55.0 ± 15.1 Male (%): 62.7 Caucasian (%): 47.1 Drop outs: No data provided				Additional outcomes: Colonisation pressure Notes: *Calculated by the NCGC team.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Puzniak 2002[387] Study design: Comparative cohort study Setting: Medical intensive care unit in US Duration of follow-up: Until patient discharge from ICU	Patient group: Patients without VRE on admission to ICU Inclusion criteria: none stated Exclusion criteria: If duration of stay <24 hr. All patients N: 2631 Age (mean): Drop outs: 748 excluded for <24hr stay 185 patients were colonised with VRE at admission and excluded from acquisition rate calculations. 3 patients excluded due to no discharge cultures Group 1 – First gown period	Group 1 Isolation procedure included wearing gowns and gloves. (01/07/97 – 30/06/98) Group 2 Isolation procedure included wearing gloves only (01/07/97 – 30/06/98) Group 3 As per Group 1 (01/07/99 – 31/06/99)	VRE acquisition rate (per 1000 MICU-days)	Group1 and 3(combined): 9.0 Group 2: 19.6	Funding: No funding sources mentioned. Limitations: Housekeeping practices were altered during the study period (May 1998) First 18months of study another intervention was tested in MICU to assess the effect of the scheduled rotation of preferred agents active against gram negative bacteria on BRE acquisition. Study conducted in ICU, not primary or community care
			Unadjusted protective effect of gown use relative to no gown use	Relative risk: 0.44 95% CI: 0.31-0.63	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	(01/07/97 – 30/06/98) N: 727 Age (mean): 58.6 ± 17.8 VRE on admission: 52/779 (6.6%) Group 2 – No gown period (01/07/97 – 30/06/98) N: 622 Age (mean): 60.4 ± 17.8 VRE on admission: 87/709 (12.2%) Group 3 – Second gown period (01/07/99 – 31/06/99) N: 335 Age (mean): 58.0 ± 17.8 VRE on admission: 46/381 (12.0%)				Healthcare workers may have influenced results as they knew they were being observed. Cluster design may have overestimated effect. <u>Additional outcomes:</u> Selected compliance results <u>Notes:</u> Authors noted better compliance with a majority of the infection control procedures during the gown period.

G.4 Sharps

G.4.1 IV cannulae

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Asai 2002 [24] Study design: RCT Setting: Matsue Red Cross Hospital, Shimane, Japan Duration of follow-up: Not stated	Patient group: Patients scheduled for elective surgery Inclusion criteria: IV cannulation of patients scheduled for elective surgery Exclusion criteria: Patients were not studied if they had blood borne infection or bleeding disorder, had any pathology of the wrist, were of ASA physical status 4 or greater, or suffered from insulin dependent diabetes mellitus. All patients N: Intravenous cannulation =150 Intra-arterial cannulation = 150 Age (range): 18-85 years Group 1 N: 100 (50 IV, 50 intra arterial) Age (mean): A: 60 (22-85) B: 62 (23-85) Group 2 N: 100 (50 IV, 50 intra arterial)	Group 1 Safeguarded needles (Insyte AutoGuard; Becton Dickinson. Insyte autoguard – needle can be retracted into the safety barrel before removal of the needle (push button). Group 2 Protective Acuvance; Johnson and Johnson). Protective Acuvance consists of 2 needles, one inside the other, when withdrawn the tip of the needle is blunted. Group 3 Conventional catheter needle (Insyte; Becton Dickinson) A) Conducted for	Ease of insertion (10 point VAS – easy to difficult)	A) IV cannulation Group 1: 1.3 (1.0, 1.6) Group 2: 1.2 (0.9, 1.6) Group 3: 0.8 (0.6, 1.0) p value: p<0.005 (3 vs 1, 3 vs 2) B) Intra-arterial cannulation Group 1: 2.8 (2.0, 3.3) Group 2: 1.9 (1.5, 2.2) Group 3: 1.0 (0.7, 1.2) p value: p<0.001 (3 vs 1, p<0.005 3 vs 2)	Funding: Japan Becton Dickinson for supplying Insyte and Insyte AutoGuard needles and Johnson and Johnson Medical for supplying Protective Acuvance needles. Limitations: Hospital setting. Lack of investigator and patient blinding. Unclear randomisation and allocation concealment. Additional outcomes: Success rate and difficulties of insertion. Blood contamination (site e.g. researcher, assistant, patient), bloodstains. Problems with backflow of blood during attempts of catheterisation. Notes: Main reasons for difficulty were noted that for the Acuvance needle,
			Ease of handling needle (10 point VAS – safe to dangerous)	A) IV cannulation Group 1: 0.6 (0.5, 0.8) Group 2: 1.2 (1.0, 1.4) Group 3: 1.3 (1.1, 1.8) p value: p<0.001 (3 vs 1, 3 vs 2) B) Intra-arterial cannulation Group 1: 0.8 (0.5, 1.0) Group 2: 1.6 (1.3, 1.9) Group 3: 1.4 (1.1, 1.9) p value: p<0.001 (3 vs 1, 3 vs 2)	
			Needle stick injury	Group 1: 0 Group 2: 0 Group 3: 0	
			Success on first	A) IV cannulation	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Age (mean): A: 58 (19-83) B: 67 (18-85) Group 3 N: 100 (50 IV, 50 intra arterial) Age (mean): A: 57 (18-80) B: 62 (21-82)	intravenous cannulation (cephalic vein) B) Conducted for intra-arterial cannulation (radial artery; under general anaesthesia and tracheal intubation)	insertion attempt	Group1: 46 Group 2: 48 Group 3: 48 B) Intra-arterial cannulation Group1: 42 Group 2: 44 Group 3: 45	backflow of blood was often too slow (authors judged more appropriate for IV cannulation), whereas for the AutoGuard, the chamber sometimes filled with blood before catheterisation (authors judged more appropriate for intra-arterial cannulation).
			Blood contamination (staff, patients or equipment)	A) IV cannulation Group1: 8 Group 2: 3 Group 3: 4 B) Intra-arterial cannulation Group1: 8 Group 2: 5 Group 3: 7	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Cote 2003 [82] Study design: RCT Setting: USA Duration of follow-up: 20 operative days	Patient group: Children requiring IV cannula Inclusion criteria: Trainees and attending anaesthesiologists performing IV cannulations. Exclusion criteria: None stated. All patients N: 330 Age (range): 6.5+/- 5.1yr Group 1 N: 211 Age (mean): Group 2 N: 119 Age (mean):	Catheters were inserted by 14 attending anaesthiologists and a number of residents and fellows. All trainees had prior experience with similar new IV catheter systems. Group 1 Retractable needle IV catheter. Angiocath Autoguard, BD Medical Systems, Inc. Group 2 Traditional IV catheter (JELCO; Johnson and Johnson)	Required one catheter (catheterised on 1st attempt)	Group 1: 150/211 Group 2: 94/119 P=0.117	Funding: Not stated Limitations: Quasi randomised (randomised by week) Limited baseline data given for each study arm. Quasi randomised; by day of the week. Hospital setting. Lack of investigator and patient blinding. Additional outcomes: Outcomes stratified by trainee and attending and also by patient age (<3 and >3 years old).
			Any blood spill or splatter (passive loss of blood from puncture site or IV catheter, or forceful propulsion of blood out of the IV catheter)	Group1: 30/211 Group 2:12/119 P=0.28	
			Time of insertion (s)	Group1: 102 +/-156 Group 2: 78 +/- 113 P=0.307	
			Poor flashback	Group1: 18 Group 2: 0	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Prunet 2008 [384] Study design: RCT Operating room and emergency department Setting: France Duration of follow-up: 5 months period	Patient group: Patients requiring peripheral IV catheters. Inclusion criteria: Patients requiring peripheral IV catheters. Exclusion criteria: If the patient's vein's were considered unsuitable for placing an 18G catheter. All patients N: 759 Group 1 N: 251 Age (mean): 55 +/- 20 Group 2 N: 254 Age (mean): 53+/-20 Group 3 N: 254 Age (mean): 54 +/- 20	Immediately after the procedure an assessment card was completed. The length of surveying previously fixed as the time necessary to obtain at least 250 informed consent assessment cards for each type of catheter. All catheters were 18 gauge diameter Group 1 Passive security catheter (Introcan Safety; B.Braun Medical). The insertion is identical to the classic catheter, with a protective shield that automatically covers the needlepoint during its withdrawal from the catheter top without any specific intervention from the operator Group 2 Active security catheter (Insyte Autoguard; BD Medical Systems) requires pressing a button to trigger the withdrawal of the needle in a plastic sleeve using a spring. Group 3 Classic catheter, usually used in the hospital (Vialon; BD Medical Systems)	Needlestick injuries	Group1: 0 Group 2: 0 Group 3: 0	Funding: Supported by Sainte Anne Hospital and Department of Anestheology Limitations: Hospital setting. Lack of investigator and patient blinding. Additional outcomes: Blood splashes to the environment. Notes: Immediately before every procedure, the type of peripheral venous catheter to use was determined randomly in a 3 ball ballot box.
			Failed on first insertion	Group1: 21 Group 2: 24 Group 3: 22	
			Difficulty to introduce catheter (VAS; 0-10; 0= very easy, 10 = very difficult), median (mean, range)	Group1: 0 (1.2, 0-2) Group 2: 0 (1.7, 0-3) Group 3: 0 (0.5, 0-0)	
			Difficulty of needle withdrawal (VAS; 0-10; 0= very easy, 10 = very difficult) median (mean, range)	Group1: 1 (1.8, 0-4) Group 2: 0 (1.3, 0-2) Group 3: 0 (0.5, 0-0)	
			Abnormal blood reflux in (when blood filling in the catheter delivery system was considered incomplete or complete but too slow (>4 S))	Group1: 18 Group 2: 41 Group 3: 7	
			Staff exposure to patients blood(when patient's blood stained the HCW's skin, gloves, mask or any other clothing.)	Group 1: 18 Group 2: 39 Group 3: 16	

G.4.2 Safety needles – phlebotomy

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
CDC 1997 [66] Study design: Observational (before and after study) Setting: 6 University affiliated hospitals (Minnesota 3, New York 1, California 2) Duration of follow-up: 12 months (after implementation)	Patient group: Healthcare workers (HCWs) Inclusion criteria: HCWs who routinely perform phlebotomies (phlebotomists, nurses on medical/surgical/intensive care/emergency departments, residents in medical/surgical/paediatric wards, medical students in third or 4th year. Exclusion criteria: Not reported All patients N: Not reported Age (range): Not reported	Before introducing safety devices, each hospital conducted a comprehensive training program for HCWs that included "hands-on" experience with the equipment. Group 1 Safety devices Resheathable winged steel needle (Safety-Lok, BD – at all 6 hospitals); a bluntable vacuum tube blood-collecting needle activated while in the patient's vein (Punctur-Guard – at 3 hospitals), and a vacuum-tube blood collection needle with a hinged recapping sheath (venipuncture Needle-Pro (Smith Industries – 4 hospitals). All require the HCW to activate the safety feature during or after phlebotomy. Phase 2 (mean duration 12 months (6-15). Investigators monitored supplies of phlebotomy equipment, continued enhanced surveillance . The HCW survey	Number of phlebotomy-related percutaneous injuries (PI) - unadjusted	Winged steel needle Group 1: 34 Group 2: 53 Vacuum tube collection (Punctur-Guard, PG) Group 1: 2 Group 2: 14 Vacuum tube collection (Venipuncture Needle-Pro, VNP) Group 1: 5 Group 2: 19	Funding: Not stated Limitations: Survey data not obtained from all HCW – response rate only 60% for one question. Additional outcomes: Under reporting rates of PI by profession
			Number of phlebotomy-related percutaneous injuries (PI) – adjusted for underreporting by profession	Winged steel needle Group 1: 58 Group 2: 102 Vacuum tube collection (PG) Group 1: 4 Group 2: 19 Vacuum tube collection (VNP) Group 1: 8 Group 2: 33	
			Estimated no. of phlebotomies performed	Winged steel needle Group 1: 2,540,500 Group 2: 1,875,995 Vacuum tube collection (PG) Group 1: 501,596 Group 2: 523,561 Vacuum tube collection (VNP) Group 1: 628,092 Group 2: 895,054	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		was repeated 1-2 months before the end of the phase. Group 2 Conventional devices. Phase 1(mean duration 10 months (9-12) – hospitals used conventional devices and conducted enhanced surveillance for injuries. An anonymous survey was conducted. The rates of PIs were estimated based on the number of reported phlebotomy-related PIs (adjusted for underreporting by occupation) by the number of phlebotomies performed (estimated based on daily average number of phlebotomies performed by each HCW, the number of HCWs and the duration of study period).	Estimated no. PIs per 100,000 phlebotomies	Winged steel needle Group1 : 3.1 Group 2: 4.0 Vacuum tube collection (PG) Group 1: 0.9 Group 2: 3.6 Vacuum tube collection (VNP) Group 1: 1.2 Group 2: 3.6	
			No (%) safety devices with activated safety features observed in disposal containers	Winged steel needle 2257/4065 (56%) Vacuum tube collection (PG) 2984/5255 (57%) Vacuum tube collection (VNP) 3250/3319 (98%)	
			No. of HCW noting technical difficulty or adverse patient effects with safety device (noted that only 60% of respondents answered this question)	Winged steel needle 97/955 (10%) Vacuum tube collection (PG) 204/452 (44%) Vacuum tube collection (VNP) 19/385 (5%)	
			Do you prefer the safety device over the conventional equipment?	Yes – 822 (44%) No – 622 (33%) Unsure - 435 (23%) (1108 HCW, 1879 responses related to one or more of the three devices used)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Mendelson 2003 [295] Study design: Observational (before and after study) Setting: Acute care hospital, NY, USA Duration of follow-up: 11 months implementation	Patient group: Healthcare workers Inclusion criteria: Exclusion criteria: All patients N: Age (range): Group 1 N: Age (mean): Group 2 N: Age (mean):	Group 1 19 month baseline period. A nonsafety winged steel needle (Terumo Corp., NJ) was used for performing phlebotomy procedures, drawing arterial blood, and obtaining venous access for some peripheral intravenous infusions. Not packaged with a vacutainer holder adapter, but one could be attached by the user prior to the phlebotomy procedure. Group 2 Training period – 3 months training, hands on simulated insertions, unit-based training, and an instructional mailing regarding the safety resheathable winged steel needle for staff. Training updates were continued during the post study period. Trainers included study nurses, nursing educators, and infection control practitioners, as well as trainers provided by the manufacturer (Becton Dickinson Corp). The study period was 11 months. The Safety-Lok winged steel needle was used for phlebotomy procedures throughout the institution. The needle was prepackaged with an adapter for vacutainer blood draws; which could also be removed before use. The safety mechanism had to be activated prior to removal of the needle from the patient. Although the Safety-Lok could be used for peripheral IV infusions, a nonsafety winged steel needle was also available in the paediatric department and the outpatient oncology clinic for this purpose.	Total number of winged steel needle injuries (per total no. needles delivered to units)	Group1: 86/641,282 Group 2: 28/436,180	Funding: Funded in part by the Centers for Disease Control and Prevention PHS Contracts 200-94-0876 Limitations: Hospital setting. Additional outcomes: Injury by occupation, work location, timing and mechanism of injury.
			Injury rate (number of injuries per 100,000 winged steel needles)	Group1: 13.41 Group 2: 6.41 RR (CI): 0.48 (0.31 to 0.73)	
			Product evaluation (survey of 536 HCWs)	Very easy or easy to use 446 (83.2%) Easy to hold and manipulate 412 (76.9%) Preferred safety needle to standard needle 337 (62.9%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Rogues 2004 [406] Study design: Observational (before and after study) Setting: Bordeaux, France Duration of follow-up: 3 years post implementation	Patient group: 8500 full time equivalent employees (2900 nurses). 3600-bed university hospital Inclusion criteria: Exclusion criteria: All patients N: Age (range): Group 1 N: Age (mean): Group 2 N: Age (mean):	Protective devices were introduced throughout the hospital on June 1996. Products evaluated were resheathable winged steel needles (SafetyLok, BD) and Vacutainer blood-collecting tubes with recapping sheaths (SafetyLok, BD). Each product required the HCW to activate the product immediately after phlebotomy. The 2 safety mechanisms required 2-handed activation. Instructions were issued on how to activate the product following removal of the needle from the patient. Group 1 Before - baseline Group 2 After safety device	Total needle stick injuries (phlebotomy related needle stick injuries)	Group 1: 1993 – 413 (77) 1994 – 399 (80 1995 – 444 (87) 1996 – 426 (86) Group 2: 1997 – 385 (46) 1998 – 365 (47) 1999 – 307 (34)	Funding: Not stated Limitations: Hospital setting. Unclear if this is prospective (missing data for half of 'before implementation group') Additional outcomes: Notes: Over the reporting period there were no reported HIV, HBV or HCV conversions.
			Estimated number of phlebotomies performed (estimated by vacuum-tube blood collecting needles and winged steel needle purchased per year by the hospital)	Group 1: 1993 – data not available 1994 – data not available 1995 – 459,499 1996 – 463,899 Group 2: 1997 – 455,700 1998 – 460,400 1999 – 458,120	
			Rates per 1000 devices purchased	Group 1: 1995 – 18.8 1996 – 16.4 Group 2: 1997 – 10.1 1998 – 10.2 1999 – 7.4	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		implementation	Phlebotomy needlestick injuries	Group 1: 19.4% of all needle related injuries Group 2: 12% of all needle related injuries RR 0.62 (95%CI 0.51-0.72)	

G.4.3 Safety needles – dental syringe

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Zakrzewska 2001 [527] Study design: Observational (before and after study) Setting: UK dental school Duration of follow-up: 2 years implementation	Patient group: Dentists Inclusion criteria: All dental trainees and qualified staff. Exclusion criteria: All patients N: Age (range): Group 1 N: Age (mean): Group 2 N: Age (mean):	A clear protocol was set up for changeover from non-disposable to disposable syringe. Key staff were aware of the need for high attendance at training sessions and the date of introduction of the new syringes which was widely publicised. Staff were trained over a 2 week period with the manufacturers personnel explaining technique. Change over occurred once staff had undergone training and training videos were available for continued training and for new staff. Follow up included careful monitoring and manufacturer's maintained close contact to make any necessary modifications. Change over occurred at year 4. Group 1 Disposable (safety) syringes. Septodont Safety Plus system. The handle of the Septodont Safety Plus syringe does not require autoclaving unless it has been contaminated with	Total number of sharps injuries relating to syringes	Qualified Year 1 Group 2: 2 Year 2 Group 2: 1 Year 3 Group 2: 2 Year 4 Group1: 2 Year 5 Group1: 0 Trainee Year 1 Group 2: 5 Year 2 Group 2: 4 Year 3 Group 2: 4 Year 4 Group1: 2 Year 5 Group1: 0	Funding: Septodont supplied equipment and training. Limitations: Small number of injuries – underpowered to see effect Authors report incidence of avoidable incidence using the second year of implementation. The first year data is excluded which has 4 needle stick injuries (3/4 reported as being due to lack of training) Equipment and training supplied by safety device manufacturer. Additional outcomes: Number of avoidable injuries, total sharps injuries. Notes: The use of non disposable syringes means that needles must be re-
			Number of staff at risk	Qualified Year 1 Group 2: 68 Year 2 Group 2: 68	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
		blood and saliva but it should be disinfected by immersal in hypochlorite solution of appropriate strength and for sufficient time as used for other dental items such as shade guides. The needle is already attached and the cartridge is disposed with the needle. Group 2 Non-disposable metal syringe The needle is not already attached and the cartridge is not disposed with the needle. The use of non disposable syringes means that needles must be re-sheathed in order for the syringes to be dismantled and the appropriate parts autoclaved.		Year 3 Group 2: 68 Year 4 Group1: 68 Year 5 Group1: 68 Trainee Year 1 Group 2: 173 Year 2 Group 2: 170 Year 3 Group 2: 186 Year 4 Group1: 176 Year 5 Group1: 176	sheathed in order for the syringes to be dismantled and the appropriate parts autoclaved. 3 safety syringes were compared and tested prior to implementation to identify the syringe of choice. The 3/4 injuries reported using the safety syringe were attributed to lack of training and were avoidable.
			Incidence of avoidable needle stick injury per 1000 employees	Group1: 20.5 Group 2: 0 (in second year)	

G.4.5 Safety needles – safety lancets

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Peate 2001 [356] Study design: Observational (before and after study) Setting: Emergency service, paramedics USA. Duration of follow-up: 12 months after implementation	Patient group: 477 emergency service workers (EMS) for a municipal fire department. Inclusion criteria: Exclusion criteria: All patients N: Age (range): Group 1 N: Age (mean): Range from 20-61 Male/female: 81%/9%	Subjects were instructed to report all needlestick injuries (NSI) due to glucometer lancets and other exposures, as directed by OSHA Bloodborne Pathogens Standard, to a designated fire department medical officer; subsequent follow-up was done by a board certified occupational medicine physician. All active-duty personnel were trained in the use of the new device, specifically to hold the point against the skin, press the plunger until the sharp was released and lanced the skin, confirm visually that the lancet had automatically retracted into its protective housing, and then dispose the lancet into a sharps container. EMS worker turnover was reported as minimal during the study. Group 1 Self-retracting glucometer lancet. Study period – 12 months. Group 2 Straight stick non-retracting lancet type device Study period – 2 years.	Needle stick injuries	Group 1: 2 (2 per 477 worker years) Group 2:16 (16 per 954 worker years) Statistically significant change at 0.05 alpha level using Z Test of Proportions (Z – 2.071787)	Funding: Not stated. Limitations: The cases of testing positive for hepatitis cannot be conclusively attributed to glucometer lancet NSI – other exposures were possible. Self reporting of needlestick injuries rather than direct observation. Rate of needlestick injury calculated using worker years rather than total number of lancets used. Number of lancets used is not reported, needle stick injury is reported against worker years. Additional outcomes: No additional hepatitis C or B cases were detected after the introduction of the new device. 7 tested positive to Hepatitis C and 2 to hepatitis B prior to implementation. No HIV positive cases were identified. Notes: Lancet-related needle stick were chosen by the authors for analysis as they represented the majority of needlestick injuries in this population. In October 2000, 6 EMS workers sustained a NSI with a straight stick non-retracting lancet type device. The decision was then made to change to a self-retracting glucometer lancet

G.5 Long term urinary catheterisation

G.5.1 Antibiotics

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Firestein 2001 [132] Study design: RCT – open label Setting: Geriatric Centre. Israel. Nov 1998 to Aug 1999 Duration of follow-up: 28 days	Patient group: Residents with long-term urinary catheters (LTUC). Inclusion criteria: All residents with LTUC Exclusion criteria: Urinary catheter in place for less than 4 weeks Antibiotics use within 2 week of enrolment. All patients N: 70 Age (mean): 79.3±9.6 years M/F: 21/49 Drop outs: 0 Group 1 N: 34 Age (mean): NR Group 2 N: 36 Age (mean): NR	Group 1 1gm of IV meropenem 30 minutes before catheterisation Group 2 No treatment received Catheters replaced every 4 weeks. Open urinary collecting catheter system and silicon catheter used.	Death	Group 1: 1/36 Group 2: 2/34 Relative risk: 0.47 [0.04, 4.97] P value: 0.53	Funding: not reported Limitations: Randomisation allocation and concealment method not reported No blinding – control group did not receive treatment Baseline values not clearly reported – more hypertension and cerebro vascular cases in intervention group Notes: Non parametric tests performed – t-tests or chi-square test
			Urine culture - positive	Day 0 Group 1:36/36 (100%) Group 2: 33/34(97%) Day 1-3 Group 1: 32/35 (91%) Group 2: 27/31 (87%) All not stat sig	
			Infection	Group 1 Group 2 RR All (total) 9/36 8/34 Urosepsis 1/36 3/34 Bacteremia 0/36 0/34 Soft tissue 2/36 1/34 Pneumonia 0/36 1/34 Unknown 3/36 3/34 All not stat sig	
			Hypersensitivity to antibiotics (meropenem)	Group 1: 0/36 Group 2: 0/34 p value: Not sig	
			Antibiotics resistance (meropenem)	Group 1: 0/36 Group 2: 0/34 p value: Not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Other baseline details not reported. "Cerebrovascular disease and hypertension more prevalent in the treatment group".				

G.5.2 Catheter type

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Bull 1991 [53] Study design: RCT Setting: England, Community Duration of follow-up: 16 weeks	Patient group: Patients undergoing long-term urethral catheterisation Inclusion criteria: Patients aged over 18 years undergoing long-term urethral catheterisation assessed to be mentally sound. Reasons for catheterisation included atonic bladder, prostate cancer, spinal injury, MS, paralysis, Parkinson's disease, incontinence, retention, prostatic enlargement and post TURP incontinence. Exclusion criteria: Patients with known sensitivity to hydrogel materials All patients N: 69 Age (mean): Drop outs: Male:female: 57:12 Group 1 N: 36 Age (mean): 75.61 (12.6) Drop outs: 9 Male:female: 31:5	Catheters were changed as necessary, patients assessed at biweekly intervals and patients kept a daily diary card recording comfort, pain and leakage on a 3 point scale (1 = good, 2 = average and 3 = bad). Any patient who required admission to hospital for more than 4 days was withdrawn from the study Group 1 Bard Biocath Foley catheter. A latex substrate coated on the inner and outer surfaces with a special hydrophilic polymer (hydrogel) Group 2 Dow Corning Silastic catheter (silicone elastomer coated	'Mean catheter time in situ, days (SD) (Student's unpaired t test)	Group 1: 89.61 (36.31) Group 2: 56.7 (38.8) p value: 0.0014	Funding: Not stated Limitations: Additional outcomes: Number of patients requiring 1 or more catheter changes and total numbers of catheter changes. Patient reported leakage. Patient preference to the catheter they were randomised to compared to their previous. Washouts, bypassing episodes (missing data from control group). Notes: Standard deviation not given for several continuous outcomes, which therefore cannot be entered into a meta-analysis.
			Encrustation leading to catheter change	Group 1: 11 Group 2: 9	
			Mean diary score	Comfort Group 1: 1.22 Group 2: 1.30 p value: not sig Pain Group 1: 1.14 Group 2: 1.24 p value: not sig	
			Mean pH over study period	Group1: 6.3 Group 2: 6..6 p value: not sig	
			Catheter related adverse events	Group1: 1 – reason not stated Group 2: 7 – 5 pain, 1 catheter did not drain, 1 catheter was repeatedly expelled.	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Mean days catheter change: 77 (66.9) Group 2 N: 33 Age (mean): 70.03 (16.6) Drop outs: 12 Male:female: 26:7 Mean days catheter change: 60 (22.6)	catheter)			

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Cardenas 2009 [59] Study design: RCT Setting: USA. Seattle. Duration of follow-up: 1 year	Patient group: Patients with spinal cord injury (SCI) Inclusion criteria: SCI 6 months or more ago, self reported history of ≥2 UTIs during the past year, use of IC with a noncoated catheter and an open system, no plan to change the method of bladder drainage during the study period, naïve to hydrophilic catheters and at least 18 years of age. Exclusion criteria: Patients with evidence of upper urinary tract abnormalities or renal or bladder calculi in a screening renal ultrasound. All patients N: 56 Drop outs: 11 (1 dropped out at subjects request, 3 lost to follow up, 3 discontinued as a result of placement of an indwelling Foley catheter, 3 withdrew as a result of nonurologic medical complications, and 1 withdrew as a result of developing renal stones Group 1 N: 22 Mean age (SD): 42.3 (10.4) Male/Female: 17/5 Group 2 N: 23 Mean age (SD): 40.1 (9.3) Male/female: 12/11	After randomisation patients were instructed how to use the hydrophilic catheter or how to use proper clean technique for those in the control group. The definition of a symptomatic UTI is significant bacteriurea (>105 cfu/mL) plus at least 1 sign or symptom suggestive of a UTI (self reported from a diary). Urine was collected at intervals of 6, 9 and 12 months, whereas the symptom diary was collected on a monthly basis. Subjects visited their regular health provider as normal for treatment of UTIs. Group 1 LoFric hydrophilic coated PVC catheter Group 2 Control catheter. Patients used their usual noncoated catheter with clean technique, but used a new catheter with each catheterization.	Total UTI at 1 year (t test) Total antibiotic treatment episodes at 1 year Subjects who had at least 1 UTI Subjects who had at least 1 antibiotic treatment episode	Group1: 1.18 (1.3) Group 2: 1.00 (1.0) p value: 0.61 Group1: 0.77 (0.87) Group 2: 1.65 (1.46) p value: 0.02 Group1: 12 Group 2: 14 p value: 0.67 Group1: 11 Group 2: 16 p value: 0.18	Funding: No commercial party had a direct financial interest in the result of the research reported. Limitations: Imbalance in male: female ratio between groups. Small sample size – author states that it may have been underpowered. Use of self reported symptoms to determine symptomatic UTIs.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
DeRidder 2005 [95] Study design: RCT Setting: Multi-centre (5 in Spain, 3 in Belgium) Duration of follow-up: 1 year	Patient group: Men with spinal cord injury presenting with functional neurogenic bladder-sphincter disorders. Inclusion criteria: Men aged 16 or over that have been injured less than 6 months Exclusion criteria: Patients with symptomatic UTI, urethral stenosis or fibrosis were excluded, as were mentally unstable patients and those participating in another clinical trial. During the trial, those that received prophylactic antiseptic or antibiotic treatment or used a permanent catheter was used for a period of more than 10 days were also excluded. All patients N: 123 Group 1 N: 61 Mean age (SD): 37.5 (14.6) Group 2 N: 62 Mean age (SD): 36.7 (14.6)	Both catheters were available for the study in size Ch10, 12 and 14. Patients kept a log book of symptoms and had visits at day 15 then 1, 2, 3, 6, 9 and 12 months. Group 1 Hydrophilic-coated SpeediCath polyurethane catheter (Coloplast). Single use ready-to-use catheter. Group 2 Uncoated PVC catheter, which were lubricated manually with a water-soluble lubricant gel, containing no active ingredients and delivered in 5g sachets (Aquagel lubricating Jelly, Adams Healthcare Ecolab.). Catheters are reused.	UTI – (clinical infection with symptoms of UTI and for which treatment was prescribed)	1 or more during the study. Group1: 39 Group 2: 51 No UTI Group1: 22 Group 2: 11 p value: 0.02	Funding: Not stated Limitations: High drop out rate (54%) due to restored urinary function and thus no further need for catheterisation, change of bladder management to an indwelling catheter and withdrawal of consent. There was a higher number of patients with microscopic hematuria and bacteriuria in the intervention group compared to control – actual numbers not stated but p = 0.02 and 0.03 respectively. Additional outcomes: (list additional outcomes reported in paper but not recorded in this table) Notes: Majority of patients had urethral indwelling catheters prior to trial. Patients still hospitalised at study inclusion.
			Mean catheterisations per day	Group1: 3.4 Group 2: 3.6	
			Haematuria	Group1: 38/55 Group 2: 32/59	
			Stenosis	Group1: 0 Group 2: 1 p value: not sig	
			Patients/helpers who were very satisfied with the catheter	6 months Group1: 10 Group 2: 6 p value: not sig 12 months Group1: 9 Group 2: 7 p value: not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Giannantoni 2001 [150] Study design: Randomised crossover trial Setting: Rehabilitation hospital, Italy Duration of follow-up: 7 weeks in each arm	Patient group: Neurogenic bladder due to recent spinal cord injury Inclusion criteria: Exclusion criteria: All patients N: 18 Age (SD): 38.2 (16.4) Drop outs: 0 Male/Female: 16/2	All patients were transferred from the intensive care unit with an indwelling catheter. Subsequently trained to perform intermittent catheterisation independently. Intermittent catheterisation was performed every 5 hours. Group 1 Sterile, single use pvc, silicone coated catheter (Orlycatnel: Nelaton, Orly General Supply, Italy). Lubricated by the patient using a gel. Group 2. Prelubricated non-hydrophilic catheter.(Isantcath: Hollister, Illinois). Silicone coated catheter prelubricated with glicerol polymethacrylate and propylene glycerol gel.	Symptomatic UTI (cloudy and odorous urine, onset of urinary incontinence, increased spasticity, automatic dysreflexia, increased sweating and malaise or a sense of unease associated with pyuria and significant bacteriuria)	Group 1: 12/54 Group 2: 4/54 P = 0.003	Funding: not stated Limitations: Where 54 is stated as the n number please note that this is a sum of 3 measurements per patients (i.e. 3 x18). Therefore sample size seems larger than it actually is. Additional outcomes: Additional patient demographics. Urethral wall trauma
			Asymptomatic bacteriuria (uropathogenic colonization of the urinary tract without symptoms of infection)	Group 1: 18/54 Group 2: 8/54	
			Patient satisfaction (visual analogue scale)	Learning Group1: 1.1 (2.7) Group 2: 1.1 (2.7) p = 0.16 Inserting Group1: 6.7 (3.4) Group 2: 3.6 (3.7) p = 0.00007 Extracting Group1: 5.0 (3.4) Group 2: 3.0 (3.0) p = 0.004 Comfort Group1: 5.8 (3.9) Group 2: 2.5 (3.1) p = 0.00002 Handling ease Group1: 5.0 (3.4) Group 2: 1.4 (2.3) p = 0.000004 Mean satisfaction score Group1: 2.33 (1.06) Group 2: 4.72 (2.13) p = 0.022	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Pachler 1999 [346] Study design: Randomised prospective crossover trial Setting: Community, Denmark Duration of follow-up: 3 weeks	Patient group: Patients with urinary retention caused by prostatic enlargement. Inclusion criteria: Men with urinary retention Exclusion criteria: All patients N: 43 Age (mean): Drop outs: 11 (5 had no lasting need for intermittent catheterisation, 3 didn't enter the study, 2 could not insert the non-hydrophilic catheter and did not want to use the hydrophilic catheter and 1 developed a rash around the external urethral meatus while using the non hydrophilic catheter. Crossover trial (all patients used both intervention) N: 32 Age (mean): 71.3 (range 50-87) 1st 3 weeks 20 patients in group 1and 12 in group 2.	Patients were taught how to perform clean intermittent self catheterisation by a specially trained nurse in the outpatient clinic. Patients used one catheter for 3 weeks then transferred to the other type for 3 weeks. Group 1 Prelubricated, (hydrophilic coated), disposable PVC catheter (Lofric, AstraZenenca, UK) Group 2 Non-hydrophilic PVC catheter (Mentor, Santa Barbara) plus lubrication (gel) applied by the patient. This catheter was used several times within 24h and was then discarded. After each use it was rinsed under lukewarm water and left to dry on a clean towel.	Bacteriuria (growth of >104 c.f.u./mL was considered significant)	Group 1: 14 Group 2: 17 p value: not significant	Funding: Not stated. Limitations: Small sample size, crossover study. Notes: Questionnaire completed after 3 weeks of using each type of catheter.
			Problems in introducing the catheter	None Group 1: 31 Group 2: 30 Some Group1: 1 Group 2: 2 Many Group1: 0 Group 2: 0 p value: not significant	
			Burning sensation when introducing the catheter	None Group1: 30 Group 2: 31 Some Group1: 2 Group 2: 1 Many Group1: 0 Group 2: 0 p value: not significant	
			Pain when introducing the catheter	None Group 1: 29 Group 2: 30 Some Group1: 3 Group 2: 2	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				Many Group1: 0 Group 2: 0 p value: not significant	
			Burning sensation or pain after removal of the catheter	None Group1: 30 Group 2: 30 Some Group1: 2 Group 2: 2 Many Group1: 0 Group 2: 0 p value: not significant	
			Handling of catheter before introduction	Easy Group1: 30 Group 2: 25 Tolerable Group1: 1 Group 2: 6 Troublesome Group1: 1 Group 2: 1 p value: not significant	
			Handling of catheter after use	Easy Group1: 30 Group 2: 27 Tolerable Group1: 2 Group 2: 3	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				<u>Troublesome</u> Group1: 0 Group 2: 2 p value: not significant	
			Transient gross haematuria	Group 1: 14 Group 2: 17 p value: not significant	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Sutherland 1996 [455] Study design: RCT Setting: Community, USA Duration of follow-up: 8 weeks	Patient group: Men with neurogenic bladder due to spinal cord injury, Hinman syndrome or spinal dysraphism Inclusion criteria: Boys who were adept at performing clean intermittent catheterisation and who had voiding dysfunction due to spinal dysraphism, spinal cord injury or non-neurogenic bladder. Exclusion criteria: Patients with a history of urethral pathology (false passage, stricture or bladder neck reconstructive surgery) All patients N: 33 Age (mean): Drop outs: 3 Group 1 N: 17 Age (mean): 11.7 (3.8) Drop outs: 1 Group 2 N: 16 Age (mean): 12.1 (5.7) Drop outs: 2	Follow-up – weekly urine C&S and microscopy x 8 weeks. Group 1 Hydrophilic coated PVC catheter (Lofric) single use Group 2 PVC reused catheter (Mentor). Non-hydrophilic polyvinyl chloride catheter.	Microscopic Haematuria > 3 red blood cells per high powered field	Group 1: 6 Group 2: 11	Funding: not stated Limitations: Unclear allocation concealment and randomisation Additional outcomes: Additional patient deomgraphics. Notes: No difference in bacteriuria between the groups
			Bacteriuria When suspected on the basis of symptoms and urinalysis, a urine culture was obtained. Positive cultures defined as10x5 CFU/ml- subjects were treated and reentered into the trial 1 week after cessation of antibiotic therapy.	Group 1: 3 Group 2: 4	
			Visual analogue scale for satisfaction (0 = most and 10 = least favourable)	Convenience Group 1: 3.3 (2.8) Group 2: 4.9 (2.7) P <0.05 Handling Group 1: 3.8 (2.7) Group 2: 3.8 (2.6) Comfort with insertion Group 1: 2.7 (2.4) Group 2: 4.2 (2.6) P <0.05 General opinion Group1: 3.3 (3) Group 2: 3.9 (2.1)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Vapnek 2003 [480] Study design: RCT Setting: 3 American sites Duration of follow-up: 12 months	Patient group: Men who perform intermittent self-catheterisation used to manage neurogenic bladder Inclusion criteria: Men able to perform intermittent self catheterisation. Exclusion criteria: Patients with a history of vesicoureteral reflux, unexplained hematuria or bladder calculi, those requiring prophylactic antibiotics and those considered incapable of following the study schedule were excluded from the analysis. All patients N: 62 Age (mean): Drop outs: Group 1 N: 31 Age (mean +/- SD): 39.8 (12.9) Drop outs: 1 (used both catheter types) 8	Following enrolment, patients presented for follow up once every 3 months for 1 year. A 3 month supply of catheters was issued at each visit. Patients were instructed to use clean technique and discard each catheter after 1 use. Most catheters were 14Fr, but some patients preferred 16Fr or 12Fr Group 1 Hydrophilic coated LoFric catheter. Plastic catheter - polyolefin-based elastomer. 120 catheters were issued monthly. Group 2 Standard polyvinyl chloride catheter. 30 catheters were issued monthly. Patients were instructed to clean and reuse the catheter 4 or 5 times before	Urinary tract infection (SD) (Baseline self reported, but during study this was self reported plus quarterly urine cultures)	Baseline Group1: 0.45 (0.62) Group 2: 0.20 (0.2) 3 months Group1: 0.16 Group 2: 0.23 6 months Group1: 0.12 Group 2: 0.17 9 months Group1: 0.12 Group 2: 0.16 12 months Group1: 0.13 (0.18) Group 2: 0.14 (0.14) p value: NS	Funding: Lead author declared financial interest and/or other relationship with Pharmacia and Merck. Limitations: Catheters re-used up to 5 times a day for control, where as intervention is single use only. Baseline rates of UTI differ.
			Microscopic hematuria (SD) (Degree of hematuria and pyuria was classified as none (0) ,mild (1), moderate (2) or heavy (3) according to the number of cells per high power field.)	3 months Group1: 0.21 Group 2: 0.71 6 months Group1: 0.28 Group 2: 0.63 9 months Group1: 0.30	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 2 N: 31 Age (mean +/- SD): 39.6 (16.0) Drop outs: 5	discarding at the end of the day.		Group 2: 0.63 12 months Group1: 0.31 (0.46) Group 2: 0.65 (0.69) p value: 0.027	
			Microscopic pyuria	<u>3 months</u> Group1: 1.6 Group 2: 1.4 <u>6 months</u> Group1: 1.6 Group 2: 1.5 <u>9 months</u> Group1: 1.6 Group 2: 1.6 <u>12 months</u> Group1: 1.7 Group 2: 1.6 p value: NS	
			Bacteriuria	Measured, but not reported. p value: NS	
			Adverse events	Group1: 3 (1 gross haematuria, 1 episode of epididymitis, 1 infected penile prothesis requiring surgical removal) Group 2: 3 (1 gross haematuria, 1 episode of epididymitis, 1 bladder stone). p value: NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Duffy 1995 [110] Study design: RCT Setting: 3 long term care sites, USA Duration of follow-up: mean 63 days in each group, range 15 to 107 days	Patient group: Residents of long term care facilities Inclusion criteria: Patients with indwelling catheters for relief of residual urine, were currently managed by intermittent catheterisation, or had significant residual urine and had an anticipated length of stay of at least 110 days. Exclusion criteria: Patients with a medical diagnosis of urethral stricture, which would put the patient at high risk for complication, or the presence of combativeness (striking out or kicking at the nurse caregiver) or other behavioural problems, which would make a program of intermittent catheterisation impossible for staff to carry out. All patients N: 82 Drop outs: 2 Group 1 N: 38 Age (mean +/- SD): 70.9 (12.1) 20 completed 90 day protocol Group 2	Consistency was assured across sites by preliminary and bimonthly staff inservice programs plus reliability checks on the nursing care units. Group 1 Clean intermittent catheterisation. Does not require a sterile field and can be done in bed or chair as patient desires. No cleaning of the meatus was done if normal daily hygiene (daily cleansing with soap and water) appeared sufficient and there was no obvious contamination with stool or other drainage. However, after the 1st use and for each catheterisation done during a one week period, the catheter was washed with mild soap and running water, dried on a clean, lint free towel and stored at the patient's bedside in a clean, dry container. Clean catheters were replaced each week. Group 2 Sterile intermittent catheterisation. This required all sterile equipment for each catheterisation, setting up of a sterile field with drapes, and cleansing of the urinary meatus	Number of symptomatic UTIs Catheter replacement / frequency of catheter change, at day 15, Mean (SD)	Group1: 29 treatment episodes/2452 days Group 2: 35 treatment episodes/2672 days Group1: 11.8/1000 days Group 2: 13.1/1000 days Group1: 3.0 (+/- 1.1) Group 2: 2.8 (+/- 1.1) P = 0.455	Funding: Supported by a grant from the Department of Health Services Research and Development, Department of Veteran Affairs, Washington, DC. Limitations: Catheterisation was performed by nurses, rather than by the patient. Length of time enrolled in study varied. Additional outcomes: Risk factors for UTI, primary diagnosis and cause of residual urine. (no statistical significance between groups) Notes: Drop out of the study before end of 90 day protocol were: death unrelated to study, request for discontinuation, hospitalisation of the patient for >21 days for an unrelated problem, subject discharged from facility, combativeness, reduction in volume of

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 42 Age (mean +/- SD): 72.6 (10.8) 19 completed 90 day protocol	with Betadine before catheterisation. All catheterisation was supplied by the pharmacy in a sterile condition.			residual urine so that patient no longer required catheterisation, and end of study funding period.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
King 1992 [224] <u>Study design:</u> RCT <u>Setting:</u> Inpatient rehab, USA. <u>Duration of follow-up:</u> 28 days, or until infection occurred. (range 1-28)	<u>Patient group:</u> Patients with spinal cord injuries (SCI) <u>Inclusion criteria:</u> Patients admitted to an inpatient rehab programme at any time postinjury, placed on intermittent catheterisation either before or during their hospitalisation. Also, if catheterisation was performed every 6 hours, had normal serum creatinine, and urinalysis, no prophylactic antibiotics, absence of drug-resistant organism on urine culture and bacteremia less than 10,000 colonies/ml <u>Exclusion criteria:</u> Patients were discontinued from the study before 28 days if catheterisations were ordered less frequently than every 6 hours or if they were discharged. All patients N: 46 Drop outs: 2 <u>Group 1</u>	Patients with sufficient hand function and willingness to learn were taught self catheterisation. Others were catheterised by a nurse or family member. Group 1 Clean intermittent catheterisation Patients did not wear gloves; staff and family care givers wore non sterile gloves. A sterile catheter was used at the beginning of each 24 hour period. The catheter was lubricated, and the urinary meatal area was cleansed with a castile soap wipe. After each use the catheter was washed with bar soap, rinsed with tap water, dried, and stored in a plastic bag for reuse. Group 2 Sterile intermittent catheterisation. Carried out using a sterile	Number of symptomatic UTIs Number of catheterisation per risk days (no. of study days on which the subject did not meet the criteria for infection.	Group1: 5 Group 2: 3 Group1: 1497 catheterisation/256 days Group 2: 1758.5 catheterisation/311 days	<u>Funding:</u> Supported by a grant from The American Association of Spinal Cord Injury Nurses and was supplemented by the Rehabilitation Institute Foundation. <u>Limitations:</u> Not possible to estimate total time on intermittent catheterisation (61% clean and 74% of sterile group started intermittent catheterisation in acute setting. <u>Additional outcomes:</u> Bacteriurea

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 23 Age (mean +/- SD): 27.9 (10.3) Drop outs: 3 patients catheterised less than 2 weeks <u>Group 2</u> N: 23 Age (mean +/- SD): 32.8 (13.7) Drop outs: 1 catheterised <2 weeks	catheterisation kit for each procedure and following principles of asepsis such that care was taken to avoid contaminating the catheter. The external meatus was cleansed with povidone iodine before sterile catheterisation.			<u>Notes:</u> 35 patients catheterised every ≤4h 10 every 6h 1 every 4h in the day and 6 at night.

G.5.3 Bladder instillations and washouts

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Kennedy1992 [220] Study design: Randomised cross over trial Setting: UK Geriatric units in 3 hospitals Duration of follow-up: 12 weeks	Patient group: "Elderly females" from 6 long-term care wards in 3 geriatric hospitals. Inclusion criteria: All long term catheterised female patients (not specified). Patients had been catheterised for a median of 12 months. Catheter type was the one the patient was already using (no further details provided). Exclusion criteria: NR All patients N: 25 Age (mean): 82 years (range 65-100 years) Drop outs: 11 (5 died, 3 had catheters removed, 2 withdrawn at request of nursing staff, 1 discharged and unavailable for follow-up). Cross over trial (all patients used all 3 interventions)	Patients allocated to all three interventions by random number tables. Patients underwent normal saline washout twice a week (neutral period) prior to and following twice weekly washouts with sodium chloride, Suby G and Solution R. Group 1: Saline (Sodium chloride 0.9%) Group 2: Solution G (Suby G) Citric acid 3.23%, light magnesium oxide 0.38%, sodium bicarbonate 0.7%, disodium edentate 0.01%. Group 3: Solution R Citric acid 6%, gluconolactone 0.6%, light magnesium carbonate 2.8%, disodium edentate 0.01%. "Washout fluid instilled" by allowing 100ml sterile pre-packed sachet contents to flow into the bladder by gravity. Solution left in the bladder for 20-30mins. Catheters were changed at weeks 1, 5, 9 and 12.	Bacteriuria (%patients with bacteriuria present in washout fluid)	Group 1: 100% Group 2: 75% Group 3: 76%	Funding: NR Limitations: No baseline data reported. Allocation concealment not reported Blinding not reported Insufficient data presented for a number of outcomes. Catheter outcomes reported per number of catheters Additional outcomes: Type and frequency of crystals in washout fluid, catheter bypassing and percentage patients with urothelia cells present in washout fluid
			Catheter blockage (catheters with lumen or eyes completely blocked resulting in no flow of urine)	Group 1: 18/44 (41%) Group 2: 14/29 (48%) Group 3: 7/27 (26%)	
			Partially blocked catheter (catheters still able to allow catheter drainage)	Group 1: 14/44 (32%) Group 2: 12/29 (42%) Group 3: 10/27 (10%)	
			Catheters Not encrusted	Group 1: 12/44 (27%) Group 2: 3/29 (10%) Group 3: 10/27 (37%)	
			Catheter removal/ replacement (mean time in situ)	Group 1: 16.3 days Group 2: 14.3 days Group 3: 14.2 days Catheters in only 3 patients remained in situ for 28 days p value: Not sig	
			Red blood cells (% patients with cells present in washout fluid)	Group 1: 21% Group 2: 17% Group 3: 14% p value: 0.028	
			White blood cells (% patients with cells present in washout fluid)	Group 1: 100% Group 2: 87% Group 3: 84% p value: Not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Moore2009[305] Study design: RCT Setting: Canada Long term care settings or patients own homes Duration of follow-up: 8 weeks	Patient group: Adults (males and females) with long term indwelling catheters that required changing every 3 weeks or less Inclusion criteria: Patients with long term (>30 days) indwelling catheters blocking more than once a month and residing in a long term care setting or receiving home care. Eighteen years or older and scoring >24 on the Mini Mental State Examination. Exclusion criteria: Symptomatic UTI on admission to the study (patients were eligible after a symptom free period of 14 days), urethral erosion, history of bladder cancer, radiation or interstitial cystitis, impaired renal function, gross haematuria or indwelling catheter changed less than every 8 weeks. All patients N: 73	Group assignment determined by computer generated list of random numbers Catheters were inserted on day 0. Assessment occurred weekly for 8 weeks, until 3 changes or a UTI was reported Group 1: Solution G (Contisol) Patients received catheter washout weekly with 50ml sterile Contisol (citric acid 3.23%, light magnesium oxide 0.38%, sodium bicarbonate 0.7% and disodium edentate 0.01%), which were squeezed through the catheter over 60 seconds. The flushing action was repeated 5 times. Group 2: Saline washout Patients received catheter washout weekly with 50ml sterile normal saline	Symptomatic UTI (at least one of five; fever >=38 degrees, urgency, dysuria or suprapubic tenderness, haematuria or positive urine culture)	Group 1: 0/17 Group 2: 0/16 Group 3: 0/20	Funding: Alberta Heritage Foundation for Medical Research and the Canadian Nurses Foundation Limitations: Authors report blinding attempted, but was not possible due to nature of intervention and packaging of washouts Authors report that 2-3 patients in each group did not complete data collection due to self reported UTI and initiation of antibiotic treatment, but none met study criteria for symptomatic UTI Additional outcomes: All patients had haematuria consistently (no data
			Mean time to first catheter change (weeks)	Group 1: 4.75 (SD 2.61) Group 2: 5.18 (SD 2.90) Group 3: 4.55 (SD 2.91) p-value: Not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Age (mean): NR Drop outs: 16 (3 catheter changes, self-reported UTI, hematuria, latex sensitivity, deceased/ severe illness, or personal choice) Group 1 N: 26 Age (mean): 63.92 (SD 17.25) Drop outs: 9 Group 2 N: 21 Age (mean): 66.24 (SD 17.38) Drop outs: 5 Group 3 N: 26 Age (mean): 68.56 (SD 18.65) Drop outs: 6 No significant differences between groups at baseline	Group 3: No washout (Control) Patients received standard care, no washout	Mean urine pH	pH 6.3 (SD 1.04) pH range 5 – 8.5 Not reported per group	reported) <u>Notes:</u> Authors acknowledge blinding not possible due to nature of sterile packaging. Authors report that measuring the cross section of catheters was not useful for comparing effectiveness of washouts.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Muncie1989[311] Study design: Randomised crossover trial Setting: USA Deaton Hospital and Medical Centre Duration of follow-up: 24 weeks	Patient group: Long term catheterised women. Catheter type: double lumen, 18F, silicone-coated latex urethral catheter. Inclusion criteria: Female patients aged 18 years and older with indwelling urethral catheter in situ for 30 consecutive days or more. Pt were afebrile (>= 37.7 degrees) for 7 days and had not received antibiotics for 14 days. Exclusion criteria: Patients with bladder malignant neoplasms or physician insistence on continued bladder irrigation. All patients N: 44 Age (mean): 71 years Drop outs: 21 (10 died, 4 discharged, 3 had catheters removed and 4 at physician's request) 32 patients analysed: 23 crossovers and 9 partial crossovers (no further details provided)	Patients entered a 2 week run-in period of no irrigation. Patients randomly allocated to 10 weeks of once daily normal saline irrigation or 10 weeks of no irrigation. Patients then entered a 2 week washout period of no irrigation before entering the alternate phase. Group 1: Saline irrigation Trained nurses "irrigated" the catheters daily by pushing 30ml of sterile normal saline into the irrigation port with the use of a catheter tipped syringe. Group 2: No washout/irrigation New catheters were inserted at the beginning and end of each study phase.	Bacteriuria (mean number of species per urine specimen, at >=105/ml)	Group 1: 4.0 Group 2: 3.8 The four most prevalent organism in each group were Providencia stuartii, Escherichia coli, P mirabilis and enterococcus	Funding: Supported by grants from the National Institute on Aging, National Institutes of Health. Limitations: Sequence generation not clear Allocation concealment not clear Blinding not reported 32 patients analysed, when 23 patients completed the study. Cross over and partial crossover patients not distinguished in results reported Additional outcomes: Febrile episodes of possibly urinary origin
			Catheter replacements per 100 days of catheterisation (mean)	Group 1: 5.5 Group 2: 4.7 p value: Not sig SD not reported	
			Number of non-prescribed catheter removals	Group 1: 87 Group 2: 63	
			Number of catheter replacements due to obstruction (absence of urine flow from catheter that irrigation did not restore)	Group 1: 39*/32 Group 2: 32/32 p value: Not sig *Some catheters replaced more than once.	
			Number of catheter replacements due to leakage (patient's bed being wet with urine when catheter still connected to connection tube)	Group 1: 11/32 Group 2: 21/32 p value: Not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Waites2006[486] Study design: Randomised non-controlled trial Setting: USA Community residence settings Duration of follow-up: 8 weeks	Patient group: Community residing persons with neurogenic bladder using indwelling catheters Inclusion criteria: Community residing men and women; at least 19 years of age; at least 6 months post spinal cord injury or other neurological disease; with an indwelling Foley catheter or suprapubic tube and evidence of microscopic bacteriuria and pyuria at enrolment. Exclusion criteria: Symptoms of UTI requiring systemic antibiotics, use of urine-acidifying agent, bladder irrigant or systemic antibiotic within the previous 7 days, prior abnormalities in renal function, pregnancy, and inability or unwillingness to provide informed consent All patients N: 89 (49 men and 40 women) Age (mean): 45.8 years (range 19-82 years) Drop outs: 37 [withdrew due to symptomatic UTIs (11), other	30mls of each irrigant was instilled for 20 mins using a bladder syringe, twice weekly. Group 1: Saline washout/irrigation Group 2: Acetic acid washout/irrigation (0.25%) Group 3: Neomycin polymyxin GU irrigation (40mg/ml neomycin sulphate and 200000 units/ml polymixcin B) Neomycin is not included in the protocol for this question, but has still been included in the evidence table for completeness.	Symptomatic UTI (number of patients discontinuing use of irrigation due to symptomatic UTI)	Group 1: 1/29 Group 2: 6/30 Group 3: 4/30	Funding: Not reported Limitations: Sequence generation not clear Allocation concealment not reported Blinding not clear Additional outcomes: Generation of antimicrobial resistant organisms, urinary pH, urinary leukocytes and patients with Enterococcus species. No data reported for bacteriuria or pyuria at study arm level.
			Adverse effects/non-acceptability	Group 1: 0/29 Group 2: 1/30 Group 3: 2/30 3 patients experienced manifestations of autonomic dysreflexia after 'instillation of irrigant'	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	health reasons (14), perceived difficulty, inconvenience or unwillingness to perform twice daily irrigations (12)] Group 1 N: 29 Age (mean): N/R Drop outs: N/R Group 2 N: 30 Age (mean): N/R Drop outs: N/R Group 3 N: 30 Age (mean): N/R Drop outs: N/R				

G.6 PEGs

No clinical evidence identified

G.7 Vascular access devices

G.7.1 Types of dressings – peripheral

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Craven 1985 [84] Study design: RCT Setting: Boston, USA Duration of follow-up: Up to 72h	Patient group: Patients with a peripheral IV catheter Inclusion criteria: Adult patients hospitalised on the medical and surgical services at Boston City Hospital Exclusion criteria: Patients who were hospitalised in the intensive care unit or who had IV catheter inserted by a house officer. All patients N: 437 Group 1 N: 200 No. of catheters randomised: 316 Age (mean): 47.8 (18.6) Male/female: 220/96 Group 2 N: 237 No. of catheters randomised: 421 Age (mean): 53.7 (19.5) Male/female: 239/182	All patients had a Teflon catheter inserted and maintained by an IV team nurse. The skin site was prepared with 70% isopropyl alcohol followed by povidone iodine solution prior to insertion of the IV catheter. IV catheters were routinely removed or replaced every 48 to 72 hours. Group 1 Transparent polyurethane dressing (OpSite, Acme United Corp., Bridgeport, CT) Group 2 Dry gauze – dressing changed daily	Catheter tip colonisation (≥15 CFU)	Group1: 28/316 Group 2: 24/421	Funding: Not stated Limitations: Catheter sites given rather than individual patient, therefore each patient was counted up to 8 times. Additional outcomes: Seasonal colonisation, insertion site colonisation, organism isolated. Notes: Once randomised patients were excluded when the IV catheter was removed without a member of the IV team being notified.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Hoffmann 1988 [194] Study design: RCT Setting: University of Virginia Hospital, USA Duration of follow-up: 48 hours	Patient group: Patients with peripheral intravenous access sites Inclusion criteria: Inpatients older than 21 years of age on 4 services: cardiac medicine, general medicine, orthopaedic surgery, and thoracic-cardiovascular surgery. Exclusion criteria: Patients under 21 years of age and those admitted with a diagnosis of vasculitis or bacteremia were excluded. All patients N: 598 Age (mean): Drop outs: 128 Group 1 N: 300 Age (mean): 58 ±18 Male/female: 154/92 Drop outs: 54 Group 2 N: 298 Age (mean): 55 ± 21 Male/female: 128/96 Drop outs: 74	Hospital policy was to rotate sites for IV catheters every 48h – policy carried out by the IV team. A Teflon IV catheter was used on all patients. A single IV site from each patient was studied and patients were only entered into the study one time. Group 1 Bioclusive transparent polyurethane dressing Group 2 Cotton gauze	Catheter tip colonisation (>15 CFU)	Group1: 14/246 Group 2: 10/224 p value: not significant	Funding: Not stated Limitations: No intention to treat analysis, allocation concealment or blinding. Additional outcomes: Organism isolated from catheter tip. Colonisation at insertion site. Notes: Reason for discontinuation given, main reasons were discontinued by staff, infiltration and transferred to another floor.
			Phlebitis (criteria-warmth and erythematous skin over an indurated or tender vein)	After 24h Group1: 10/246 Group 2: 4/224 p value: 0.179 After 48h Group1: 14/246 Group 2: 13/224 p value: 1.000	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Maki 1987 [281] Study design: RCT Setting: Wisconsin Hospital, Madison, USA Duration of follow-up: 3 days	Patient group: Patients with peripheral venous catheters Inclusion criteria: Consenting adult patients older than 18 years, without granulocytopenia, who were scheduled to have a peripheral venous catheter inserted. Exclusion criteria: Catheters that had been in place for less than 24h. The N given below is for number of catheters All patients N: 1259 Age (mean): Drop outs: Group 1 N: 544 Age (mean): 53.5 % intensive care: 30 Mean hours in place: 54 ±38 Group 2 N: 519 Age (mean): 51.9	Each catheter was inserted by a house officer or nurse percutaneously into a new site. A team of research nurses randomised each catheter to the appropriate dressing group. 10% povidone-iodine was used for cutaneous antisepsis before catheter insertion and for recleansing the skin at later dressing changes. Whenever dressings became soiled or non adherent, the old dressing was removed, the site was assessed, and after recleansing the site with povidone-iodine, a new sterile dressing of the same type was applied. Group 1 Sterile gauze and tape, replaced every 48 hours Group 2 Sterile gauze and tape, left on for the lifetime of the catheter Group 3 Polyurethane transparent dressing, left on until the catheter was removed (Tegaderm, 3M)	Local catheter-related infection (a positive semi quantitative culture of the catheter, ≥15 colony-forming units)	Group 1: 25 Group 2: 24 Group 3: 32 Group 4: 26	Funding: This study was supported in part by a grant from the Medical-Surgical Division/3M, St Paul Limitations: Catheters randomised rather than patients, some patients were entered into the study more than once. Additional outcomes: Adherence, moisture accumulation, contamination of catheter hubs, contamination of IV fluid, infecting organisms. Notes: Over half of the catheters were inserted in the operating room or in an intensive care unit, a quarter had been in place for over 72 hours
		Phlebitis (2 or more signs or symptoms at the catheter site – tenderness, erythema, swelling, purulence, or a palpable venous cord)	Group 1: 50 Group 2: 50 Group 3: 48 Group 4: 49	
		Bacteraemia	Group 1: 0 Group 2: 0 Group 3: 0 Group 4: 0	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	% intensive care: 25 Mean hours in place: 55 ±35 Group 3 N: 527 Age (mean): 51.5 % intensive care: 27 Mean hours in place: 52 ±33 Group 4 N: 498 Age (mean): 51.9 % intensive care: 27 Mean hours in place: 52 ±31	Group 4 Iodophor antiseptic incorporated in the adhesive, left on until the catheter was removed (transparent dressing with a poly-N-vinyl-pyrolidone-acrylated adhesive that contained 3% titratable iodine).			

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Tripepibova 1997 [473] Study design: RCT Setting: Cleveland Clinic Foundation. 6 units (2 medical oncology, surgical cardiology, general internal medicine, orthopaedic, and neurological intensive care USA Duration of follow-up: 3 days	Patient group: Patients with peripherally inserted lines. Inclusion criteria: Adult patients with a physician's prescription for peripheral IV therapy to be initiated in a vein in the forearm. Exclusion criteria: Patients were excluded if they were less than 18 years old, showed evidence of thrombocytopenia or immunosupression, or if they were pregnant. All patients N: 229 Age (mean): Drop outs: Group 1 N: 108 Group 2 N: 121	Preparation of the IV site included determination of the vein on which to initiate therapy, cleansing of the area with a pad saturated with povidone-iodine preparation, and allowing the area to dry. Catheter insertion sites were rotated every 72h. One RN from each shift on each study unit was designated as a shift research co-ordinator Group 1 Transparent polyurethane dressing (Opsite, Smith and Nephew) The dressing was applied directly over the insertion site for the IV catheter; no additional tape was used to secure the catheter in place. Group 2 Dry gauze (Mirasorb Sponges, Johnson and Johnson) Gauze dressings were applied over the IV catheter with tape applied to secure the IV tubing Dressing changed every 24 hours.	Phlebitis (Inflammation of a vein as evidenced by redness, pain, warmth, or swelling)	Group 1: 2 Group 2: 4 p value: not significant	Funding: Support for this study was provided by The Cleveland Clinic Foundation Research Programs Committee grant #4833 Limitations: No blinding, no baseline characteristics given. Additional outcomes: Infiltration, catheter dislodgment by patients

G.7.2 Types of dressings – Centrally inserted VADs

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Brandt 1996 [45] Study design: (e.g. RCT) Setting: Bone marrow transplant unit, Oncology centre. Pittsburgh, PA USA Duration of follow-up: Mean 21.7 days (range 3-68 days)	Patient group: Bone marrow transplant recipients with tunnelled, long-term central venous catheters Inclusion criteria: Patients aged 18 years or older, alert, orientated and able to give written and verbal informed consent. They had to have had a central venous catheter inserted following hospital admission for autologous bone marrow transplant. Exclusion criteria: Preexisting bacteremia or fungemia within 14 days of study entry or if the CVC placement was intended to be short term. All patients N: 101 Group 1 N: 53 Age (mean): 40.7 Male/female: 13/40 Catheter duration: 22.3 days Group 2 N: 48 Age (mean): 42.3 Male/female: 10/38 Catheter duration: 21 days	Patients received assigned dressing until one of the following occurred: development of definitive catheter-related sepsis and subsequent catheter removal, removal of catheter for any reason, or hospital discharge. Skin cleansing – 3 alcohol swabs, followed by 3 povidone-iodine swabs and povidone iodine ointment to the catheter site at the time of dressing change. – same for each group. Dressings were changed sooner than protocol specifications if the dressing became wet or contaminated or lost adherence or if drainage at the site compromised dressing integrity. Group 1 Standard care protocol with dry, sterile gauze dressing changed every 24h Group 2 Opsite 3000 moisture vapour permeable (transparent) dressing changed weekly.	Exit site infection (erythema, tenderness, induration, purulence within 2cm of skin exit of catheter exclusive of the first 48h following catheter placement.)	Group1: 2 Group 2: 4	Funding: Not stated Limitations: Unclear randomisation, allocation concealment and blinding Additional outcomes: Dressing occlusiveness, tunnel infection, suspected CVC sepsis, microbiologic isolates.
			Catheter-related sepsis (systemic signs and symptoms consistent with infection, fungemia or bacteremia, catheter tip culture growth more an 30 cfu)	Group1: 1 Group 2: 5	
			Bacteremia/fungemia – unknown origin (more than 15 colonies culture forming units of bacteria/ml)	Group1: 6 Group 2: 3	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Petrosino 1988 [362] Study design: RCT Setting: Medical oncology units, Texas USA Duration of follow-up: 60 days	Patient group: Adults with long-term indwelling central venous catheters. **Inclusion criteria:** Oncology patients with a long term central venous catheter. **Exclusion criteria:** Patients who were not on the study for at least the first 7 days to collect basic culture data. All patients N: 52 Age (mean): 56 (range 17-73) Male/Female: 21/31 Drop outs:	Staff watched a video tape covering the covering the specifics of each protocol for patient teaching. The catheters used were all either single-or multiple lumen tunnelled catheters. Group 1 Tegaderm transparent –changed every 3 days Skin cleansed with peroxide, alcohol and povidone-iodine swab Group 2 Opsite transparent –changed every 3 days Skin cleansed with peroxide, alcohol and povidone-iodine swab Group 3 Gauze – changed daily Skin cleansed with peroxide, alcohol and povidone-iodine swab Group 3 No dressing Skin cleansed with peroxide, alcohol and povidone-iodine swab and povidone-iodine ointment - daily	Infection (skin culture, erythema, tenderness, and drainage) at 7-10 days	Group 1: 4/7 Group 2: 3/7 Group 3: 1/7 Group 4: 2/10	Funding: Supported in part by the University Research Institute of the University of Texas at Austin. Limitations: Data at 60 days was not reported as none of the remaining patients had any infection. Baseline data for each arm is not given. Unclear randomisation, allocation concealment or blinding. Unclear which study arm the drop outs were from. Additional outcomes: Mean composite infection rates, observation 2 (infection defined by skin culture and drainage – only available for n = 28),

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Shivnan 1991 [435] Study design: RCT Setting: Hepa-filtered bone marrow transplant unit of a regional oncology centre. Baltimore, USA Duration of follow-up: 30 days	Patient group: Patients undergoing bone marrow transplant Inclusion criteria: Patients with long term central venous catheters. Hematologic malignancy or immune-deficiency disease, had a pre-existing indwelling silastic right atrial catheter or a catheter recently inserted under sterile conditions in an operating room, and were admitted to the unit for either allogenic or autologous bone marrow transplant. All patients N: 103 Age: range 2-60y Drop outs: 5 (3 – unexpected discharge or transfer from the unit, 2 – dissatisfaction with the assigned dressing) Group 1 N: 47 Age (SD): 31.5 (12.2) Male/female: 31/16 Group 2 N: 51 Age (SD): 34.1 (13.1) Male/female: 28/23	All subjects received dry sterile gauze dressings for the first 24h, then began their assigned dressing regimen. Gauze dressing were covered during showers, whereas transparent dressings were not. Staff nurses caring for the subjects assessed catheter sites daily and recorded dressing change times. Decontamination technique – cleanse exit site with hydrogen peroxide, cleanse with povidone-iodine twice, allow to dry for 2 minutes, apply ½ cm antibiotic ointment (bacitracin, neomycin, and polymyxin). Group 1 Dry sterile gauze – changed daily Group 2 Transparent adherent dressing (Tegaderm, 3M, MN) – changed every 4 days	Exit site infection (defined in aplastic subjects at the study institution as ≥3 days of pain and erythema ± induration with a positive site culture) Catheter-related sepsis (positive blood culture with growth of the organism from the tip of the LTCC following its removal)	Group 1: 1 Group 2: 2 Group 1: 0 Group 2: 1	Funding: Provided in part by the 3M Company; a grant awarded by the American Nurses' Foundation Competitive Extramural Granted Program; by the Sigma Theta Tau International Nursing Honour Society Grants Program; and by the Nursing Department at JHOC Limitations: Blood cultures reported for entire group, not given for each dressing type – stated that there is no difference across the groups. Skin cultures only analysed for the first 75 subjects – n not given for each group. High number of dressings requiring modification – 27.5% Additional outcomes: Skin irritation, wet dressings, other complications, patient comfort and satisfaction.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Wille 1993 [503] Study design: RCT Setting: Bleuland Hospital, district general hospital with medical and surgical wards. Netherlands Duration of follow-up: Up to 3 weeks	Patient group: Patients hospitalised for major elective surgery Inclusion criteria: Patients older than 16 years, hospitalised for major elective surgery and scheduled to have a single – lumen subclavian or jugular central venous catheter All patients N: 101 Age (mean): Drop outs: (13 patients were randomised, but not analysed – no intention to treat performed) Group 1 N: 50 Age (mean): 70.1 Male/female: 27/23 No of catheters: 50 Total catheter days: 402 No. of dressings: 79 Group 2 N: 51 Age (mean): 64.1 Male/female: 27/24 No of catheters: 51 Total catheter days: 378 No. of dressings: 74	All catheter sites were newly created and the central-lines were inserted by one of the anaesthetists in the operating theatre. Topical antiseptics or antibiotic creams were not used. After 7 days the dressing was removed and the site inspected and re-cleansed Group 1 Transparent dressing (polyurethane film, continuously spread with vinyl ether adhesive) – (OpSite, Smith and Nephew, Hull, UK) Group 2 Transparent dressing (hydrophilic polyurethane film pattern-spread with a water-based acrylic adhesive) - (OpSite IV3000, Smith and Nephew, Hull, UK)	Catheter-related sepsis (Defined by a semi-quantitative catheter culture and a peripheral blood culture positive for the same species.) N = catheters	Group 1: 3 Group 2: 1	Funding: Supported by Smith and Nephew Research Limited Limitations: Additional outcomes: Dressing condition, durability, moisture accumulation, pain, ease of removal.
			Mean days in place	Group 1: 5.1 Group 2: 5.1	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Lecorre 2003 [256] Study design: RCT Setting: Canada Duration of follow-up: 6 months	Patient group: Haemodialysis patients with a long term central venous catheter. Inclusion criteria: Patients aged at least 18 years old, require hemodialysis treatment for chronic terminal renal insufficiency, had a tunnelled central venous catheter inserted in the jugular vein by a vascular radiologist and were competent and able to sign the informed consent form. Exclusion criteria: Patients with any other type of permanent or temporary catheter or a catheter inserted at a different site than the jugular vein, were on systemic antibiotic therapy, had a history of bacteremia during the last 3 months and their catheter was not changed. Also subjects with known dermatitis at the exit site or known hypersensitivity to a component of either dressing. All patients N: 62 (58 enrolled)	The catheter used for haemodialysis was a double lumen, tunnelled and inserted in the intern jugular vein. An aqueous solution of chlorhexidine 2% was used for skin asepsis. The exit site was covered temporarily with dry gauze until the next dressing change. No ointments or topical antimicrobial creams were used. Group 1 Standard polyurethane transparent dressing (3M Tegaderm 1635 transparent Iv dressing) that was replaced every 7 days during scheduled visit to the Haemodialysis unit Group 2 4x4 sterile dry gauze attached with stretch bandage (Mefix Tendra) that was replaced every 2-3 days depending on the scheduled visit for hemodialysis treatment (3 times/week)	Bacteremia	Group1: 1 Group 2: 2 Per 1000 catheter days Group1: 0.30 Group 2: 0.47 P = 0.44	Funding: Funded in part by research grants from 3M Canada Company, CR Bard Canada and SoluMed Canada. Limitations: Additional outcomes: Skin condition, quality of life – states no significant difference between the 2 groups, but actual values not given.
			Local infection (exit site infection)	Group1: 0 Group 2: 1 Per 1000 catheter days Group1: 0 Group 2: 0.23 P = 0.43	
			Total catheter days	Group1: 3348 Group 2: 4286	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Age (mean): Drop outs: 2 voluntarily withdrew, 1 catheter was removed prior to study start date, 1 patient died. Group 1 N: 29 Age (mean): 74 (36-87) Male/female: 13/16 Group 2 N: 29 Age (mean): 71 (50-88) Male/female: 14/15				

G.7.3 Frequency of dressing change

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Vokurka 2009[484] Study design: RCT Setting: Hospital, Czech Republic Duration of follow-up: 1 month	Patient group: Patients with acute myeloid leukaemia treated with intensive chemotherapy. Inclusion criteria: Adults with AML treated with intensive chemotherapy containing cytosine-arabinoside and anthracyclines. Exclusion criteria: Patients with damaged skin at baseline, those allergic to disinfectant, acrylate, or polyurethane, and patients with radiotherapy of the chest in their history were excluded. All patients N: 81 Group 1 N: 42 Age (mean + SD): 49.9 (10.7) Male/female: 26/16 Mean days (SD) with occlusive dressing: 22.8 (8.6) Mean (SD) number of dressing changes: 5.9 (2.5) Group 2 N: 39	Transparent polyurethane semi-permeable occlusive dressings (Bioclusive, Johnson and Johnson) and non-tunneled polyurethane CVCs were used. The CVCs were inserted into the vena subclavia. Povidone-iodine was used for skin disinfection at the time of CVC insertion and before any occlusive dressing application. Group 1 Dressing changed twice weekly (3-4 days) Group 2 Dressing changed once weekly (every 7 days) The dressings could be changed sooner in case of an unstitched, loose, or soiled dressing, insertion site inflammation, local	Local cutaneous damage	Healthy skin Group1: 25 Group 2: 26 Erythema Group1: 11 Group 2: 6 Erythema with itching or dry desquamation, Group1: 5 Group 2: 7 Moist desquamation, Group1: 1 Group 2: 0 Deep ulceration, necrosis Group1: 0 Group 2: 0 p value: not significant	Funding: Unsponsored Limitations: In the once weekly group, only 58% of the dressing changes were performed to protocol The mean interval was reduced to 5.4 days, instead of the original 7 days. The main reasons for these unplanned dressing changes were an unstitched or soiled dressing (52%), local bleeding (28%), insertion site inflammation in 10% and other reasons 10%. 80% of the changes were performed to protocol in group 1, with a mean interval of 3.8 days. Additional outcomes: Tolerance and pain
			CVC insertion site inflammation (local circular redness accompanied, in the case of larger reactions, with swelling and pain on palpation in the area	Group1: 55% Group 2: 25% p value: 0.008	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Age (mean + SD): 41.4 (14.9) Male/female: 19/20 Mean (SD) days with occlusive dressing: 25.1 (13.2) Mean (SD) number of dressing changes: 4.5 (2.4)	cutaneous damage, in-site bleeding, or other significant (technical) reason.	surrounding the point of percutaneous insertion).		
			Blood culture positivity	Group1: 21% Group 2: 21%	

G.7.4 Skin decontamination during dressing change for vascular access devices (peripheral and central access)

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Maki1991 [282] Study design: RCT Setting: Surgical ICU, US 1986-1987 Duration of follow-up:	Patient group: patients with CVC inserted Inclusion criteria: All patients over 18 years old scheduled for insertion of central or arterial catheters All patients N: 306 catheters in 125 patients Drop outs: 83/306 catheters did not meet inclusion criteria Group 1: 2% CHG aqueous N: 214 catheters included in analysis Drop outs: *Age mean : 51±19 M/F: NR Group 2: 10% aqueous iodine N: 227 catheters included in analysis Drop outs: *Age mean: 53±19 M/F: NR Group 2: 70% isopropyl	Group 1 2% chlorhexidine gluconate aqueous Group 2 10% povidone iodine aqueous solution Group 3 70% isopropyl alcohol For both groups: Catheter insertion: All catheters were inserted by house officers wearing sterile gloves using the Selfdinger technique. Before insertion, the entry site was scrubbed vigorously with the solution for 30s, and the excess wiped off with sterile gauze. Catheters were dressed with sterile gauze and tape Dressing change:	Catheter tip colonisation defined as growth of ≥ 10 3 cfu per ml from the distal 4-5 cm of the catheter.	Group 1: 5/214 Group 2: 21/227 Group 3: 11/227 Relative risk: see full guideline	Funding: Stuart Corporation, manufacturer of CHG gluconate Limitations: Methods of randomisation allocation and concealment unclear Randomised according to catheter, not patients Blinding not possible for staff, but microbiologist blinded.
			VAD line removal or frequency of line removal	Not reported	
			Infection-related mortality	Not reported	
			Septicaemia	Not reported	
			VAD related bacteraemia: Semiquantitative catheter culture and blood cultures positive for the same microbial species, with a negative culture of infusate and no other apparent source of septicaemia	Group 1: 1/214 Group 2: 6/227 Group 3: 3/227 **Relative risk: see full guideline P value: Not stat sig	
			VAD related phlebitis	Not reported	
			VAD related local infection	Erythema Group 1: 45.3% Group 2: 28.3% Group 3:39.2% Pain at site of insertion: Group 1: 20.4% Group 2: 19.3%	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	alcohol N: 227 catheters included in analysis Drop outs: *Age mean: 53±19 M/F: NR	Dressing removed every 48 hours, site inspected and released with the designated agents.		Group 3: 20.4% Tenderness Group 1: 31.1% Group 2: 32.7% Group 3: 25.0%	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Valles2008 [476] Study design: RCT, block randomisation Setting: Medical surgical ICU of teaching hospital, Spain from January 1, 2005, to June 30, 2006, Duration of follow-up:	Patient group: Consecutive central venous catheter or arterial catheter inserted Inclusion criteria: > 18 years of age Exclusion criteria: catheters inserted into patients before they were admitted to the ICU catheters inserted with the use of a guidewire catheters inserted for hemodialysis or for long-term total parenteral nutrition or chemotherapy pulmonary artery catheters catheters removed within less than 24 hour of their	Group 1 2% CHG in aqueous solution (prepared in the pharmacy) Group 2 0.5% CHG in alcohol Group 3 10 % PVP-I in aqueous solution For all groups: For insertion: The site of CVC or AC insertion was prepared with the appropriate agent and was allowed to dry according to a standardized protocol. All catheters were	Catheter tip colonisation defined as growth of ≥ 15 cfu from a semiquantitative culture of the catheter tip by the roll plate technique	Intention to treat analysis Group 1: 36/116 (31%) Group 2: 27/116 (23%) **Relative risk: 1.33 [95% CI: 0.87, 2.04] P value: Not stat sig Catheter tip colonisation (per protocol analysis) Group 1: 31/92(34%) 34 cases per 1000 catheter days Group 2: 24/88 (27%) 46 cases per 1000 catheter days **Relative risk: 1.24 [95% CI: 0.79, 1.93] P value: Not stat sig	Funding: MediFlex (supplier of 0.5% tincture of chlorhexidine), and Physician Services Incorporated. Limitations: Allocation concealment potentially compromised – block randomisation followed by treatments that are visually different Baseline catheter characteristics only reported for patients who had catheter in place for more than 72 hours Additional outcomes:
			VAD line removal or frequency of line removal	Not reported	
			Infection-related mortality	Not reported	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	insertion catheters that remained in place 72 hours after patients were discharged from the ICU. All patients N: 631 CVCs and ACs inserted into 329 patients were included in the study for per protocol analysis out of 998 catheters were inserted in 420 patients Group 1: Chlorhexidine 2% aq Tincture N: 339 catheters for ITT 107 patients, 211 catheters for per protocol analysis Age, mean ± SD, years: 60±16 APACHE II score, mean ± SD: 20±7 Duration of catheterization, mean ± SD: 7.5±4.5 CVC used: 129/211(61.1%) AC used: 82/211(38.9% Group 2 Chlorhexidine 0.5% alc N: 329 catheters for ITT, 116 patients, 226 catheters	inserted by medical or nursing staff using maximal barrier precautions (ie, using sterile gloves, gowns, masks, and large drapes). Dressing change: Sterile gauze dressings were changed every 72 hours, or sooner if soiled or wet, and the catheter insertion site was cleansed with the agent to which the patient had been randomized. All catheters were cared for in a similar manner.		All cause mortality Group 1: 29/106(27.1%) Group 2: 22/106(19%) Group 3: 25/106(23.6%)	Hypersensitivity: none reported Notes: ** values calculated by NCGC Microbiological techniques performed by laboratory staff blinded to treatment assignment
			VAD related Septicaemia semiquantitative catheter-tip culture was positive for a microorganism, the patient had a temperature of 38.5°C or more, and the patient had a sustained reduction of at least 1°C of body temperature within 48 hours after catheter removal, with no other apparent cause of fever	Per protocol analysis Group 1: 17 per 211 catheters (8%) Group 2: 15 per 226 catheters (6.6%) Group3: 19 Per 194 catheters (10%) **Relative risk: Group 1 vs 2: Group 1 vs 3: Group 2 vs 3: P value: Not stat sig for all	
			VAD related bacteraemia, the same microorganism (ie, the same species with the same antibiotic susceptibility profile) was recovered from the catheter-tip culture and from blood culture.10	Group 1: 9 per 211 catheters (4.26%) Group 2: 9 per 226 catheters (3.98%) Group3: 9 Per 194 catheters (4.63%) **Relative risk: Group 1 vs 2: 1.07 [0.43, 2.65] Group 1 vs 3: 0.92 [0.37, 2.27] Group 2 vs 3: 0.86 [0.35, 2.12] P value: Not stat sig for all	
			VAD related phlebitis Measured as local inflammation at the site	Per protocol analysis Group 1: 35 per 211 catheters (16.8%) Group 2: 38 per 226 catheters (17%)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	for per protocol analysis Age, mean ± SD, years: 61±17 APACHE II score, mean ± SD: 19±6 Duration of catheterization, mean ± SD: 7.1±4.1 CVC used: 139/226(61.5%) AC used: 87/226(38.5 %) Group 3: 10% PVP-I in aq N: 329 for ITT, 106 patients, 194 catheters for per protocol analysis Age, mean ± SD, years: 61±17 APACHE II score, mean ± SD: 18±9 Duration of catheterization, mean ± SD: 7.7±4.8 CVC used: 112/194(57.7%) AC used: 82/194(42.3%)		of catheterisation	Group3: 30 per 194 catheters (15.6%) P value: Not stat sig for all	
			VAD related local infection	Not reported	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Humar2000 [199] Study design: RCT, block randomisation Setting: 3 teaching hospitals, including 2 surgical ICUs, 1 medical ICU and 1 neurological ICU Duration of follow-up:	Patient group: Patients with central venous catheter inserted for any purpose Inclusion criteria: > 18 years of age Treating physician felt that the inserted catheter would be present for minimum of 72 hours The CVC consistent of conventional singe- or multi-lumen polyurethane catheters, silicone catheters, and pulmonary arterial catheters All patients N: 374 Drop outs: 132/374 had line removed before 72 hours or died Group 1: Chlorhexidine 0.5% tincture N: 193 (baseline data for 125 patients reported) Drop outs: 68/193 (35.3%) Age mean±SD (range): 58.3±16.8 M/F: 78/47	Group 1 0.5% tincture of chlorhexidine (alcoholic) Group 2 10% povidone iodine For both groups: The agents were prior to insertion and subsequent catheter care. For insertion: Site for the CVC cannulation was prepared with the agent and allowed to dry according to standard protocol. All catheters were inserted by staff who used maximum barrier precautions with sterile gloves, gown, mask and large drapes. Dressing change: Sterile gauze dressings were changed every 72 hours or sooner if soiled or wet. The catheter exit site was cleansed for 20-30s with the agent.	Catheter tip colonisation defined as growth of ≥ 15 cfu from a semiquantitative culture of the catheter tip by the roll plate technique.	Intention to treat analysis Group 1: 36/116 (31%) Group 2: 27/116 (23%) **Relative risk: 1.33 [95% CI: 0.87, 2.04] P value: Not stat sig Catheter tip colonisation (per protocol analysis) Group 1: 31/92(34%) 34 cases per 1000 catheter days Group 2: 24/88 (27%) 46 cases per 1000 catheter days **Relative risk: 1.24 [95% CI: 0.79, 1.93] P value: Not stat sig	Funding: MediFlex (supplier of 0.5% tincture of chlorhexidine), and Physician Services Incorporated. Limitations: Allocation concealment potentially compromised – block randomisation followed by treatments that are visually different Baseline catheter characteristics only reported for patients who had catheter in place for more than 72 hours Additional outcomes: Purulent exit site infection: CHG: 0/125, mean 3.1±1.9 x105 cfu/mL per 25cm2 Povidone Iodine: 4/117 (3.4%), mean 5.9±2.6 x105 cfu/mL per 25cm2 Secondary bacteraemia (from a source other than CVC): 22/125 (17.6%) in the
			VAD line removal or frequency of line removal	Not reported	
			Infection-related mortality	Not reported	
			Septicaemia	Stated in protocol but not reported in results	
			VAD related bacteraemia, defined as single positive blood culture, with no other source of bacteraemia in the presence of a culture of a catheter segment from which the same organism was	Intention to treat analysis Group 1: 4/193 (2.1%) 3.9 cases per 1000 catheter days Group 2: 5/181(2.8%) 4.4 cases per 1000 catheter days **Relative risk: 0.75 [95% CI: 0.20, 2.75] P value: Not stat sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	APACHE II score: 21.2±8.9 Other devices: Endotracheal tube: 97/125(77.6%) Mean amount of time catheter in situ (days): 6.9 ± 3.6 Group 2: Povidone Iodine N: 181 (baseline data for 117 patients reported for baseline data) Drop outs: 64/181 (35.4%) Age mean±SD (range):62.2±16.0 M/F: 96/204 APACHE II score: 19.7±8.1 Other devices: Endotracheal tube: 89/125 (76.1%) Mean amount of time catheter in situ (days): 8.3 ± 6.9 days – reported in text (reported as 8.3 ±7.8 in table 2)	No silver antiseptic or antimicrobial impregnated catheters were allowed for patients involved in the study.	isolated. If results of molecular subtyping was discordant, patients were considered to have bacteraemia from another source	These were two other "probable cases" – catheter tip not retrieved to verify diagnosis, one in each treatment arm. VAD related bacteraemia Group 1: 4/125 (3.2%) 4.6 cases per 1000 catheter days Group 2: 4/117(3.4%) 4.1 cases per 1000 catheter days **Relative risk: 0.94 [95% CI: 0.24, 3.66] P value: Not stat sig	chlorhexidine and 13/117 (11.1 %) patients in the povidone iodine group Notes: ** values calculated by NCGC Study reported the intention to treat analysis results and per protocol analysis (only including patients who had catheter for more than 72 hours) Catheter sites inspected every 72 hours for evidence of infection, including erythema, and purulent discharge at the exit site. Decisions to remove catheters were made independently by the treating physicians. Microbiological techniques performed by laboratory staff blinded to treatment assignment
			VAD related phlebitis	Not reported	
			VAD related local infection – purulent discharge from the exit site, regardless of whether an organism was cultured from the site	Intention to treat analysis: Group 1: 0/193 Group 2: 4/181 **Relative risk: 0.10 [95% CI: 0.01, 1.91] P value: 0.053 Per protocol analysis: Group 1: 0/125 Group 2: 4/117 (4.1/1000 catheter days) **Relative risk: 0.10 [95% CI: 0.01, 1.89] P value: 0.053	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Mimoz2007 [298] Study design: RCT – randomised by catheter Setting: May 2004 to June 2006 in ICU surgical unit of a university affiliated hospital Duration of follow-up: 72 hours post IV line removal	Patient group: Patients in a surgical ICU with central venous catheter Inclusion criteria: Consecutively scheduled non-tunnelled central venous catheters expected to remain in place for 3 days or more. Ultrasound was not used to guide catheter reinsertion Exclusion criteria: Catheters inserted outside ICU, in patients with a history of allergy to any of the agents, at an existing site of a guide wire, via femoral route or for hemodialysis Group 1: Chlorhexidine based solution N: 195 patients, 242 catheters Drop outs: 28 catheters not evaluable out of 270 randomised Age mean±SD (range):57±18 M/F: 163/32) SAPSII: 42±17 Group 2: 5% Povidone Iodine in 70% ethanol N: 204 patients, 239 catheters Drop outs: 29 catheters not	Group 1 0.25% chlorhexidine gluconate, 0.025 benzalkanium chloride, and 4% benzylic alcohol (Biseptine TM, Bayer) Group 2 5% povidone Iodine in 70% alcohol (Betadine TM Viatris) Method of disinfection: At insertion: Skin was disinfected twice (once before and once after placement of large disposal drapes) with the assigned solution for at least 30s and allowed to dry between each antiseptic application. Dressing change: every 72 hours, dressings removed by nurse wearing a cap, a surgical mask and sterile gloves. Catheter insertion	Catheter tip colonisation defined as quantitative culture of at least 1 microorganism at a concentration of 1000cfu/ML or greater.	All evaluable cases Group 1: 28/242 (11.6%) 9.7 per 1000 catheter days Group 2: 53/239 (22.2%) 18.3 per 1000 catheter days Relative risk: 0.52 [0.34, 0.80] P value: 0.002 Catheter in place for > 3 days Group 1: 28/204 (13.7%) Group 2: 52/211(24.6%)	Funding: Bayer Healthcare, Viatris Pharmaceuticals, Centrale Hospitalier et Universitaire de Pottiers Limitations: Consecutively scheduled CVC insertion was randomised and stratified by site of insertion in blocks of 8 Allocation concealment potentially compromised because interventions are visually different (non blinded). However, investigators assessing outcomes and microbiologists were blinded to intervention type. Additional outcomes: Independent factors for catheter
			VAD line removal or frequency of line removal	Mean duration of catheter placement: Group1:12.0±9.1 Group2: 12.1±9.2	
			Infection-related mortality	3 patients with VAD related blood stream infection died, but “the medical staff did not consider any death to be unequivocally linked to catheter related sepsis)	
			Septicaemia	Not reported	
			VAD related blood stream infection defined as the isolation of the same microorganism from the catheter and from ≥ 1 cultured peripheral blood sample drawn 48 hours before or after catheter removal in patients with clinical manifestations	Group 1: 4/242 (1.7%) 1.4 per 1000 catheter days Group 2: 10/239 (4.2%) 3.4 per 1000 catheter days Relative risk: 0.40 [0.13, 1.24] P value: 0.09	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	evaluable out of 268 randomised Age mean±SD (range):58±19 M/F: 181/23* SAPSII: 43±16 *More male patients in povidone iodine group (P=0.04)	sites was then inspected for signs of infection or inflammation and disinfected with the assigned antiseptic solution, and a new sterile gauze was applied Catheter: 20-cm long, 7F triple lumen, unimpregnated polyurethane central venous catheters were placed percutaneously using Seldinger techniques	and no other apparent source except the catheter		colonisation were insertion at the jugular vein (ARR2.01), use of povidone iodine(ARR 1.87) and time from ICU admission to catheter insertion(ARR1.02). <u>Notes:</u> SAPSII = Simplified Acute Physiology Score II
			VAD related phlebitis Skin inflammation at insertion sites	Group 1: 64/242 (26.4%) Group 2: 64/239 (26.8%) Relative risk: 0.99 [0.73, 1.33] P value: 0.93	
			VAD related local infection	Not reported	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Parienti 2004 [347] Study design: Cross over trial, randomised by unit Setting: Two medical ICU units in a teaching hospital, Jan 2001 to Jan 2002. France Duration of follow-up: 12 month study period, cross over every 3 months	Patient group: All consecutive CVCs inserted Inclusion criteria: All consecutive CVC inserted Exclusion criteria: CVC insertion over a guidewire (allowed in case of CVC malfunction if no infection was present) CVC removal within 72 hours All patients N: 306 catheters in 125 patients Drop outs: 83/306 catheters did not meet inclusion criteria Group 1: 10% aqueous iodine N: 117 catheters included in analysis Drop outs: *Age mean: 61.5 M/F: NR APACHE II score: 26.3 *Organ failure score ≥2: 68/117 Mean amount of time catheter in situ (days):	Group 1 10% PVP-I aqueous solution Group 2 5% PVP-I in 70% ethanol solution For both groups: Catheter insertion: All catheters were inserted by staff who used maximum barrier precautions with sterile gloves, gown, mask and large drape using Selfdinger technique. Before insertion, the entry site was scrubbed with 4% povidone iodine solution, rinsed with sterile water and dried with sterile gauze. Protocol solution was then applied for ≥2 minutes. After placement of sterile drapes, the physician again disinfected the skin with the protocol solution. Dressing change:	Catheter tip colonisation defined as growth of ≥ 10 3 cfu per ml from the distal 4-5 cm of the catheter.	Group 1: 41 per 117 catheters (35.0%) Group 2: 14 per 106 catheters (13.2%) **Relative risk: 2.65 [1.54, 4.58] P value: <0.001	Funding: Supported in part, by government grants Limitations: The denominators are the number of catheters used, instead of number of patients. Number of patients randomised to each arm not reported This was a cluster randomised trial Additional outcomes: Notes: ** values calculated by NCGC A random number was used to assign the alcoholic povidone iodine to one of two units. Every 3 months, each unit switched from one product to another. The assigned product was used before CVC insertion and during the following care. When protocols are switched,
			VAD line removal or frequency of line removal	Not reported	
			Infection-related mortality	One death was a consequence of CVC related bacteraemia (MRSA endocarditis) in the aqueous povidone iodine arm	
			Septicaemia	Not reported	
			VAD related bacteraemia defined as catheter tip colonisation plus a peripheral or central blood culture yielding the same species as catheter tip within 48 hours of CVC removal with no other apparent source of sepsis	Group 1: 4 per 117 catheters (3.4%) Group 2: 1 per 106 catheters (0.9%) **Relative risk: 3.62 [0.41, 31.91] P value: Not stat sig	
			VAD related phlebitis	Not reported	
			VAD related local infection	Not reported	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	9.0±4.4 Group 2: 5% PI in 70% ethanol N: 106 catheters included in analysis Drop outs: *Age mean : 54.4 M/F: NR APACHE II score: 27.8 *Organ failure score ≥2: 87/106 Mean amount of time catheter in situ (days): 8.7±4.8 *statistically significant (P<0.05) between the two groups	Transparent sterile dressings were inspected daily and changed every 72 hours. Connections were manipulated with gauze soaked in the protocol solution. Others: Peripheral skin disinfection before catheter ablation were performed with 10% aqueous povidone iodine			CVCs already in place continued to be cared for using the same antiseptic until their ablation.

G.7.5 Skin decontamination prior to insertion of vascular access devices (peripheral access)

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Small et al 2008 [442] Study design: RCT Setting: University Hospital Birmingham, United Kingdom. Duration of follow-up: Unclear	Patient group: Elective cardiology patients admitted for ablation or pacemaker insertion at Inclusion criteria: Not stated Exclusion criteria: Less than 18 years of age, had skin dermatoses, had a chlorhexidine allergy All patients N: 230 Age (mean): 61.3 years (range, 21–96 years) M/F: 107/63 Drop outs: 60** Group 1 N: 91 Age (mean): Not reported M/F: 60/31 Drop outs: Not reported Group 2 N: 79 Age (mean): Not reported	Group 1 2% chlorhexidine gluconate (CHG) in IPA solution (in a Sepp 0.67 mL applicator; Enturia) Applied using a standard back-and-forth stroke over the entire skin insertion site for 30 seconds. Group 2 Wipes containing 0.6 mL of 70% IPA (Steret; Seton Prebble) Applied for 30 seconds, utilizing a circular movement as in routine clinical practice. Both groups: Each antiseptic was allowed to dry for 2 minutes before a polyurethane PVC (Optiva 2, Medex Medical) was inserted into a superficial vein of the hand. A semipermeable dressing was applied over the insertion site.	Catheter tip colonisation, determined by quantitative tip culture. The distal 3 cm of each PVC tip was vortexed in 1 mL of saline solution for 60 seconds, then 100 µL of the liquid was inoculated onto a blood agar plate (Oxoid) that was incubated in air at 37° C for 48 hours. The number of colony-forming units was determined, and microorganisms were identified by routine methods	Group 1: 18/91 (19.8%) Group 2: 39/79 (49.4%) Relative risk (95% CI): 0.40 (0.25, 0.64) p value: 0.0001 Calculated by NCGC using methods in Cochrane Handbook Additional info: Mean number of CFUs yielded from each culture-positive PVC tip : Group 1: 4 Group 2: 2 More than one type of microorganism was present on 5 tips from the CHG in IPA group and on 8 tips from the IPA group.	Funding: Enturia, manufacturer or 2 % CHG tips used Limitations: Large proportion of drop outs 60/230 (26%) Not blinded – interventions physically different Length of follow up not specified Only reported there were no evidence of infection* (see "Notes") Method of randomisation and allocation concealment unclear Additional outcomes: Chlorhexidine sensitivity: None Treatment with antibiotics: None Antibiotic prophylaxis for the cardiologic procedure (flucloxacillin) : given for 24 hours to 16
			VAD line removal or frequency of line removal (measured as mean indwelling period of the PVC tips)	Group 1: 2.3 days (range, 1–6 days) Group 2: 2.2 days (range, 1–4 days) Mean difference: 0.1 days P value: 0.07	
			Infection-related mortality*	Group 1: 0/91 Group 2: 0/79	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	M/F: 47/32 Drop outs: Not reported ** Reasons for exclusions: discharged prior to study completion (n=1) the PVC was in situ less than 24 hours (n=10), the PVC was accidentally discarded (n=23), a PVC different from all the others in the study was used (n=1) the explanted PVC was placed in a nonsterile dressing (n=25).	Prior to PVC removal, the insertion sites were cleaned with 70% IPA. Clean, non-sterile gloves, but not masks, were worn by the operator, and the PVC tips were not handled during explantation.		Relative risk: Not estimable	patients in the 2% CHG in IPA group and to 18 patients in the IPA group. Notes: *the paper only reported that "None of the patients exhibited evidence of infection" Clarifications obtained from author – VAD related blood stream infection and local infections were measured. With the achieved sample sizes, the study had a 90% power to detect a difference of infection rates of 50% with 70% IPA and a 25% with 2% CHG in IPA; the level of significance was set at 0.05
			Septicaemia	Not reported	
			VAD related blood stream infection/ Bacteraemia	Group 1: 0/91 Group 2: 0/79 Relative risk: Not estimable	
			VAD related phlebitis –	Not reported	
			VAD related soft tissue infection/local infection/skin infection*	Group 1: 0/91 Group 2: 0/79 Relative risk: Not estimable	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
deVries et al 1997 [96] Study design: RCT Setting: 400 bed municipal teaching hospital, Netherlands Duration of follow-up: 96 hours	Patient group: Admitted to pulmonary ward for parenteral prednisone for exacerbation of COPD Inclusion criteria: Not reported Exclusion criteria: Previous skin reactions to one of the skin disinfectants Imminent death All patients N: 125 Age (mean): NR Drop outs: 16 (4 accidental removal of catheter, 3 removed catheter because of technical problems, 4 had dressings which did not conform to protocol and 5 had stopped prednisone infusion before endpoint) Group 1 N: 54 Age (mean): 65.3 (12.4) M/F: 38/17 Catheters inserted on hands: 7(13.0%) Inserted by physicians: 13(24.1) Drop outs: not reported Group 2 N: 55 Age (mean): 69.5(10.5) M/F: 38/17 Catheters inserted on hands: 4 (7.3%) Inserted by physicians: 16(29.1%) Drop outs: not reported (%)	Group 1 2% iodine in 70% alcohol Group 2 70% alcohol Both groups: Catheters inserted by medical students or house officers. Skin shaved before inserted in patient consented. Following skin disinfection, skin was allowed to dry. The infusion sites covered with gauzes measuring 5x5cm, and an open dressing(Hypafix Smith & Nephew, Hull UK). Venflon 2 catheters, 18 and 20 G were used (BOC Ohmeda AB, Helsingborg, Sweden). Usual infusion scheme: 2 days of prednisone infusion 60mg/day, dissolved in normal saline, two days 50 mg/day, and 2 days 40mg/day after which prednisone was continued orally. Theophylline 600mg/day added in indicated.	Catheter tip colonisation, VAD line removal or frequency of line removal Infection-related mortality Septicaemia VAD related blood stream infection/ Bacteraemia* VAD related phlebitis "Phlebitis" diagnosed if two or more of these criteria were present at the insertion site : pain, tenderness, erythema, swelling, purulence and a palpable venous cord VAD related soft tissue infection/local infection/skin infection*	Not reported Not reported Not reported Not reported Not reported Group 1: 12/54 (22.6%) Group 2: 6/55 (10.6%) Relative risk (95% CI): 2.04 (0.82, 5.04) P value: 0.12 Calculated by NCGC using methods in Cochrane Handbook None of these patients had purulence Not reported	Funding: Not reported Limitations: Not blinded Small sample size Additional outcomes: Phlebitis rates with and without theophylline infusions Notes: Chi square test was used

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Cobbett 1999 [77] Study design: RCT Setting: Canadian regional hospital Duration of follow-up: 72 hours post IV line removal	Patient group: Patients from various nursing units, including medical, surgical, obstetrical and outpatient/emergency Inclusion criteria: Ability to read in English and providing consent required a peripheral IV line All patients N: 300 Drop outs: not reported Age mean±SD (range):55.1±19.5 (13 to 94) M/F: 96/204 Most common category of admission: gynaecological (32%) Received continuous IV solution: 94% Mean amount of time IV in situ (hours): 43.5 ±48.9 Note: Baseline information for each group not reported separately. Authors reported no significant difference in the following variables: age, gender, medical diagnosis, type of IV fluid, catheter size, type of IV medication, classification of initiator, and length of time IV in place.	Group 1 0.5% chlorhexidine gluconate/70% isoprophyl alcohol swab Group 2 Alcohol swab followed by povidone iodine swab Group 3 Povidone iodine swab followed by alcohol swab	Catheter tip colonisation defined as growth of ≥ from a proximal or distal catheter segment in the absence of accompanying clinical symptoms	Not significant (p=0.62) different between groups.	Funding: Not reported Limitations: Number of patients followed up or analysed in each group not reported Additional outcomes: There were significantly less redness (p=0.001), pain (p<0.0001) and increase in temperature (p=0.03) in Group 1 compared to the others at 72 hours post IV removal at the insertion site Notes: Chi square test was used
			VAD line removal or frequency of line removal	Not reported	
			Infection-related mortality	Not reported	
			Septicaemia	Not reported	
			VAD related blood stream infection/ Bacteraemia*	Not reported	
			VAD related phlebitis	Not reported	
			VAD related local infection, "probable infection" defined as one or more of the following: fever, (>38.5%) or pain, erythema or heat at the involved vascular access site and more than 15 colony forming units cultured from intravascular cannula tip using semi quantitative culture method.	Group 1: 1.2% Group 2: 12.5% Group 3: 9.88% P value: 0.008 ("analysis of variance", reported by author) There were a total of 19 infections. The number of patients followed up in each group not reported. "majority of identified infections were assessed in post-discharge patients".	

Appendix H: Economic evidence tables

H.1 Hand decontamination

H.1.1 When to wash hands

K.L. Cummings, D.J. Anderson, K.S. Kaye. Hand hygiene noncompliance and the cost of hospital-acquired methicillin-resistant staphylococcus aureus infection. Infection Control and Hospital Epidemiology. 31(4):357-364. 2010. [87]

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CCA **Approach to analysis:** A stochastic model was developed to simulate a scenario in which the healthcare worker contacts 2 patients consecutively and fails to comply with hand hygiene guidelines after contact with the first patient and before contact with the second patient (NDCs). One million NDCs were simulated in order to quantify the cost of a single NDC. **Perspective:** USA Hospital **Time horizon:**	**Population:** Healthcare settings with a risk of MRSA transmission **Scenario 1:** Normal risk Healthcare worker hand decontamination noncompliance between contacts with two patients of unknown MRSA status. **Scenario 2:** High risk Healthcare worker hand decontamination noncompliance between two patient contacts when the first patient was colonised or infected with MRSA and the MRSA status of the second patient was unknown. Scenario 3: Alternative model Transmission of MRSA was not caused exclusively by	**Total cost of MRSA infection (mean):** Scenario 1: £30, 610 Scenario 2: £34, 839 Scenario 3: £37, 337 **Currency & cost year:** US dollars, year NR (assumed to be 2009; presented here as 2009/10 UK pounds‡) **Cost components incorporated:** Total hospital cost of treating an MRSA infection.	**Primary outcome measure:** Contaminated encounters (per 1 million noncompliant direct patient contacts): Scenario 1: 44, 284 Scenario 2: 953, 912 Scenario 3: 44, 173 **Other outcome measure:** Episodes of hospital-acquired MRSA colonisation (per 1 million noncompliant direct patient contacts): Scenario 1: 143 Scenario 2: 3, 340 Scenario 3: 83 Episodes of hospital-acquired MRSA infection (per 1 million noncompliant direct patient contacts): Scenario 1: 42 Scenario 2: 980	**Primary ICER (Intvn 2 vs Intvn 1):** NA **Other:** Mean cost per noncompliant direct patient contact : Scenario 1: £1.29 (95% CI, £0.59 - £1.98) Scenario 2: £34.14 (95% CI, £31.02 - £37.25) Scenario 3: £1.01 (95% CI, £0.30 - £1.71) **Analysis of uncertainty:** The simulation analyses were applied to a hypothetical 200-bed hospital at 85% occupancy. Sensitivity analysis was performed on the hand decontamination compliance rate to determine the cost-benefit of increasing hand decontamination compliance by 1% and 5%. Increasing hand decontamination compliance by 1% resulted in a decrease of annual NDCs by 20,046, prevention of 0.84 MRSA infections and a mean decrease in expected

K.L. Cummings, D.J. Anderson, K.S. Kaye. Hand hygiene noncompliance and the cost of hospital-acquired methicillin-resistant staphylococcus aureus infection. Infection Control and Hospital Epidemiology. 31(4):357-364. 2010. [87]				
Treatment effect duration: NA **Discounting:** N/A	direct patient contact – transmission could occur via contaminated environmental surfaces. This scenario assumed that each noncompliant event exhibited an equal probability of MRSA transmission regardless of whether direct patient contact had occurred.		Scenario 3: 27	MRSA-related costs of £25, 772. Increasing compliance by 5% resulted in a decrease in NDCs of 100, 232, prevention of 4.21 MRSA infections and a mean decrease in MRSA-related costs of £128, 863.
Data sources				
Health outcomes: Data regarding hospital admissions and episodes of contact obtained from Duke University Medical Centre. MRSA prevalence rates and rates of hand decontamination compliance obtained from reports by Jarvis 2007 and Dedrick 2007. The daily noncompliant direct patient contact rate was calculated by multiplying daily healthcare worker-patient contact rate by (1 - rate of compliance). **Quality-of-life weights:** NA **Cost sources:** The cost of each episode of MRSA infection was based on the median value reported by Abramson and Sexton 1999, who reported the cost distribution among published studies. The autors used the upper and lower estimates of the published ranges as the upper and lower CIs in order to generate a lognormal distribution for this range.				
Comments				
Source of funding: National Institute of Aging; John A. Hartford Foundation; Department of Infectious Disease at Duke University Medical Centre. **Limitations:** Cost of hand decontamination product not accounted for; rate of patient contact, exposure, and transmission may be different in a UK community setting; health effects not expressed as QALYs. **Other:** In the model it is assumed that: every day a healthcare worker enters a patient's room 56.38 times and 57.24% of room visits involve direct patient contact (=32.27 direct contacts per day), hand decontamination compliance is 55.13%, the prevalence of MRSA is 4.63% (therefore the probability of being MRSA +ve is 0.463), 31% of MRSA cases would be detected more than 48 hours after admission, transmission of MRSA to previously uncolonised patients is 1.43%.				
Overall applicability*: Partially applicable **Overall quality**: Minor limitations**				

Abbreviations: CEA = cost-effectiveness analysis; NDC = noncompliant direct patient contact; CI = confidence interval; NR = not reported; ‡ Costing year not reported – assumed 2009 – converted using 2009 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

P.W. Stone, S. Hasan, D. Quiros, E.L. Larson. Effect of guideline implementation on costs of hand hygiene. Nursing Economics. 25(5): 279-284. 2007.[451]				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CCA **Study design:** Observational study designed to investigate the costs of hand decontamination in hospitals with high and low hand decontamination compliance, as well as high and low frequency of alcohol hand rub use. **Perspective:** USA Hospital **Time horizon:** 1 year **Treatment effect duration:** NA **Discounting:** N/A	**Population:** 40 hospitals with a mean number of 417 active hospital beds each. **Intervention 1:** CDC Guideline stating that hand decontamination should be preformed: - before direct patient contact - before donning sterile gloves when inserting CVCs - before inserting invasive devices - before moving from a contaminated to a clean body site in the same patient - after touching the patient's intact skin, body fluids, or wounds - after contact with inanimate objects in patient's vicinity - after removing gloves For each hand decontamination indication, whether or not hand decontamination was preformed was recorded and if so, whether the healthcare worker used soap and water or an alcohol hand rub.	**Total cost (per 100 beds):** Intvn 1: £847 (range: 0- to £18, 385) **Currency & cost year:** 2002 US dollars (presented here as 2009/10 UK pounds‡) **Cost components incorporated:** Hand decontamination products and costs associated with implementaiotn of the guideline (e.g. educational materials, staff time, posters/flyers, mailings, etc).	**Primary outcome measure:** Compliance (mean) Intvn 1: 56.6% (range: 24% to 89%) **Other outcome measures (median per hospital):** Ratio of alcohol product use compared to soap and water Intvn 1: 2.87 (range: 0-22)	**Primary ICER:** Hospitals with high compliance† had an annual hand decontamination product cost that was £2, 995 greater than hospitals with low compliance†. **Other:** Hospitals with more frequent alcohol product use had an annual hand decontamination product cost that was £3, 174 greater than hospitals with less frequent alcohol product use. **Subgroup analyses:** None **Analysis of uncertainty:** None

P.W. Stone, S. Hasan, D. Quiros, E.L. Larson. Effect of guideline implementation on costs of hand hygiene. Nursing Economics. 25(5): 279-284. 2007.[451]
Data sources
Health outcomes: The Hand Hygiene Observation Instrument was used to observe hand decontamination at each hospital. The rate of compliance was calculated by dividing the numberof actual hand decontamination episodes by the total number of indications for hand decontamination. To estimate the ration of alcohol rub usage for hand decontamination, the number of hand decontamination episodes that occureed with alcohol was divided by the number of episodes that occurred with soap and water. **Quality-of-life weights:** NA **Cost sources:** Cost data were collected from each hospital using standardised abstraction forms.
Comments
Source of funding: National Institute of Nursing Research **Limitations:** should match checklist ; **Other:**
Overall applicability*: Partially applicable Overall quality: Potentially serious limitations**

‡ Converted using 2002 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

H.1.2 Cleaning preparation

J.P. Cimiotti, P.W. Stone, E.L. Larson. A cost comparison of hand hygiene regimes. Nursing Economics. 22(4):196-204. 2004. [74]

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CEA **Study design:** Non-randomised cross-over study. Intervention 1 was used by the subject group for 12 months, followed by intervention 2 for 12 months. Follow-up at monthly intervals. **Perspective:** USA Hospital	**Population:** Neonatal ICU nurses at two sites N: NR Age (mean): NR M/F: NR **Intervention 1:** 2% chlorhexidine gluconate hand soap **Intervention 2:** Water-less, 61% alcohol-based hand sanitizer and mild soap	**Cost components incorporated:** Product cost, nurse time **Total costs (mean):** Mean cost per 1,000 patient days (product cost only):: Intvn 1: £229 Intvn 2: £880 **Other:** Mean cost per 1,000 hand decontamination episodes (includes cost of nurse time): Intvn 1: £147 Intvn 2: £117	**Primary outcome measure:** Hand decontamination quality Intvn 1: 3.9 Intvn 2: 4.6 **Other outcome measures (mean):** Mean time required for hand decontamination regime: Intvn 1: 17.0 seconds Intvn 2: 13.2 seconds	**Basecase ICER (Intvn x vs Intvn 1):** Alcohol based hand rub was the dominant intervention (less costly with better hand decontamination quality) **Other:** None **Subgroup analyses:** None **Analysis of uncertainty**: None

J.P. Cimiotti, P.W. Stone, E.L. Larson. A cost comparison of hand hygiene regimes. Nursing Economics. 22(4):196-204. 2004. [74]				
Time horizon: Follow-up time of 2 years **Discounting:** NA		**Currency & cost year:** 2003 US dollars (presented here as 2009/10 UK pounds‡) **Cost components incorporated:** Product cost (including additional hand lotion)		
Data sources				
Health outcomes: Hygiene quality reported by two trained observers with good inter-rater reliability. **Quality-of-life weights:** NA **Cost sources:** Product costs provided by the manufacturer.				
Comments				
Source of funding: NR **Limitations:** No patient outcomes, non-community setting, US cost data, observational design, no control of unknown sample size.				
Overall applicability*: Partially applicable Overall quality: Potentially serious limitations**				
Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SA=sensitivity analysis, SD= standard deviation				

‡ Converted using 2003 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

E.L. Larson, A.E. Aiello, J. Bastyr, C. Lyle, J. Stahl, A. Cronquist, L. Lai, P. Della-Latta. Assessment of two hand hygiene regimens for intensive care unit personnel. Critical Care Medicine. 29(5):944-950. 2001 [250]				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CCA **Study design:** RCT **Perspective:** USA Hospital **Time horizon:** 4 week follow-up	**Population:** Full-time healthcare workers in the surgical ICU at a single site N: 50 Age (mean): 40.5 M/F: 11/39 **Intervention 1:** 2% chlorhexidine gluconate	**Total costs (mean):** Per healthcare worker per shift: Intvn 1:£ 0.83 Intvn 2:£0.74 **Currency & cost year:** 2003 US dollars (presented here as 2009/10 UK pounds‡) **Cost components**	**Primary outcome measure:** Mean microbial count Intvn 1: 4.64 Intvn 2: 4.72 **Other outcome measures (mean):** Deviations from protocol: Intvn 1: 22.6% Intvn 2: 7.9%	**Basecase ICER (Intvn x vs Intvn 1):** Alcohol based hand rub was dominant (less costly and reduction in microbial hand cultures). **Other:** None **Subgroup analyses:** None

E.L. Larson, A.E. Aiello, J. Bastyr, C. Lyle, J. Stahl, A. Cronquist, L. Lai, P. Della-Latta. Assessment of two hand hygiene regimens for intensive care unit personnel. Critical Care Medicine. 29(5):944-950. 2001 [250]				
Discounting: NA	(CHG) hand soap **Intervention 2:** 61% alcohol-based hand rub with emollients	**incorporated:** Product costs	Mean application time: Intvn 1: 21.5 seconds Intvn 2: 12.7 seconds	**Analysis of uncertainty:** None
Data sources				
Health outcomes: Microbial counts were measured using the glove juice technique. **Quality-of-life weights:** N/A **Cost sources:** Mean cost per shift calculated from reported values of applications (16.7 hand washes/shift for CHG; 6.1 hand washes and 17.7 applications/shift for alcohol group at a cost of $0.05/application and $0.025/application, respectively). Calculation does not account for cost of staff time or use of hand lotion.				
Comments				
Source of funding: 3M Health Care **Limitations:** No patient outcomes, intensive care setting, US perspective, no prospective costing, small sample size, short time duration. **Other:** Those in the alcohol-based group had significantly improved skin condition – based on both subjective and objective measures.				
Overall applicability*: Partially applicable Overall quality: Potentially serious limitations**				
Abbreviations: NR = not reported, N/A= not applicable, M/F = male/female, N = total number of patients randomized, RCT = randomized control trial, SE = standard error, CFU = colony forming units.				

‡ Converted using 2003 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

H.1.3 Bare below the elbow

No economic evidence was identified.

H.2 Sharps

H.2.1 IV cannulae

No economic evidence was identified.

H.2.2 Safety needles – phlebotomy

No economic evidence was identified.

H.2.3 Safety needles – dental syringe

No economic evidence was identified.

H.2.4 Safety needles – safety lancets

W.F. Peate. Preventing needlestick injuries in emergency medical system workers. Journal of Occupational and Environmental Medicine. 2001;43: 554-557.[356]				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CBA **Study design:** Before and after study of introduction of a spring-loaded automatic retracting glucometer lancet. **Perspective:** USA hospital perspective **Time horizon:** 3 years	**Population:** Active duty EMS workers for a municipal fire department **Cohort settings:** N: 477 Age (range) =20-61 M = 81% **Intervention 1:** Standard straight stick non-retracting glucometer used for two years **Intervention 2:** Self-retracting safety	**Total costs (mean):** Intvn 1: £16, 430 Intvn 2: £2, 052 Incremental (1-2):£14, 014 **Currency & cost year:** 1998 US dollars (presented here as 2009/10 UK pounds‡) **Cost components incorporated:** Device cost, physician evaluation and counselling for needlestick injury, antiviral medication, hepatitis boosters, and laboratory tests for both health care worker	**Primary outcome measure:** Needlestick injuries Intvn 1: 16 injuries over 2 years (954 worker-years) Intvn 2: 2 injuries over 1 year (477 worker-years) **Other outcome measures (mean):** None	**Primary ICER (Intvn 2 vs Intvn 1):** NA **Other:** The use of self-retracting safety lancets resulted in a department-wide net benefit of £14, 014. This figure was calculated based on estimated averted treatment costs from sharps injuries. **Subgroup analyses:** None **Analysis of uncertainty:** None

W.F. Peate. Preventing needlestick injuries in emergency medical system workers. Journal of Occupational and Environmental Medicine. 2001;43: 554-557.[356]				
Treatment effect duration: (e.g. 5 yrs) **Discounting:** N/A	glucometer used for one year	and source patient. Indirect costs were included but not reported here.		
Data sources				
Health outcomes: All health outcomes were obtained from the current study. **Quality-of-life weights:** None **Cost sources:** Cost source not specified. It was reported that each needlestick injury was associated with a medical cost of £1, 026, with indirect costs including time lost from active duty and decreased working efficiency due to the side effects of medication and stress.				
Comments				
Source of funding: NR **Limitations:** Resource use and cost source not clearly stated, observational before-after study; US setting **Other:** None				
Overall applicability*: Partially applicable Overall quality: Potentially serious limitations**				

H.3 PPE

H.3.1 Gloves

No economic evidence was identified.

H.3.2 Aprons and gowns

L.A. Puzniak, K.N. Gillespie, T. Leet, M. Kollef, L.M. Mundy. A cost-benefit analysis of gown use in controlling vancomycin-resistant enterococcus transmission: is it worth the price? Infection Control and Hospital Infection. 2004. 24; 418-425. [386]

Study details	Population & interventions	Costs	Health outcomes	Cost effectiveness
Economic analysis: CBA **Study design:** A decision pathway was built based on an observational before and after study comparing isolation procedures with gowns and gloves against isolation procedures with gloves alone. The primary outcome was prevention of the acquisition of vancomycin resistant enterococci. **Perspective:** USA Hospital **Time horizon:** 1 year **Discounting:** NA	**Population:** Patients admitted to the medical ICU for more than 24 hours **Intervention 1:** All healthcare workers and visitors were required to wear gowns and gloves on entry to rooms of patients colonised or infected with VRE from July 1997 to June 1998 and July 1999 to December 1999. **Intervention 2:** Between June 1998 to July 1999, healthcare workers and visitors were not required to wear gowns.	**Total costs (mean):** Intvn 1:£164 194 Intvnn 2:£96 627 **Currency & cost year:** 1998 US dollars (presented here as 2009/10 UK pounds‡) **Cost components incorporated:** Cost of gowns, gloves, hand decontamination, microbiology tests, isolation cart components, time required for staff to don and doff gowns.	**Primary outcome measure:** VRE infections and associated intensive care costs averted. Attributable cost per case of VRE: £10 947 Total averted attributable cost for annual gown period: £450 481 **Other outcome measures (mean):** None	**Basecase ICER (Intvn x vs Intvn 1):** Intvn 1: dominant strategy Net benefit of gown policy: £382 914 **Other:** None **Subgroup analyses:** None **Analysis of uncertainty:** Results were most sensitive to the probability of acquiring VRE. Gowns are more likely to impact transmission when there are high rates of VRE colonisation. The breakeven point (at which gowns become cost-saving) was 80% of the no-gown transition probability. Variation in the number of patient contacts, cultures per patient, cost of labour and materials did not change the dominant strategy, but did change the magnitude of the net benefit.

Data sources

Health outcomes: A matched before and after study design was used to determine the attributable cost of VRE: patients with and without VRE were matched based on APACHE II scores, DRG code, and age; clinical endpoints obtained from hospital system used to check for differences in co-infections between pairs. Number of VRE cases averted calculated by multiplying the difference in VRE rates between the study periods by the number of patients in the gown period.

Quality-of-life weights: NA

Cost sources: Costs estimated from Barnes-Jewish Hospital: ICU costs estimated by dividing patient's total hospitalisation cost by total days of hospitalisation and multiplying the quotient by the patient's total ICU days; time required to don and doff gowns obtained from observation of 128 healthcare workers on three occasions,

L.A. Puzniak, K.N. Gillespie, T. Leet, M. Kollef, L.M. Mundy. A cost-benefit analysis of gown use in controlling vancomycin-resistant enterococcus transmission: is it worth the price? Infection Control and Hospital Infection. 2004. 24; 418-425. [386]
multiplied by average nurse salary; microbiology costs inclusive of all related testing costs.
Comments
Source of funding: NR **Limitations:** Based on a cross-over trial designed to assess the impact of a policy change; results could be biased by behaviour change; USA hospital perspective; ICU setting. **Other:**
Overall quality*: Potentially serious limitations Overall applicability: Partially applicable**

Abbreviations: CBA = cost-benefit analysis; ICU = intensive care unit; VTE = vancomycin-resistant enterococcu; ICER = incremental cost-effectiveness ratio; N/A= not applicable; NR = not reported; ‡ Converted using 1998 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

H.4 Long term urinary catheterisation

H.4.1 Antibiotics

No economic evidence was identified.

H.4.2 Catheter type

No economic evidence was identified.

H.4.3 Bladder instillations and washouts

No economic evidence was identified.

H.5 PEGs

No economic evidence was identified.

H.6 Vascular access devices

H.6.1 Types of dressings – peripheral

No economic evidence was identified.

H.6.2 Types of dressings – Centrally inserted VADs

A.G. Crawford, J.P. Fuhr, B. Rao. Cost-benefit analysis of chlorhexidine gluconate dressing in the prevention of catheter related bloodstream infections. Infection Control and Hospital Epidemiology. 2004. 668-674. [85]				
Study details	**Population & interventions**	**Health outcomes**	**Costs**	**Cost effectiveness**
Economic analysis: CEA **Study design:** Decision analytic model. Primary clinical outcomes based on one RCT, other outcomes based on published literature **Perspective:** Healthcare system **Time horizon:** Duration hospitalised (5-7 days) **Discounting:** NA	**Population:** Adult patients requiring a central venous or arterial catheter N: 589 Age (mean):NR M/F: NR Drop outs: NR **Intervention 1:** CHD impregnated dressing (Biopatch) covered with transparent dressing – changed every 5-7 days **Intervention 2:** Transparent film dressing – changing regime NR	**Primary outcome measures based on RCT:** CRBSI Intvn 1: 2.37% Intvn 2: 6.12% (P=<.05) Local infection Intervention 1: 28.14% Intervention 2: 45.24% (P=<.001) **Other outcome measures based on literature:** Catheter colonisation leading to local infection 40% CRBSI-related mortality 1% to 4%	**Total costs (mean per patient):** NR **Other:** CHD dressing: £3.44 each x 2 every 5-7 days. Transparent dressing: NR Local infection: £367 CRBSI: £7, 336 to £22, 925 **Currency & cost year:** 2000 US dollars (presented here as 2009/10 GBP‡)	**Basecase ICER (Intvn 2 vs Intvn 1):** N/A **Other:** Use of chlorhexidine dressings results in 3.76% fewer CRBSIs, 6.84% fewer local infections and £300 to £885 in averted treatment costs compared to transparent film dressings. **Subgroup analyses:** None **Analysis of uncertainty**: Scenario analysis: As the cost of treating CRBSI was adjusted to a low of £7, 336 and high of £22, 925, the estimated averted treatment cost varied between £367 and £885, respectively.
Data sources				
Health outcomes:				

Incidence of local infection and CBRSI based on industry sponsored, non-published RCT (Chiacchierni et al, An evaluation of Biopatch antimicrobial dressing compared to routine standard of care in the prevention of catheter-related blood stream infection, Sommerville, NJ: Johnson and Johnson Wound Management; 1999; Maki et al, The efficacy of a chlorhexidine-impregnated sponge (Biopatch) for the prevention of intravascular catheter-related infection: a prospective, randomised controlled, multicenter study. Washington, DC: American Society for Microbiology; 2000); percentage of catheter colonisations leading to local infection based on an estimate by Saint et al 2000; mortality attributed to CRBSI based on estimates by Veenstra et al 1999, Saint et al, 2000, Wenzel and Edmond 2001, Mermel et al 2000, Byers et al 1995. **Quality-of-life weights:** NA **Cost sources:** Cost of dressings obtained from Johnson and Johnson; cost of local infection obtained from Saint et al 2000; cost of treating CRBSI based on estimates by Pittet et al 1994; Saint et al 2000 and O'Grady et al 2002.		
Comments		
Source of funding: Johnson & Johnson Wound Management **Limitations:** Key clinical data was based on an industry-funded non peer-reviewed study, efficacy study lacking key methodological details, short time horizon, US perspective, secondary-care setting, limits to generalisability of results, no incremental sensitivity analysis **Other:** Industry funded		
Overall quality*: Potentially serious limitations	**Overall applicability**: Partially applicable**	

Abbreviations: CEA = cost-effectiveness analysis; ICER = incremental cost-effectiveness ratio; CHD = chlorhexidine; CRBSI = catheter-related blood stream infection; NR = not reported; N/A= not applicable; GBP = Great British Pounds

‡ Converted using 2000 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices.

** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

J.C. Shivnan, D. McGuire, S. Freedman, E. Sharkazy, G. Bosserman, E. Larson, P. Grouleff. A comparison of transparent adherent and dry sterile gauze dressings for long-term central catheters in patients undergoing bone marrow transplant. Oncology Nursing Forum. 1991. 18(8):1349-1356. [435]				
Study details	**Population & interventions**	**Health outcomes**	**Costs**	**Cost effectiveness**
Economic analysis: CEA **Study design:** RCT with secondary consideration of costs and nursing time **Perspective:** Healthcare system **Time horizon:** Duration of follow-up 30 days **Discounting:** N/A	**Population:** Patients undergoing bone marrow transplant N: 103 Age (range): 2 to 60 Dropouts: 5 **Intervention 1:** Dry sterile gauze – changed daily **Intervention 2:** Transparent dressing (Tagaderm) – changed every 4 days	**Health outcomes measured:** Exit site infections Intervention 1: 1/47 Intervention 2: 2/51 Exit site infection progression to systematic infection Intervention 1: 0/1 Intervention 2: 0/2 CRBSI Intervention 1: 0/47 Intervention 2: 1/51	**Cost components incorporated:** Dressing unit cost, number of dressings per patient, nursing time and cost **Total costs (mean per patient per 30 days):** Intervention 1: Dressings per patient: 26 Total material cost: £83 Nurse time: 377 min (range 201-515) Total cost of nursing time: £120 Intervention 2: Dressings per patient:10.7 Total material cost: £27 Nurse time: 172.7 min (range 100-360) Total cost of nursing time: £45 **Currency & cost year:** 1989 US dollars (presented here as 2009/10 GBP‡)	**Primarly ICER (Intvn 2 vs Intvn 1):** N/A **Other:** Transparent dressings were less costly in terms of resource use and nursing time than gauze dressings. However, they were associated with a small (non significant) increase in infections. **Subgroup analyses:** NA **Analysis of uncertainty** NA
Data sources				
Health outcomes: Outcomes assessed based on the current study (Shivnan et al, 1991) **Quality-of-life weights:** NA **Cost sources:** Cost of materials based on hospital supply costs, cost of nurse time based on the hospital unit's average nursing salary in 1989.				
Comments				
Source of funding: 3M Scholar's Award, Sigma Theta Tau International Nursing Honour Society Grants Program, and the Nursing Department at Johns Hopkins Oncology Center. **Limitations:** US perspective, secondary care setting, short time frame. **Other:** Industry funded				

J.C. Shivnan, D. McGuire, S. Freedman, E. Sharkazy, G. Bosserman, E. Larson, P. Grouleff. A comparison of transparent adherent and dry sterile gauze dressings for long-term central catheters in patients undergoing bone marrow transplant. Oncology Nursing Forum. 1991. 18(8):1349-1356. [435]		
Overall quality*: Potentially serious limitations	**Overall applicability**: Partially applicable**	

*Abbreviations: CEA = cost-effectiveness analysis; ICER = incremental cost-effectiveness ratio; CHD = chlorhexidine; CRBSI = catheter-related blood stream infection; NR = not reported; N/A= not applicabl; GBP = Great British Pounds; USD = United States Dollars; ‡ Converted using 1998 Purchasing Power Parities and Hospital and Community Health Services Pay and Prices Inflation Indices. * Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

I. LeCorre, M. Delorme, S. Cournoyer. A prospective, randomised trial comparing a transparent dressing and a dry gauze on the exit site of long term central venous catheters of hemodyalisis patients. Journal of Vascular Access. 2003. 4; 56-61. [256]				
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: CCA **Study design:** RCT **Approach to analysis:** An estimate of the cost of each dressing change was analysed during a 4-week period on 10 subjects randomly selected from each group. Efficacy estimates related to the patients enrolled in the whole study – these results along with the cost estimates derived from the 10 patients are reported here. **Perspective:** Canadian healthcare system	**Population:** Haemodyalisis patients with a long-term central venous catheter. **Cohort settings:** N: 58 Mean age = 72.5 M =47% **Intervention 1:** Dry sterile gauze – changed every 2-3 days **Intervention 2:** Transparent dressing – changed every 7 days	**Total costs (mean per patient per week):** Intvn 1: £8.23 Intvn 2 : £5.11 Incremental: £3.11 **Currency & cost year:** 2000 Canadian dollars (presented here as 2009/10 GBP‡) **Cost components incorporated:** Material cost per week (included costs of masks, non sterile gloves, dressings, chlorhexidine sticks, and tape), cost of nursing time.	**Primary outcome measure:** Bacteraemia Intvn 1: 2 Intvn 2: 1 **Other outcome measures (mean):** Bacteraemia per 1000 catheter days Intvn 1: 0.47 Intvn 2: 0.30 Local infection Intvn 1: 1 Intvn 2: 0 Local infection per 1000 catheter days Intvn 1: 0.23 Intvn 2: 0 Quality of life Report that there was no significant difference	**Primary ICER (Intvn 2 vs Intvn 1):** Transparent dressings were less costly and more effective than gauze dressings. **Other:** None **Subgroup analyses:** None **Analysis of uncertainty:** None

I. LeCorre, M. Delorme, S. Cournoyer. A prospective, randomised trial comparing a transparent dressing and a dry gauze on the exit site of long term central venous catheters of hemodyalisis patients. Journal of Vascular Access. 2003. 4; 56-61. [256]				
Time horizon: Study duration: 6 months **Treatment effect duration:** 4 weeks **Discounting:** NA			between the two groups in quality of life. SF-36 values NR.	
Data sources				
Health outcomes: LeCorre 2003. **Quality-of-life weights:** NA **Cost sources:** NR				
Comments				
Source of funding: Funded in part by research grants from 3M Canada Company, CR Bard Canada and SoluMed Canada. **Limitations:** Cost source not reported, Canadian healthcare system **Other:** Industry funded				
Overall applicability*: Partially applicable Overall quality: Potentially serious limitations**				

Abbreviations: CCA = cost consequence analysis; ICER = incremental cost-effectiveness ratio; CRBSI = catheter-related blood stream infection; NR = not reported; N/A= not applicabl; GBP = Great British Pounds; ‡ Converted using 2000 Purchasing Power Parities) and Hospital and Community Health Services Pay and Prices Inflation Indices.
** Directly applicable / Partially applicable / Not applicable; ** Minor limitations /Potentially serious Limitations / Very serious limitations*

H.6.3 Frequency of dressing change

No economic evidence was identified.

H.6.4 Skin decontamination during dressing change for vascular access devices (peripheral and central access)

No economic evidence was identified

H.6.5 Skin decontamination prior to insertion of vascular access devices (peripheral access)

No economic evidence was identified

Appendix I: Forest plots

I.1 Hand decontamination

I.1.1 Before vs. after implementation of a hand hygiene guideline (when to wash hands)

Figure 1: Hand hygiene compliance - overall (APIC guideline)

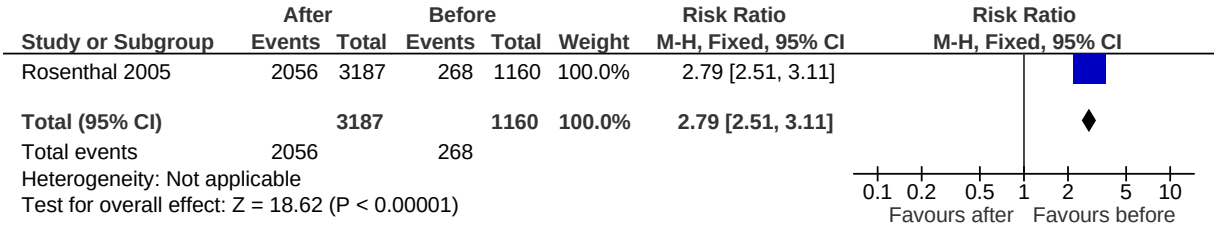


Figure 2: Nosocomial infections per 1000 bed days (APIC guideline)

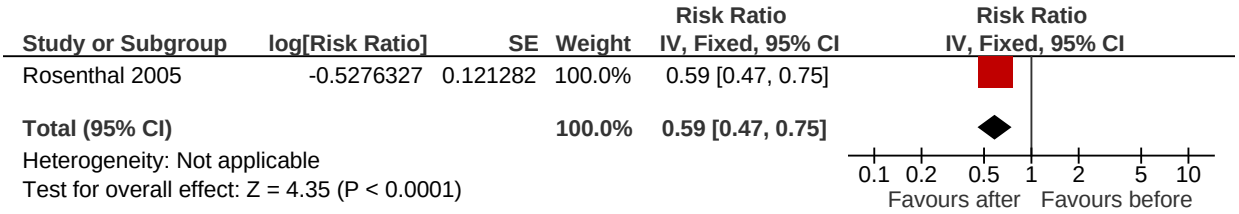


Figure 3: Hand hygiene compliance - overall (WHO 5 moments)

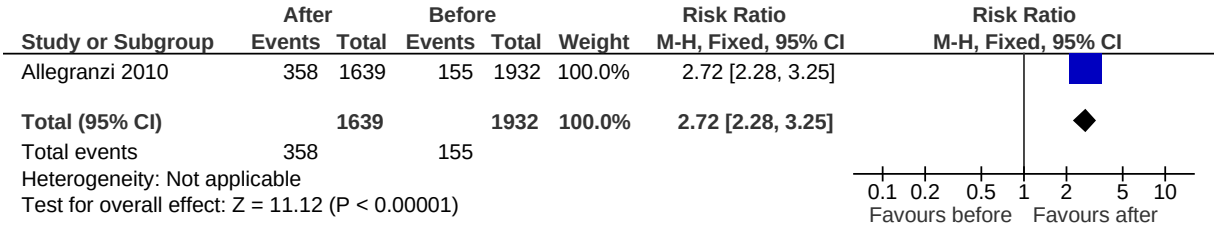


Figure 4: Hand hygiene compliance - WHO 5 moments

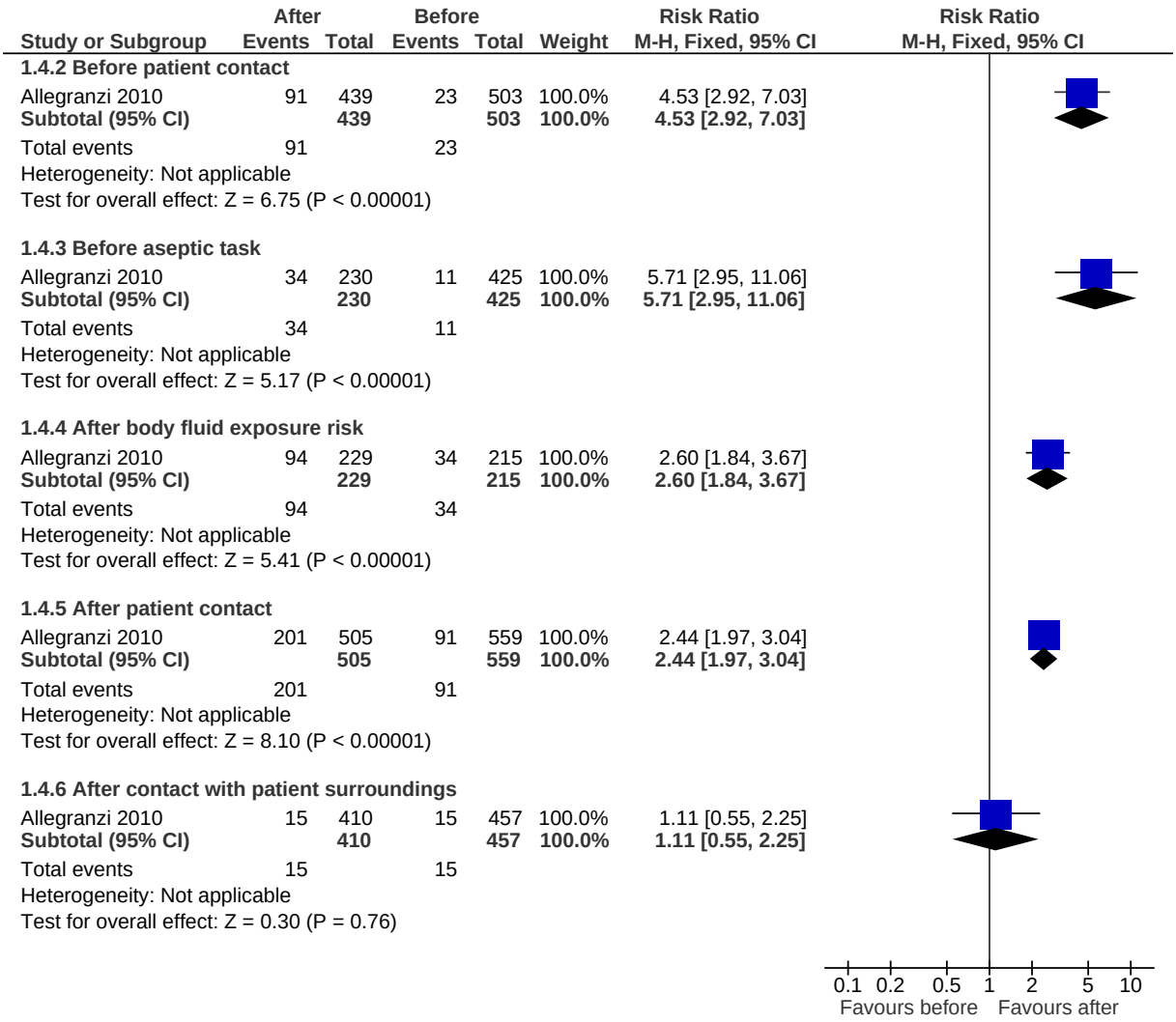


Figure 5: Healthcare associated infections - WHO 5 moments

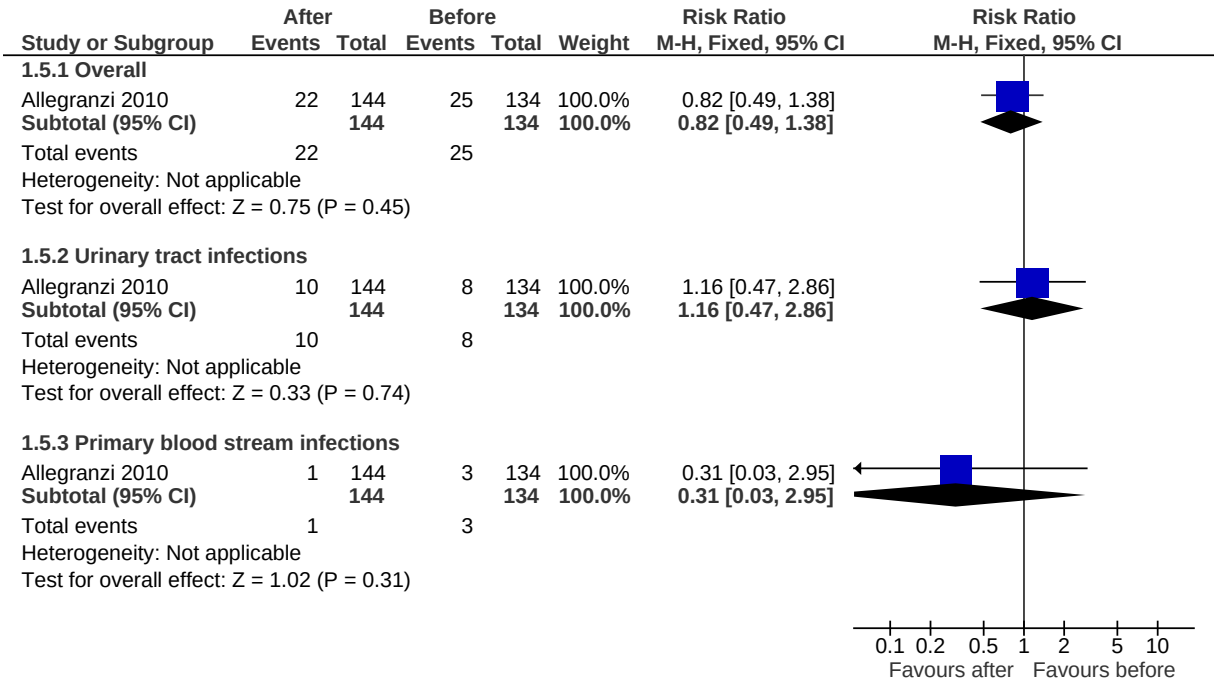


Figure 6: Hand hygiene compliance (CDC 2002 guideline)

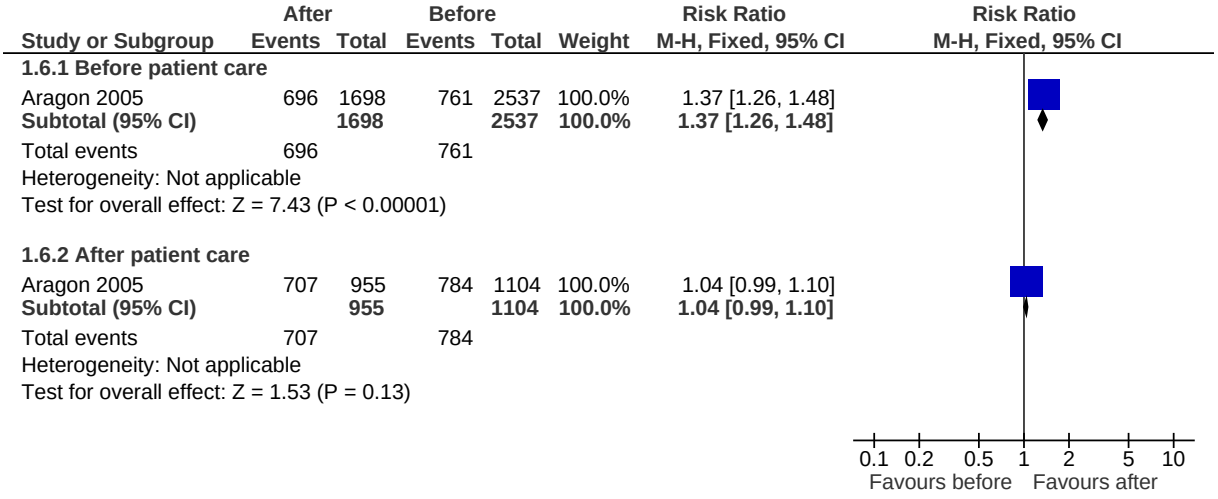
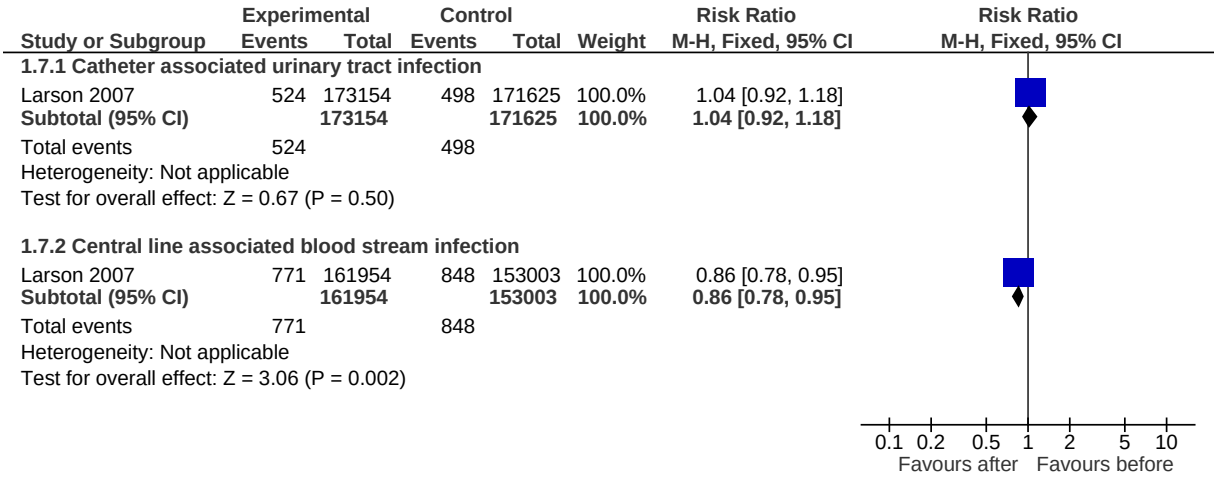


Figure 7: Healthcare associated infections (CDC 2002 guideline)

Cleaning preparation



I.1.1.1 Alcohol handrub vs non-antiseptic soap hand wash

Figure 8: Colony forming units (Log10)

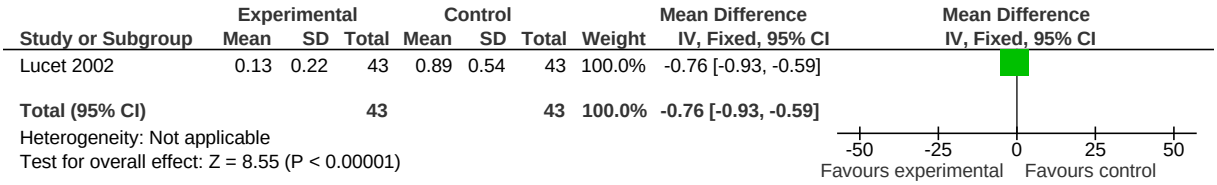
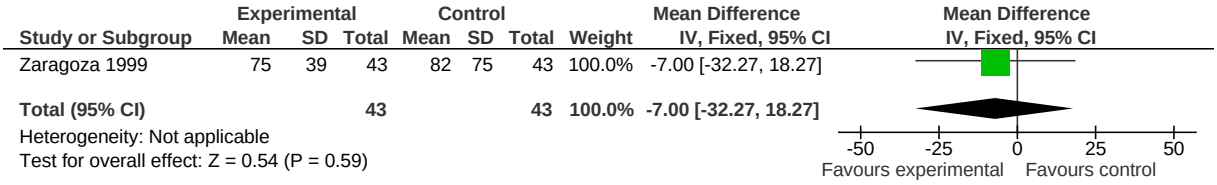


Figure 9: Mean colony forming units



I.1.1.2 Alcohol handrub vs 4% CHG soap hand wash

Figure 10: Colony forming units (Log10)

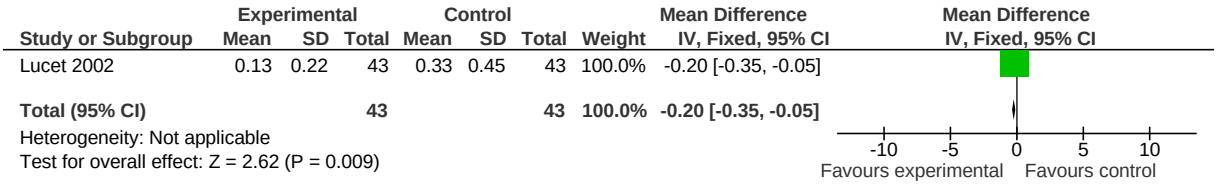
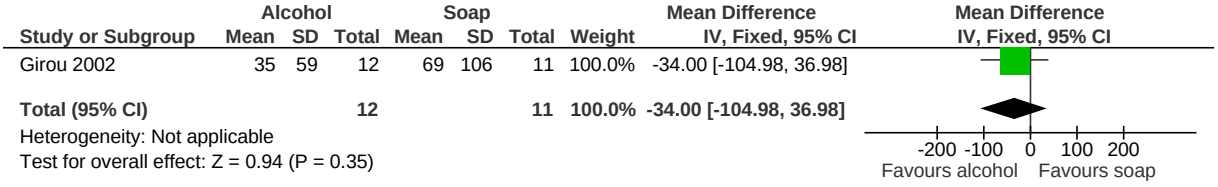
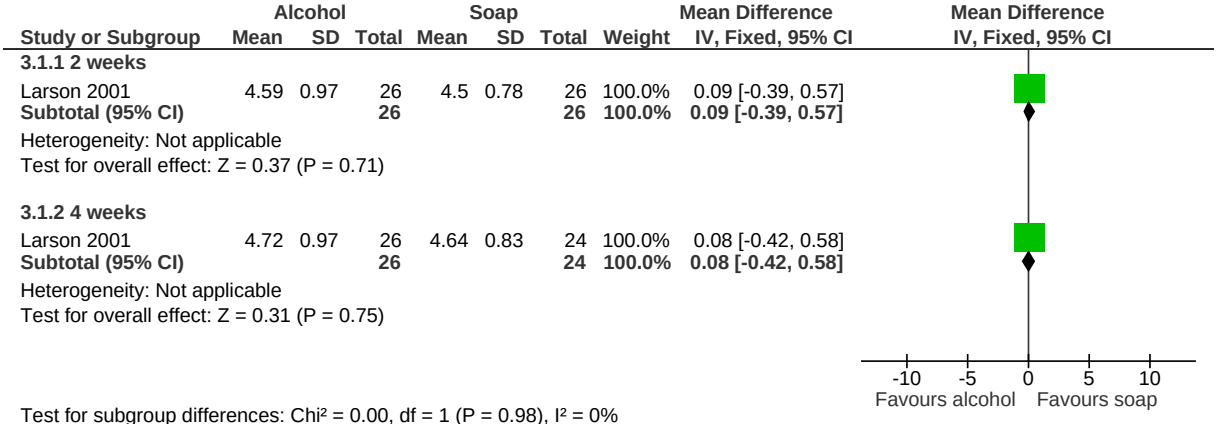


Figure 11: Colony forming units



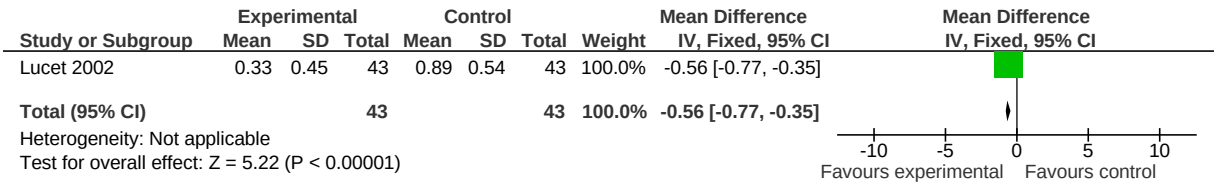
I.1.1.3 Alcohol handrub vs 2% Chlorhexidine gluconate (CHG) soap hand wash

Figure 12: Colony forming units



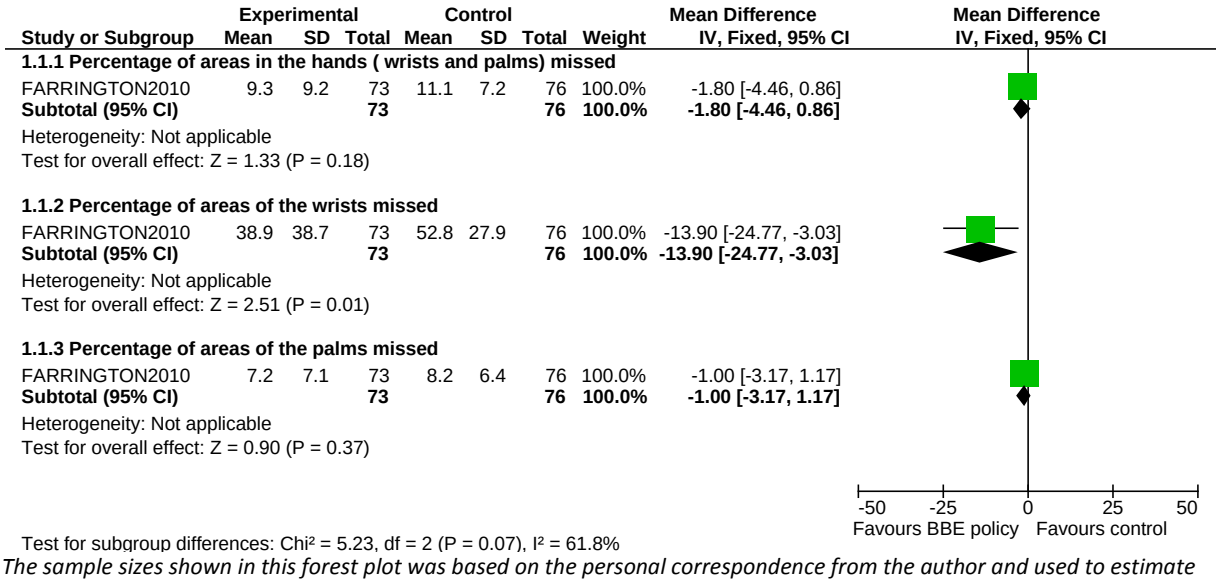
I.1.1.4 4% CHG soap hand wash vs non-antiseptic soap hand wash

Figure 13: Colony forming units (Log10)



I.1.2 Bare below the elbow vs usual policy

Figure 14: Percentage of areas of different parts of the hands missed in hand washing



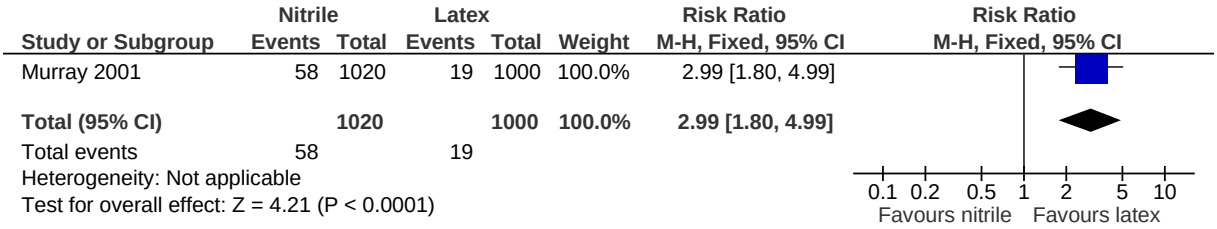
The sample sizes shown in this forest plot was based on the personal correspondence from the author and used to estimate the effect sizes.

I.2 Personal protective equipment

I.2.1 Gloves

I.2.1.1 Nitrile versus latex gloves

Figure 15: Glove punctures



I.2.2 Aprons and gowns

I.2.2.1 Aprons vs no aprons

Figure 16: MRSA Positive Clothing - Care assistants

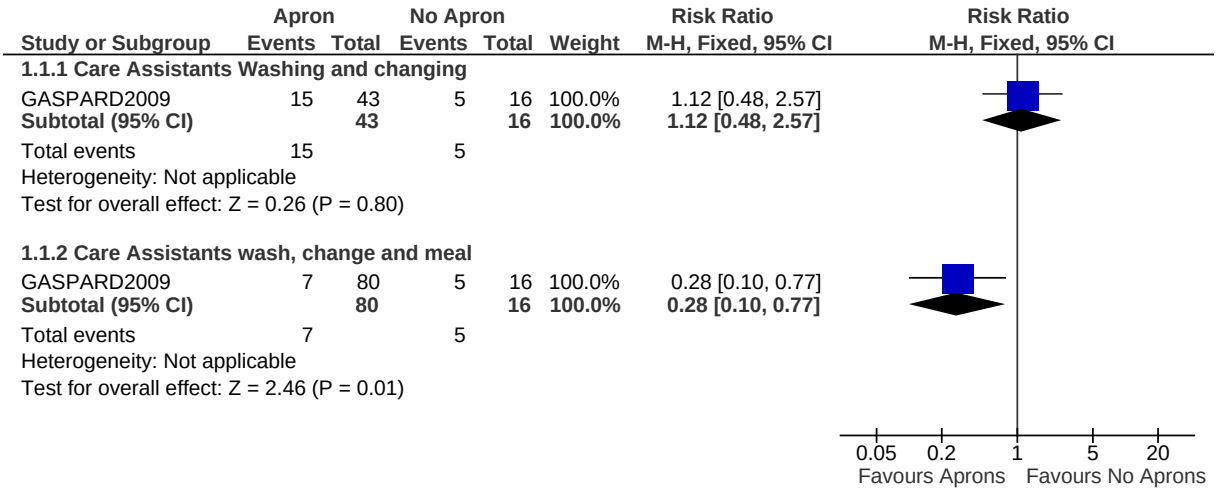
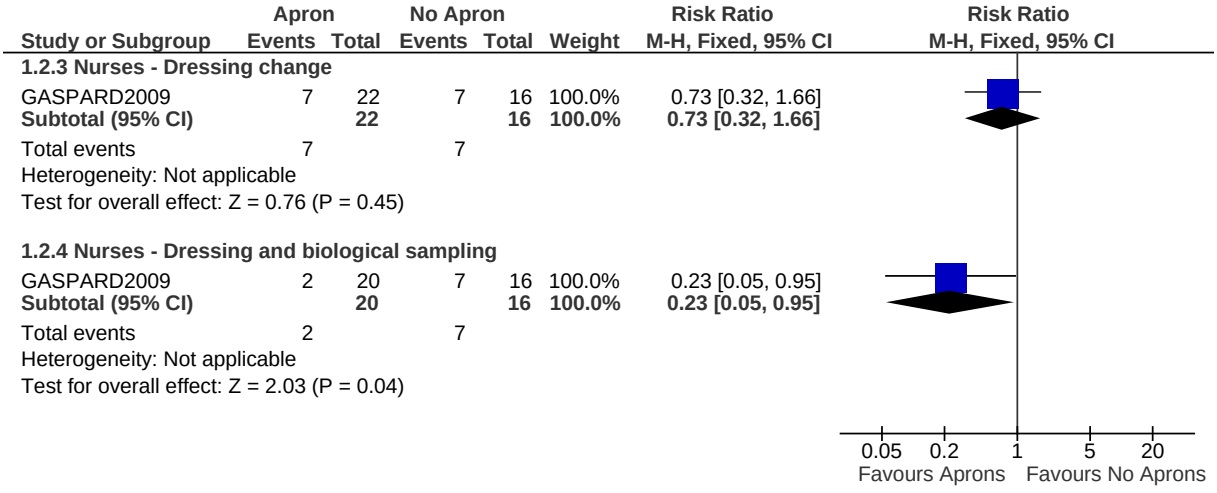


Figure 17: MRSA positive clothing



I.3 Sharps

I.3.1 Safety cannulae (active) vs. standard cannulae

Figure 18: Needlestick injury

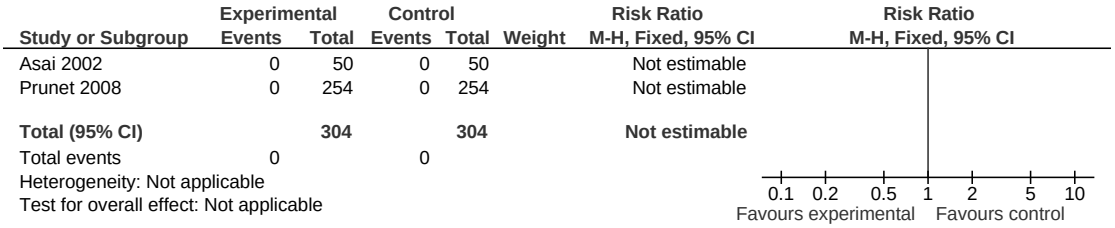


Figure 19: Success on first insertion attempt

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Asai 2002	46	50	48	50	12.0%	0.96 [0.87, 1.06]
Cote 2003	150	211	94	119	30.0%	0.90 [0.79, 1.02]
Prunet 2008	230	254	232	254	58.0%	0.99 [0.94, 1.05]
Total (95% CI)		**515**		**423**	**100.0%**	**0.96 [0.91, 1.01]**
Total events	426		374			

Heterogeneity: Chi² = 2.32, df = 2 (P = 0.31); I² = 14%
Test for overall effect: Z = 1.59 (P = 0.11)

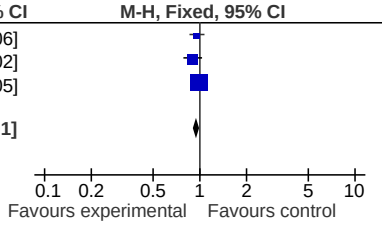
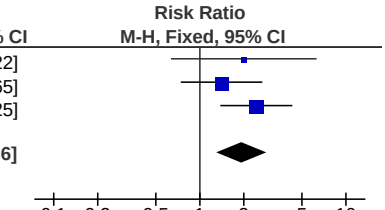


Figure 20: Blood contamination

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Asai 2002	8	50	4	50	11.3%	2.00 [0.64, 6.22]
Cote 2003	30	211	12	119	43.4%	1.41 [0.75, 2.65]
Prunet 2008	39	254	16	254	45.3%	2.44 [1.40, 4.25]
Total (95% CI)		**515**		**423**	**100.0%**	**1.94 [1.32, 2.86]**
Total events	77		32			

Heterogeneity: Chi² = 1.64, df = 2 (P = 0.44); I² = 0%
Test for overall effect: Z = 3.35 (P = 0.0008)



I.3.2 Safety cannulae (passive) vs. standard cannulae

Figure 21: Needlestick injury

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Asai 2002	0	50	0	50		Not estimable
Prunet 2008	0	251	0	254		Not estimable
Total (95% CI)		**301**		**304**		**Not estimable**
Total events	0		0			

Heterogeneity: Not applicable
Test for overall effect: Not applicable

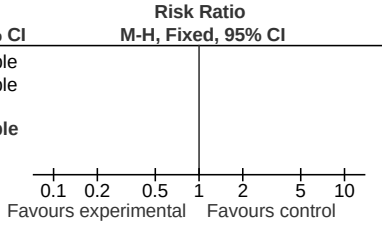


Figure 22: Success on first insertion attempt

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Asai 2002	48	50	48	50	17.2%	1.00 [0.92, 1.08]
Prunet 2008	230	251	232	254	82.8%	1.00 [0.95, 1.06]
Total (95% CI)		**301**		**304**	**100.0%**	**1.00 [0.96, 1.05]**
Total events	278		280			

Heterogeneity: Chi² = 0.00, df = 1 (P = 0.95); I² = 0%
Test for overall effect: Z = 0.11 (P = 0.91)

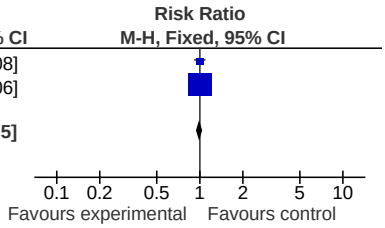
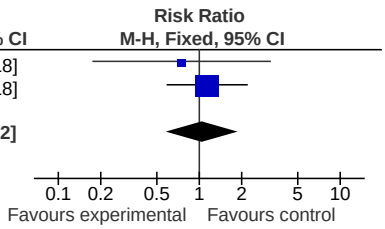


Figure 23: Blood contamination

Study or Subgroup	Experimental Events	Experimental Total	Control Events	Control Total	Weight	Risk Ratio M-H, Fixed, 95% CI
Asai 2002	3	50	4	50	20.1%	0.75 [0.18, 3.18]
Prunet 2008	18	251	16	254	79.9%	1.14 [0.59, 2.18]
Total (95% CI)		**301**		**304**	**100.0%**	**1.06 [0.59, 1.92]**
Total events	21		20			

Heterogeneity: Chi² = 0.27, df = 1 (P = 0.61); I² = 0%
Test for overall effect: Z = 0.19 (P = 0.85)



I.3.3 Safety resheathable winged steel needle vs conventional devices

Figure 24: Needlestick injury

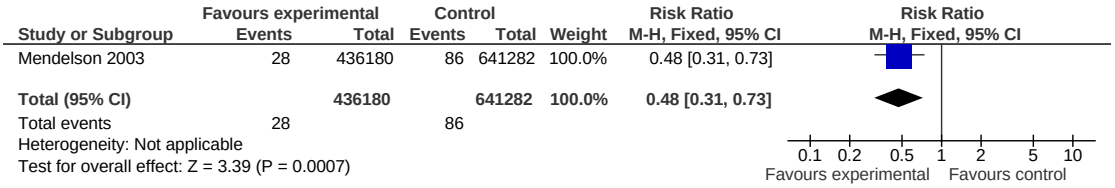


Figure 25: Needlestick injury

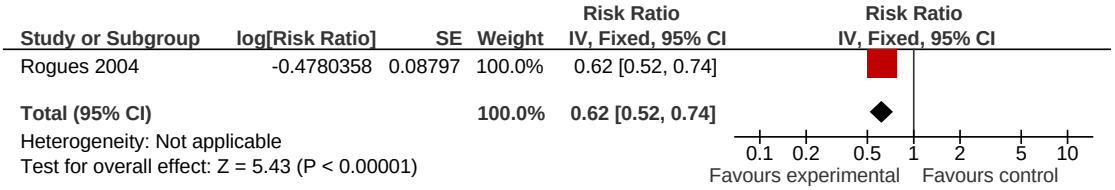


Figure 26: Needlestick injury

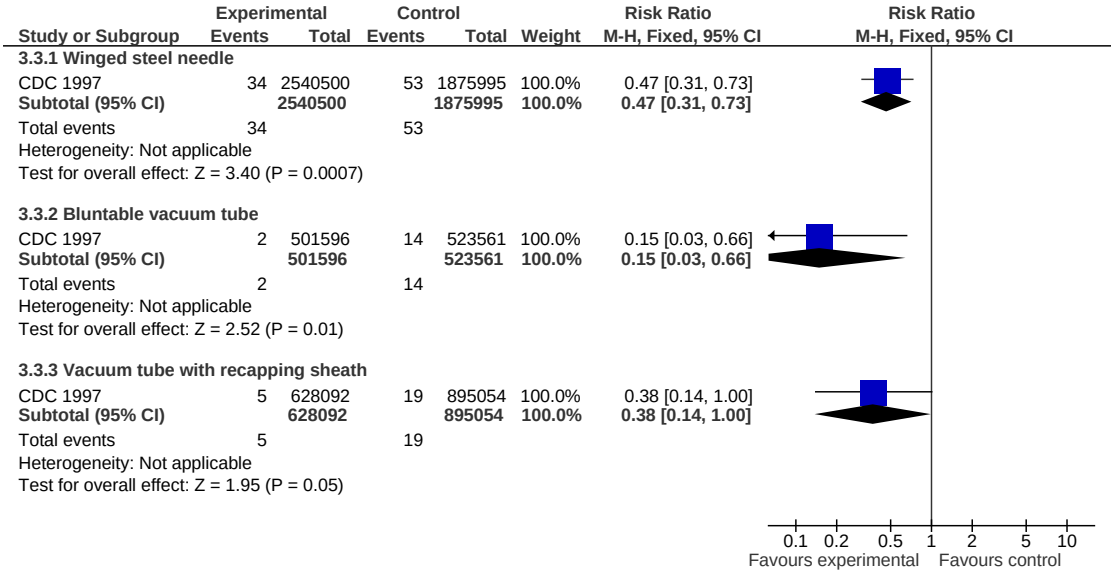


Figure 27: User preference

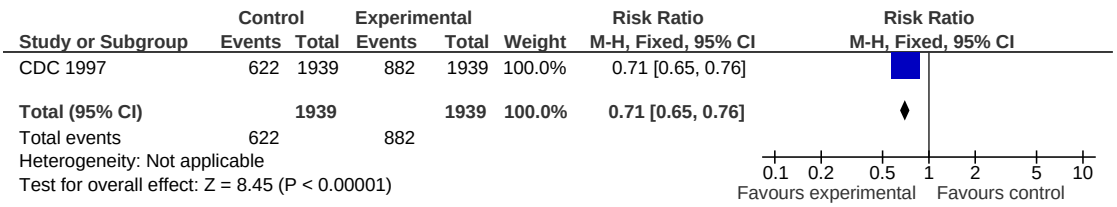
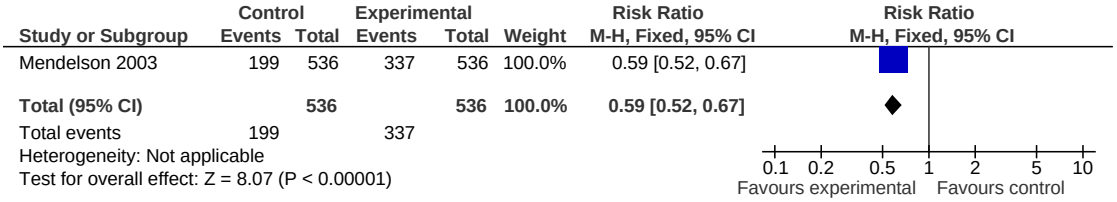
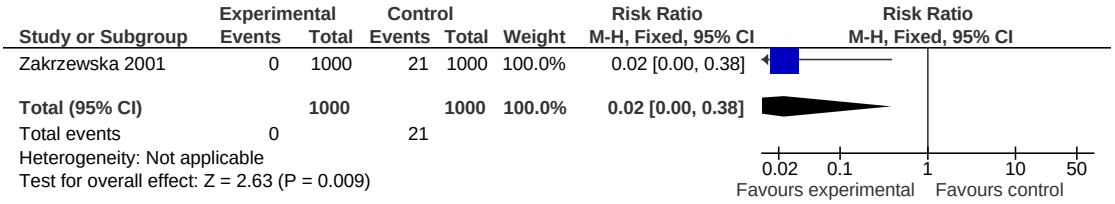


Figure 28: User preference



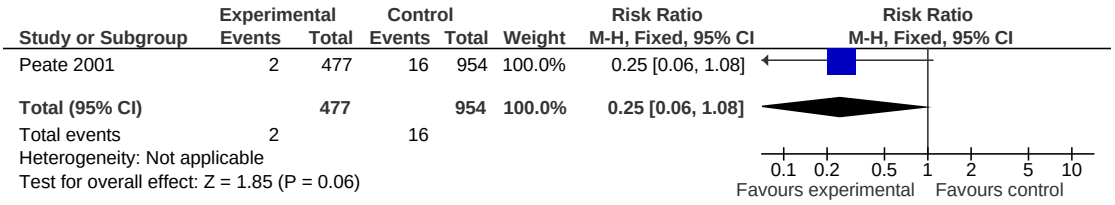
I.3.4 Disposable safety syringe vs non-disposable syringe

Figure 29: Needlestick injury



I.3.5 Safety lancet vs standard lancet

Figure 30: Needlestick injury



I.4 Long term urinary catheterisation

I.4.1 Catheter type

I.4.1.1 Hydrogel coated latex vs. control (silicone elastomer coated) for long term indwelling catheterisation

Figure 31: Mean catheter time in situ

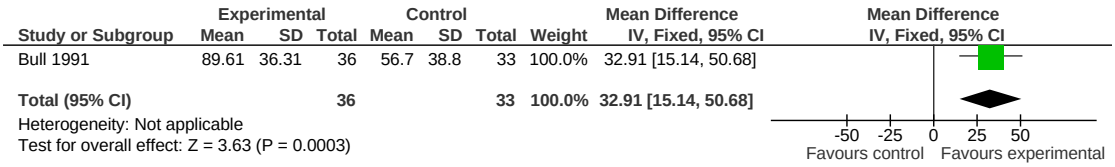


Figure 32: Encrustations leading to catheter change

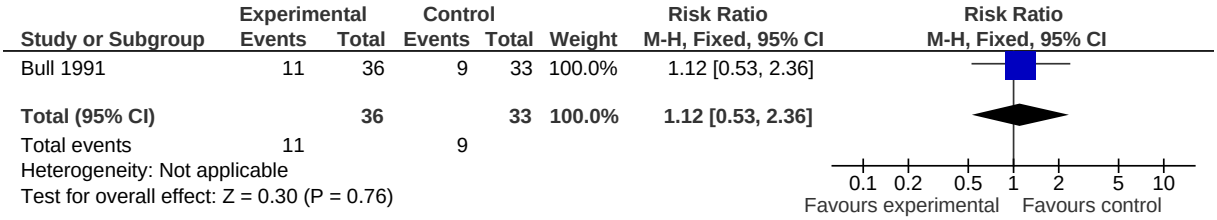
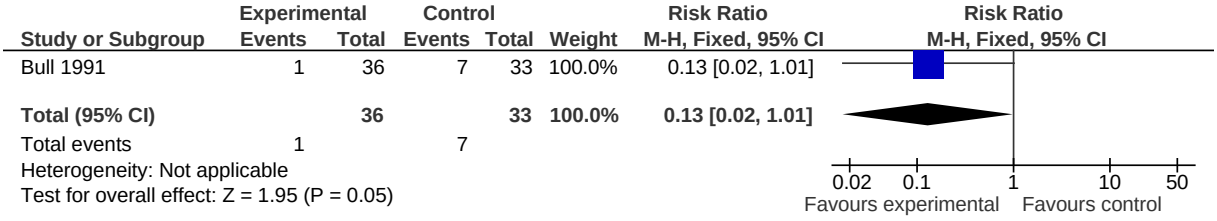


Figure 33: Catheter related adverse events



I.4.1.2 Hydrophilic coated vs. control (non-coated) for long term intermittent catheterisation

Figure 34: Mean monthly urinary tract infection

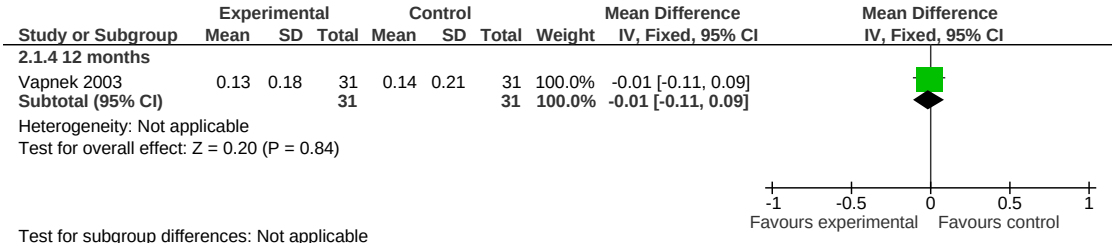


Figure 35: UTIs and antibiotics (per year)

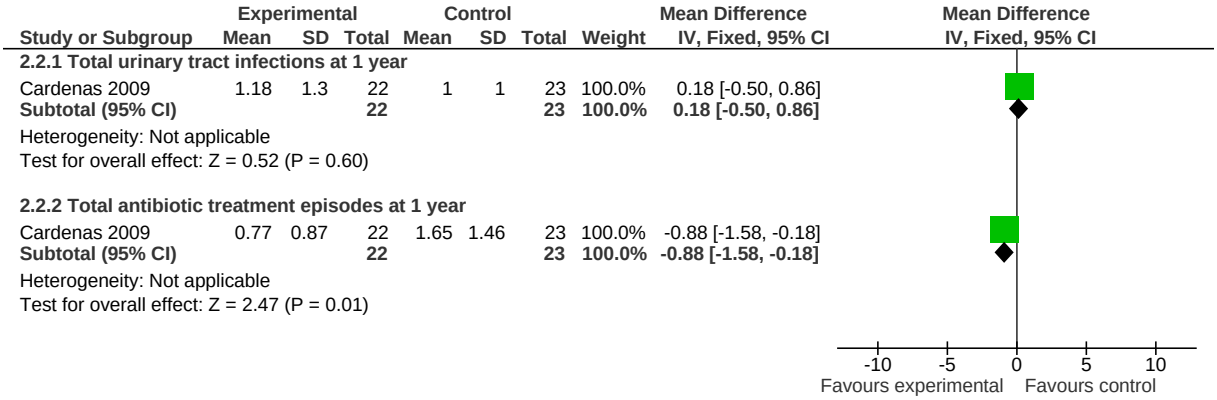


Figure 36: Patients with 1 or more urinary tract infection

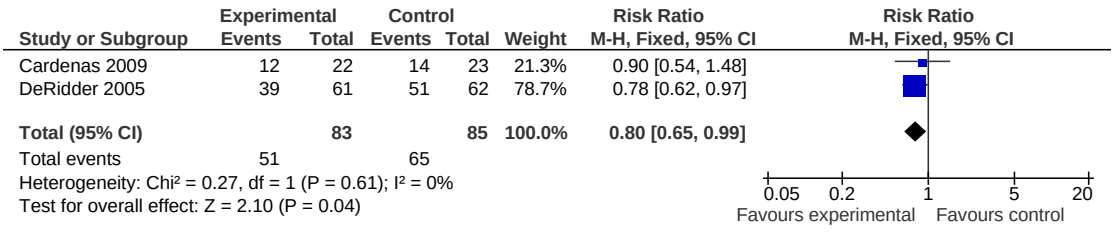


Figure 37: Patients/helpers who were very satisfied with the catheter

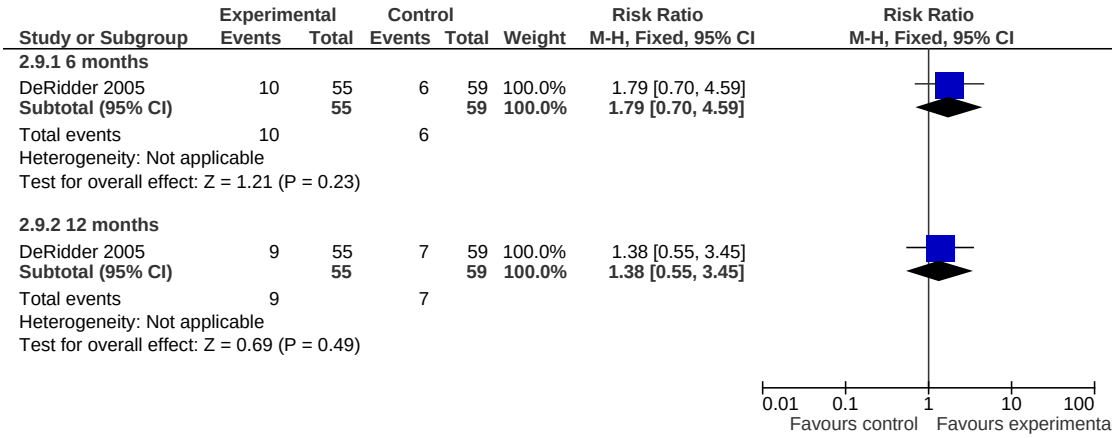


Figure 38: Patient satisfaction (Low = good)

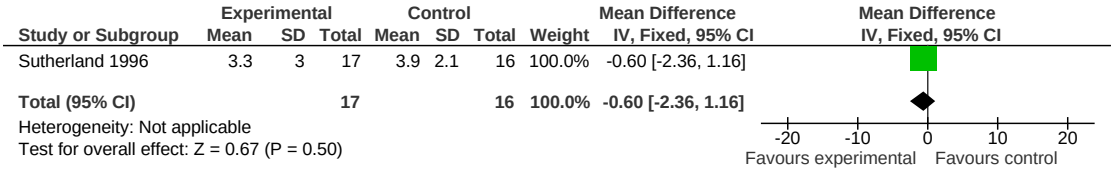
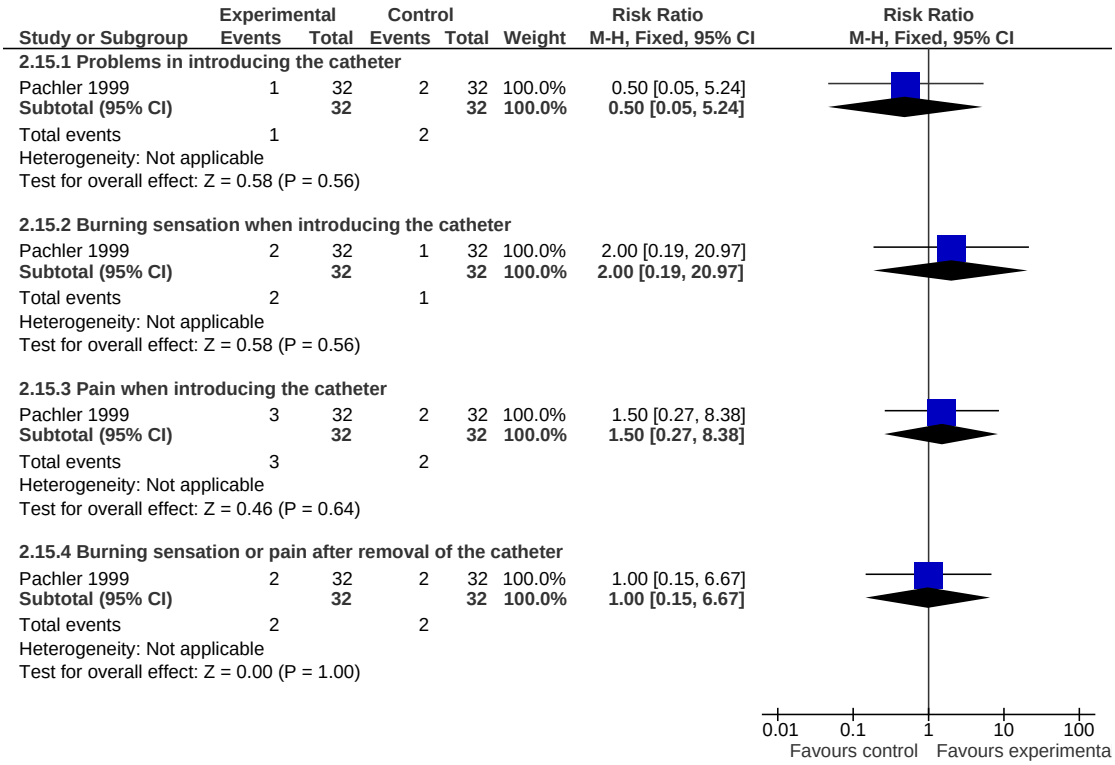


Figure 39: Catheter preference



I.4.1.3 Gel reservoir vs. control (non-coated) for long term intermittent catheterisation

Figure 40: Patients with 1 or more urinary tract infection

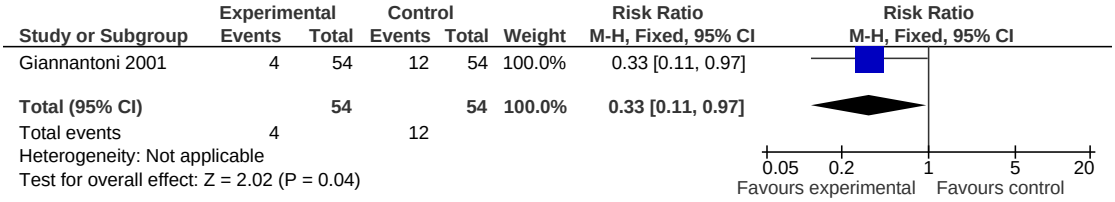
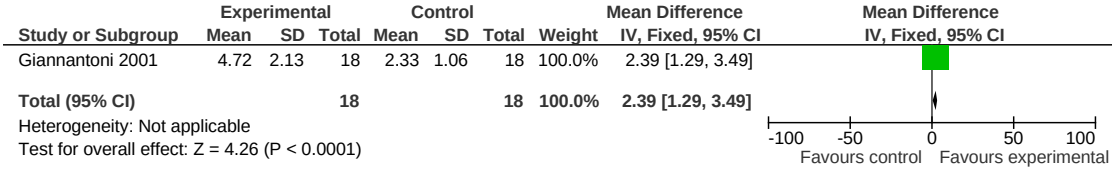


Figure 41: Patient comfort (High = good)



I.4.1.4 Noncoated catheters reused multiple times vs. single use for long term intermittent catheterisation

Figure 42: Symptomatic UTI

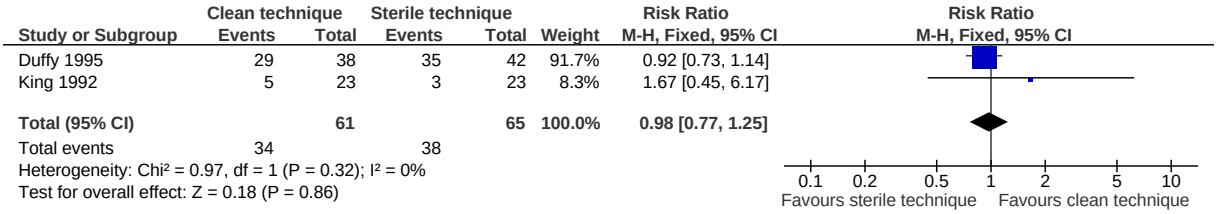
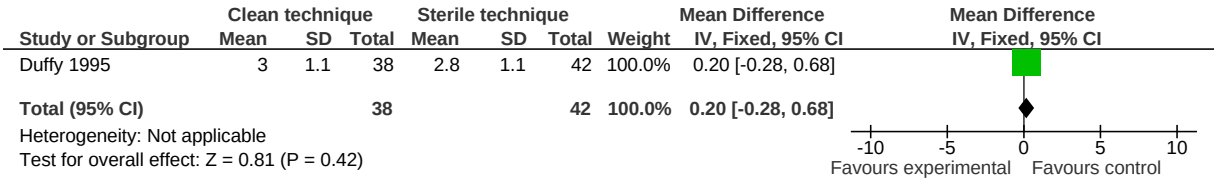


Figure 43: Frequency of catheterisations, per day



I.4.2 Washouts and instillations

I.4.2.1 Solution G vs. saline (sodium chloride 0.9%)

Figure 44: Catheter blockage

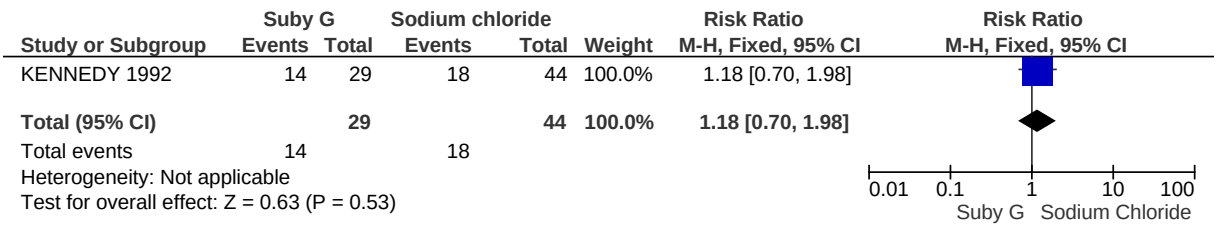


Figure 45: Partial catheter blockage

Study or Subgroup	Suby G Events	Total	Sodium chloride Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
KENNEDY 1992	12	29	14	44	100.0%	1.30 [0.71, 2.40]
Total (95% CI)		**29**		**44**	**100.0%**	**1.30 [0.71, 2.40]**
Total events	12		14			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.84 (P = 0.40)

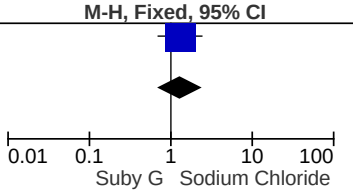


Figure 46: Cathters not encrusted

Study or Subgroup	Suby G Events	Total	Sodium chloride Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
KENNEDY 1992	3	29	12	44	100.0%	0.38 [0.12, 1.23]
Total (95% CI)		**29**		**44**	**100.0%**	**0.38 [0.12, 1.23]**
Total events	3		12			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.62 (P = 0.11)

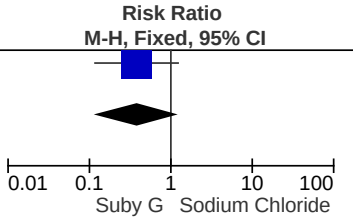
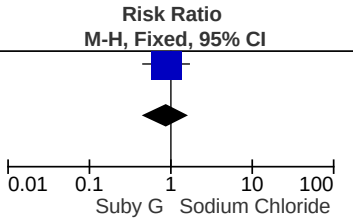


Figure 47: Catheter removal/ replacement

Study or Subgroup	Suby G Events	Total	Sodium chloride Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
KENNEDY 1992	14	84	16	84	100.0%	0.88 [0.46, 1.68]
Total (95% CI)		**84**		**84**	**100.0%**	**0.88 [0.46, 1.68]**
Total events	14		16			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.40 (P = 0.69)



I.4.2.2 Solution R vs. saline (sodium chloride 0.9%)

Figure 48: Catheter blockage

Study or Subgroup	Solution R Events	Total	Sodium chloride Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
KENNEDY 1992	7	27	18	44	100.0%	0.63 [0.31, 1.31]
Total (95% CI)		**27**		**44**	**100.0%**	**0.63 [0.31, 1.31]**
Total events	7		18			

Heterogeneity: Not applicable
Test for overall effect: Z = 1.22 (P = 0.22)

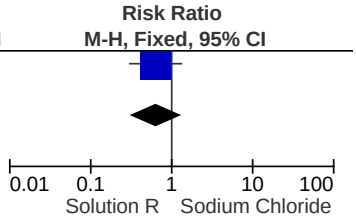


Figure 49: Partial catheter blockage

Study or Subgroup	Solution R Events	Total	Sodium chloride Events	Total	Weight	Risk Ratio M-H, Fixed, 95% CI
KENNEDY 1992	10	27	14	44	100.0%	1.16 [0.60, 2.24]
Total (95% CI)		**27**		**44**	**100.0%**	**1.16 [0.60, 2.24]**
Total events	10		14			

Heterogeneity: Not applicable
Test for overall effect: Z = 0.45 (P = 0.65)

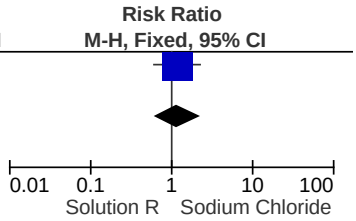


Figure 50: Catheters not encrusted

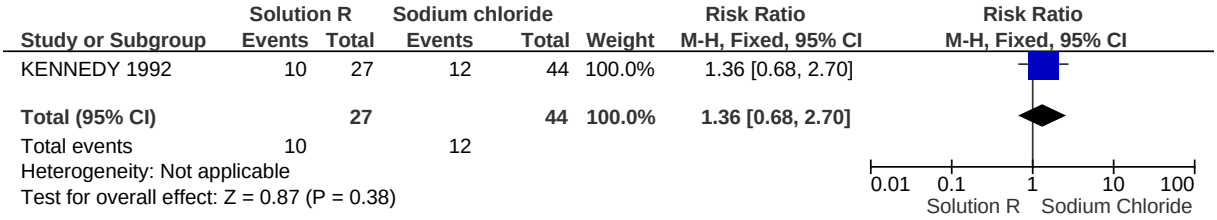
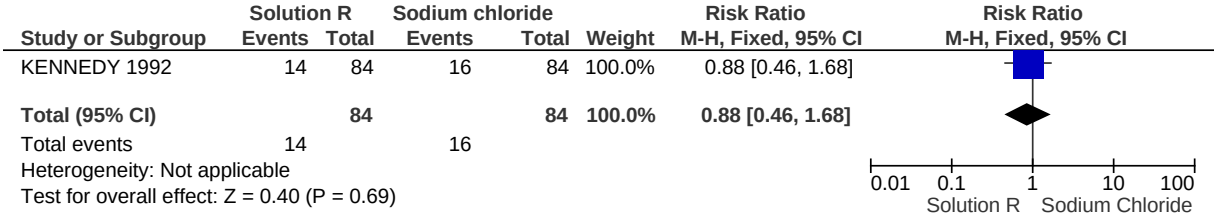


Figure 51: Catheter removal/ replacement



I.4.2.3 Solution G vs. solution R

Figure 52: Catheter blockage

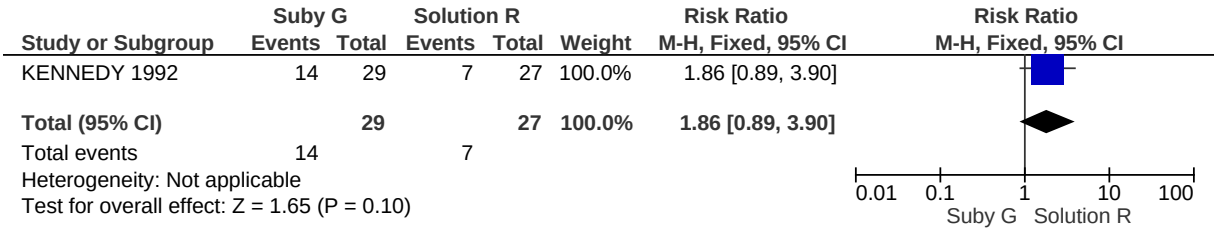


Figure 53: Partial catheter blockage

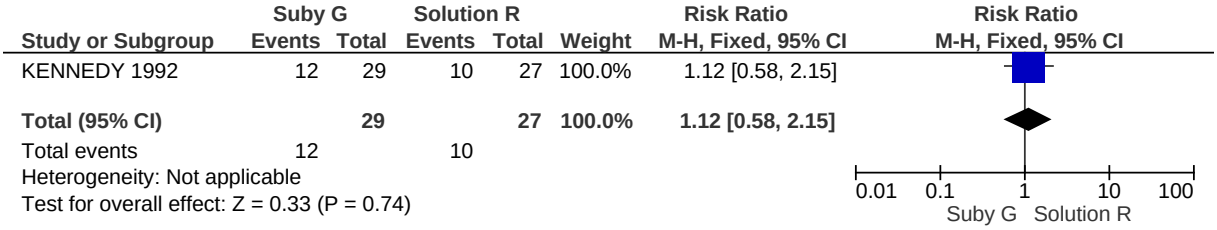


Figure 54: Catheters not encrusted

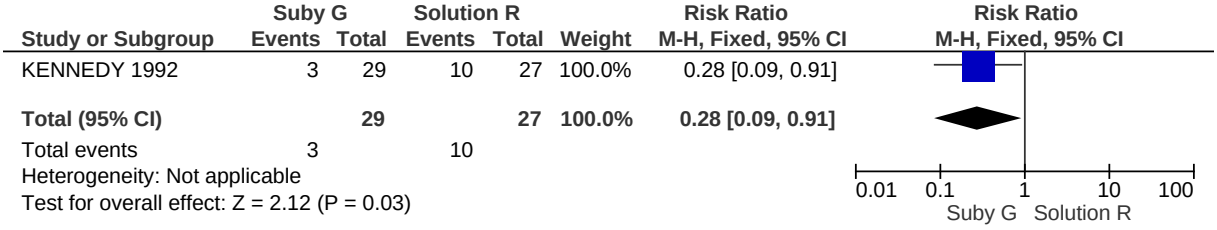
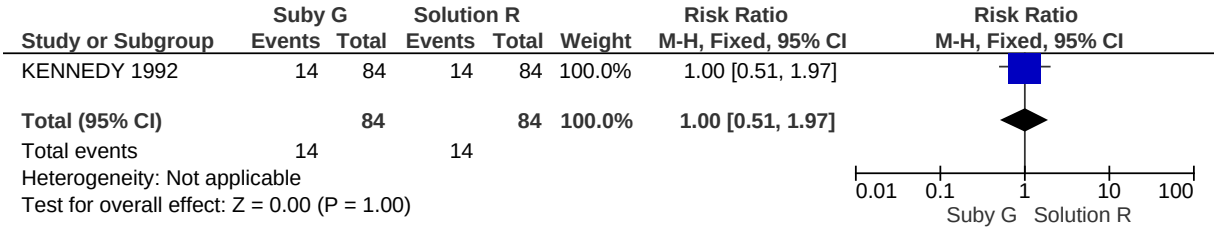
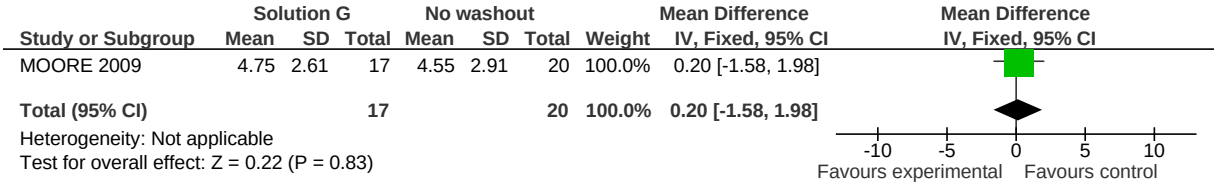


Figure 55: Catheter removal/ replacement



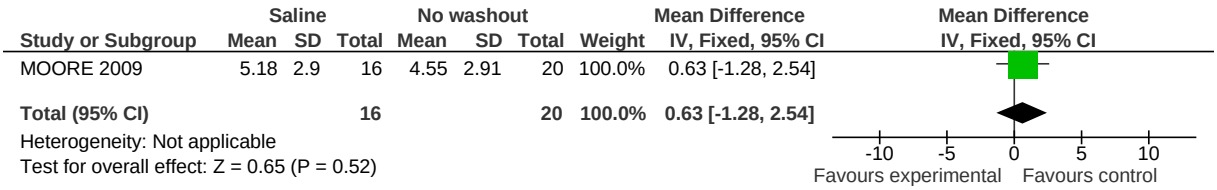
I.4.2.4 Solution G vs. no washout

Figure 56: Mean time to first catheter change



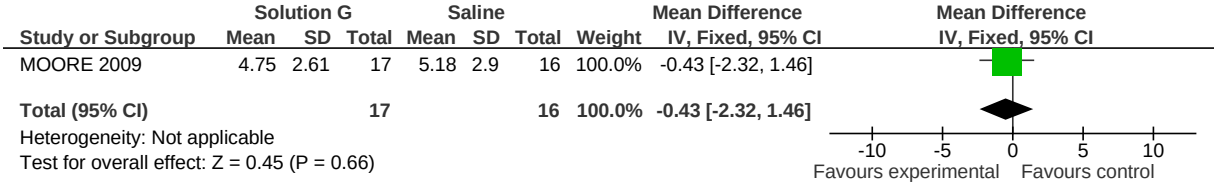
I.4.2.5 Saline vs. no washout

Figure 57: Mean time to first catheter change



Solution G vs. saline

Figure 58: Mean time to first catheter change



I.4.2.6 Acetic acid vs. Saline

Figure 59: Symptomatic UTI

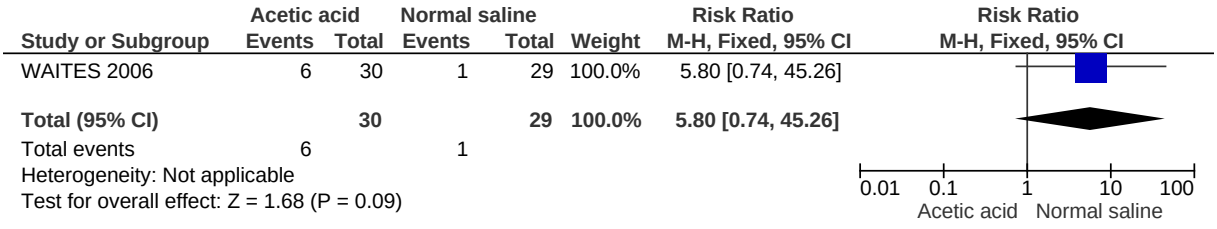
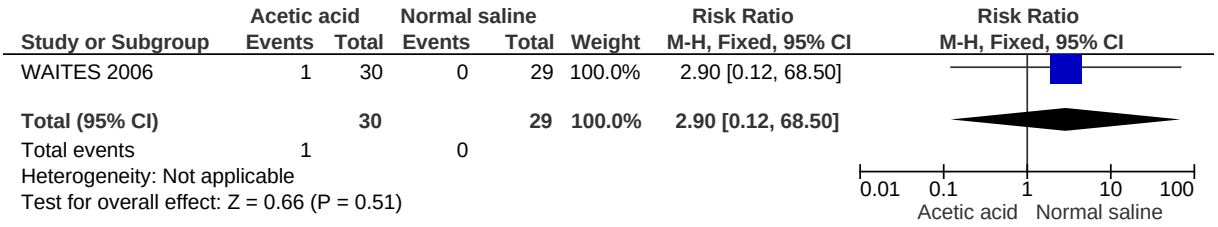


Figure 60: Adverse events



I.4.3 Antibiotics

Figure 61: Antibiotics resistance

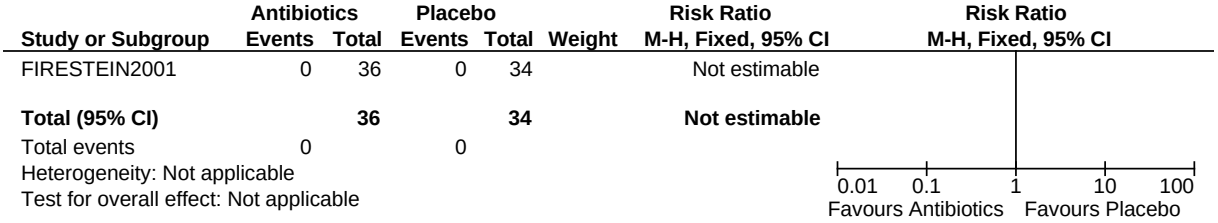


Figure 62: Mortality

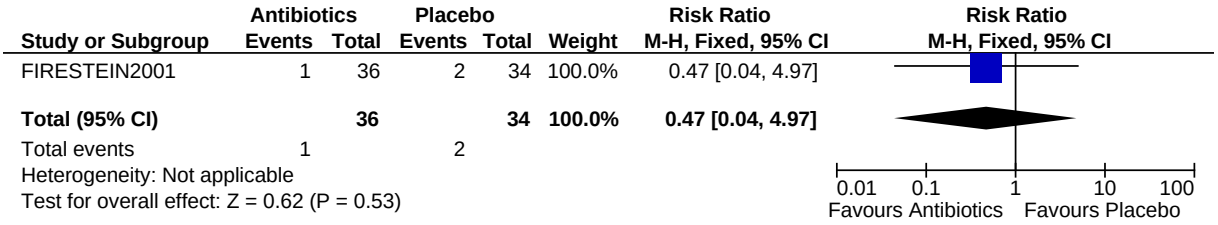
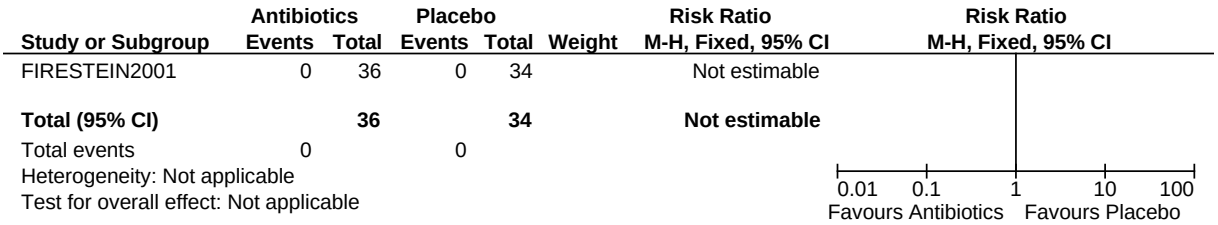


Figure 63: Bacteraemia



I.5 PEGs

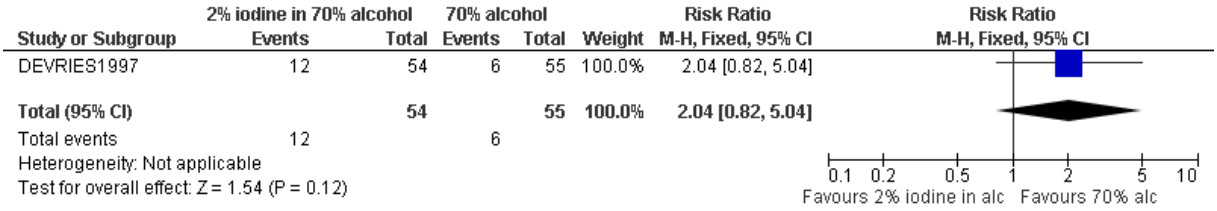
No clinical evidence.

I.6 Vascular access devices

I.6.1 Skin decontamination prior to insertion of peripheral vascular access devices

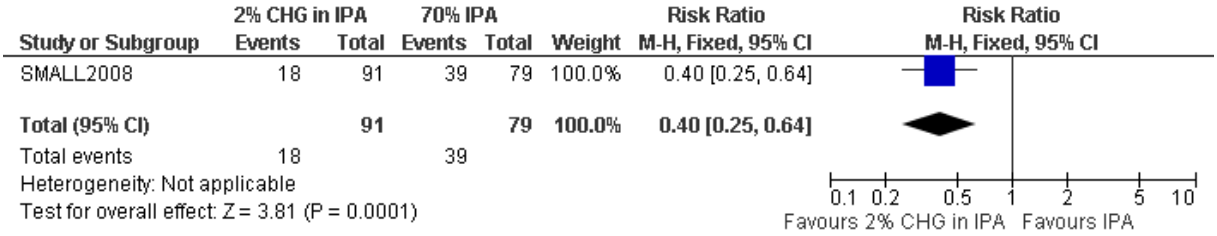
2% Iodine in 70% alcohol vs. 70% alcohol

Figure 64: VAD related phlebitis



2% Chlorhexidine gluconate in alcohol vs. 70% alcohol

Figure 65: Catheter tip colonisation



I.6.2 Dressing type

I.6.2.1 Peripherally inserted VADs - transparent polyurethane vs. gauze and tape

Figure 66: Catheter tip colonisation

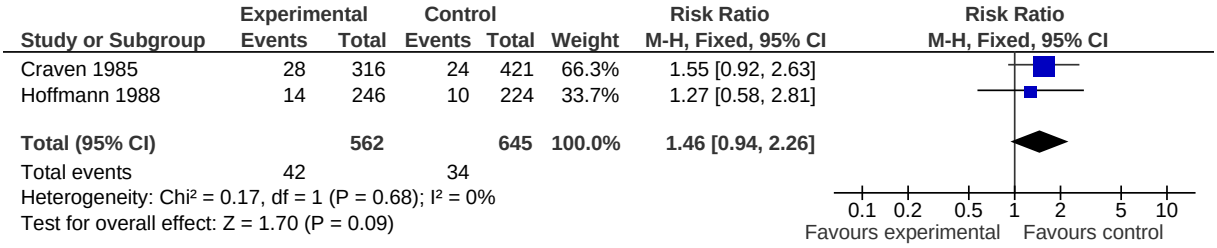
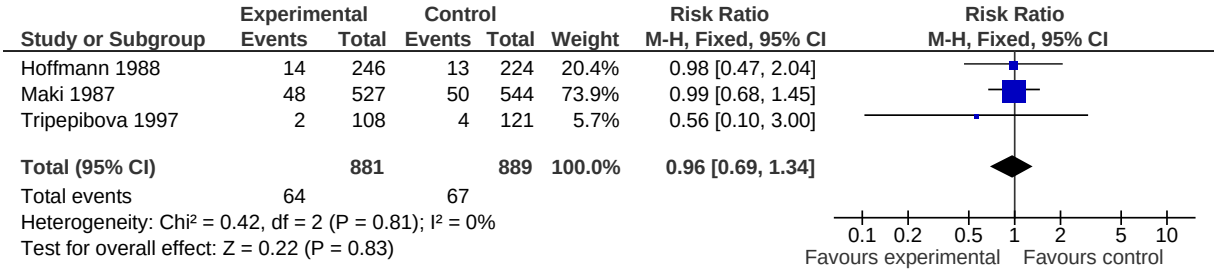
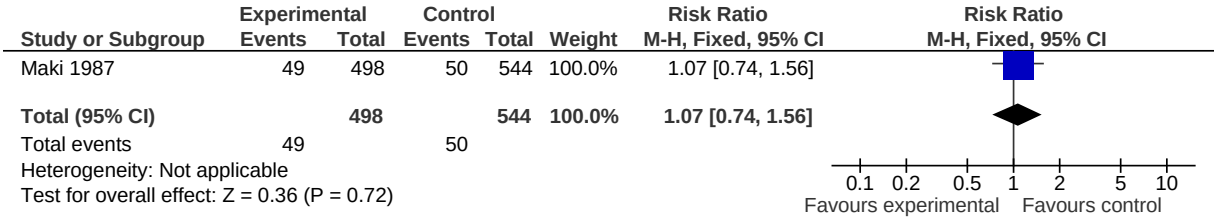


Figure 67: Phlebitis



I.6.2.2 Peripherally inserted VADs - transparent polyurethane + iodophor antiseptic vs. gauze and tape

Figure 68: Phlebitis



I.6.2.3 Centrally inserted VADs - highly permeable transparent polyurethane vs gauze and tape

Figure 69: Catheter related sepsis

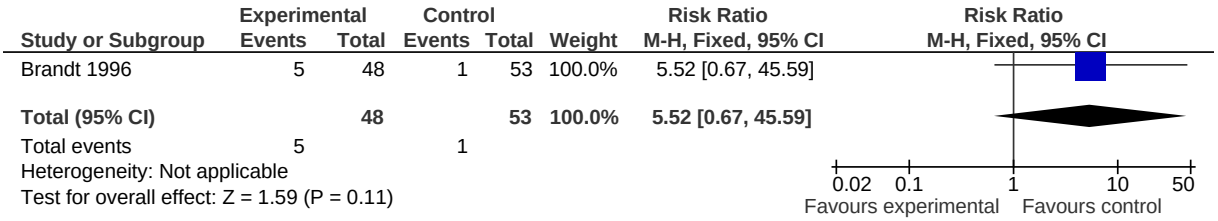


Figure 70: Exit site infection

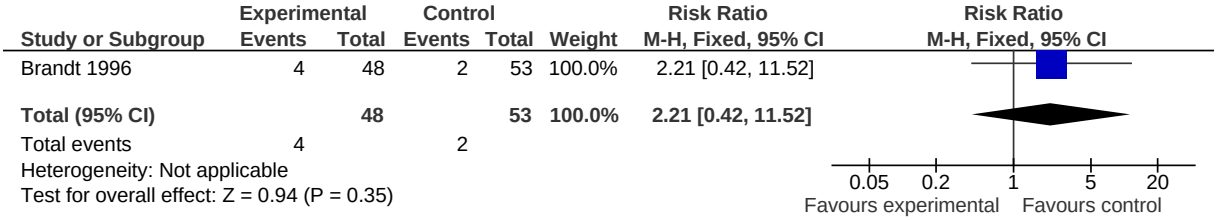
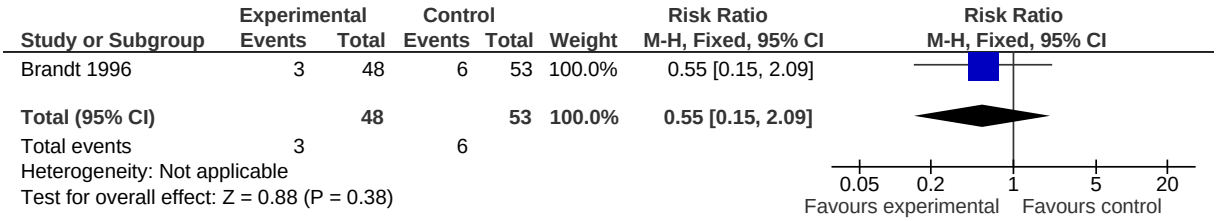
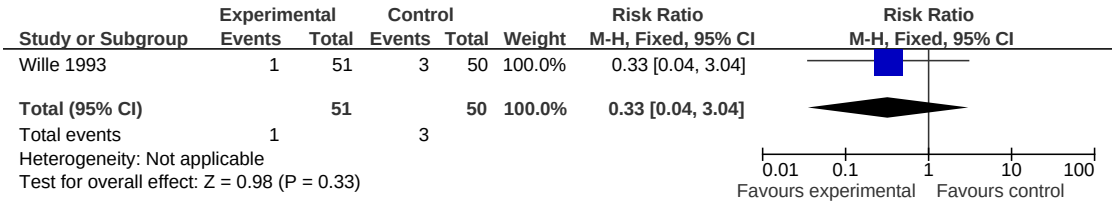


Figure 71: Bacteraemia/fungemia



I.6.2.4 Centrally inserted VADs - highly permeable transparent polyurethane vs transparent semi permeable membrane

Figure 72: Catheter related sepsis



I.6.2.5 Centrally inserted VADs - transparent semi permeable membrane vs gauze and tape

Figure 73: Catheter related sepsis

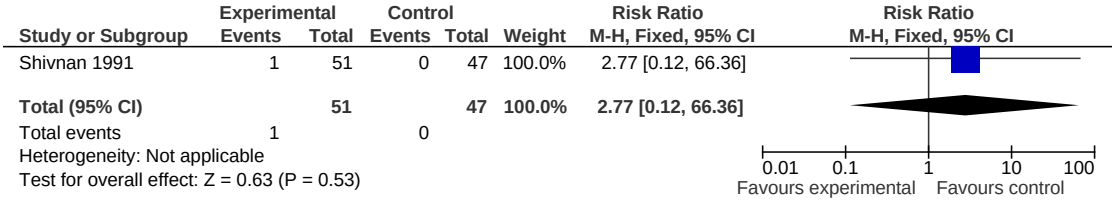


Figure 74: Exit site infection

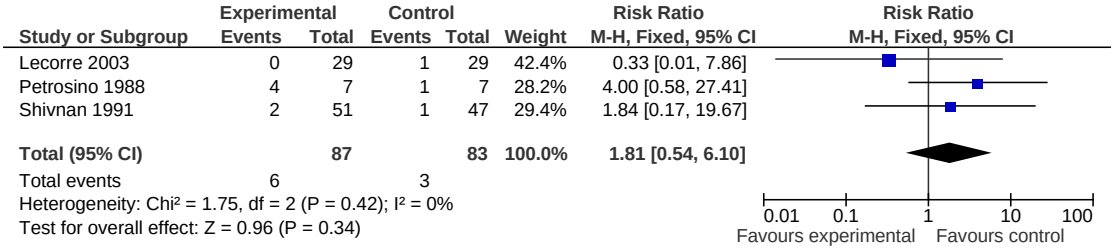
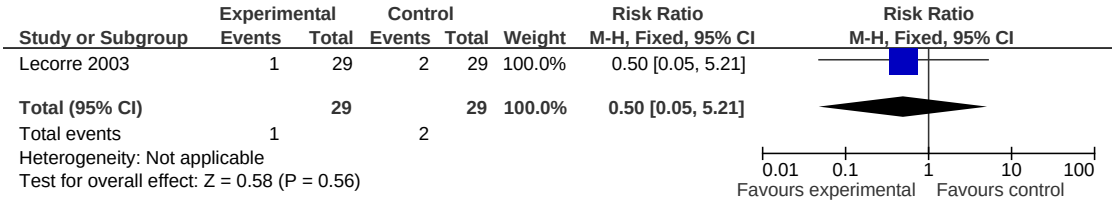


Figure 75: Bacteraemia



I.6.2.6 Frequency of dressing change

Figure 76: Positive blood culture

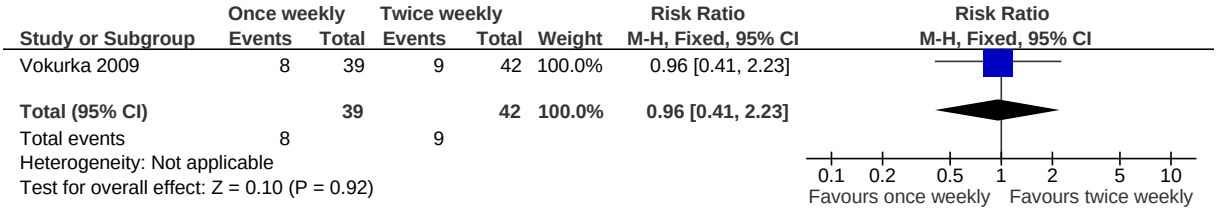


Figure 77: CVC insertion site inflammation

I.6.2.7 Decontaminating skin when changing dressings

2% Chlorhexidine gluconate (CHG) vs 10% Povidone Iodine (PVP-I) in aqueous

Figure 78: VAD related bacteraemia

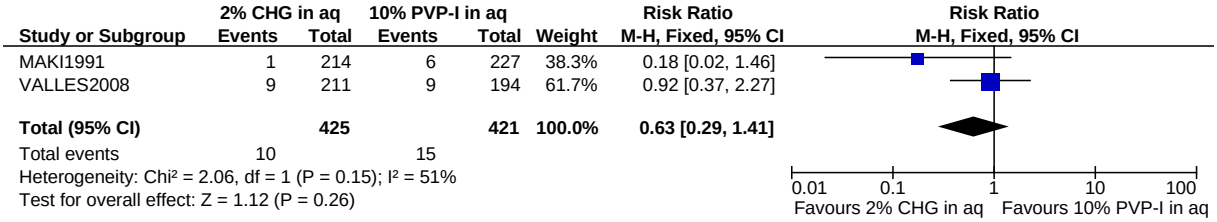


Figure 79: VAD related septicaemia

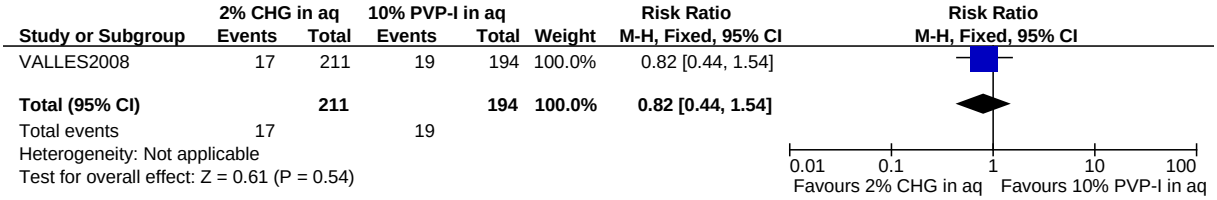


Figure 80: Catheter tip colonisation

2% Chlorhexidine gluconate (CHG) in aqueous vs 70% Isopropyl alcohol (IPA)

Figure 81: VAD related bacteraemia

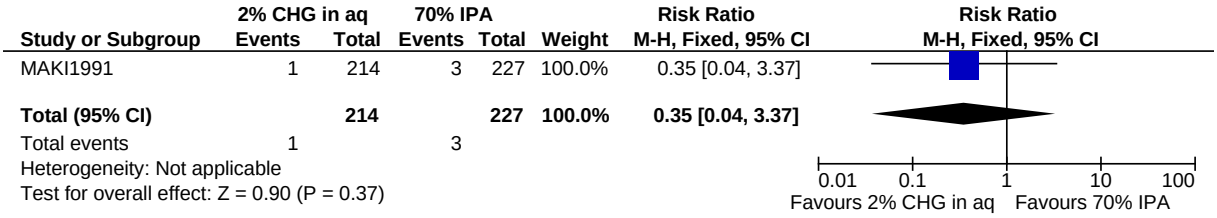
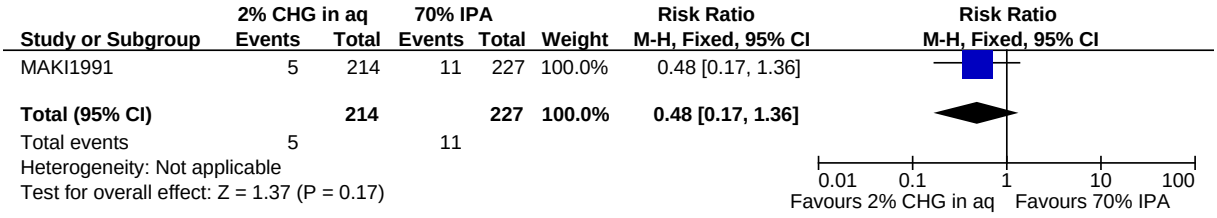


Figure 82: Catheter tip colonisation



2% Chlorhexidine gluconate (CHG) in aqueous vs 0.5% Chlorhexidine gluconate (CHG) in alcohol

Figure 83: VAD related bacteraemia

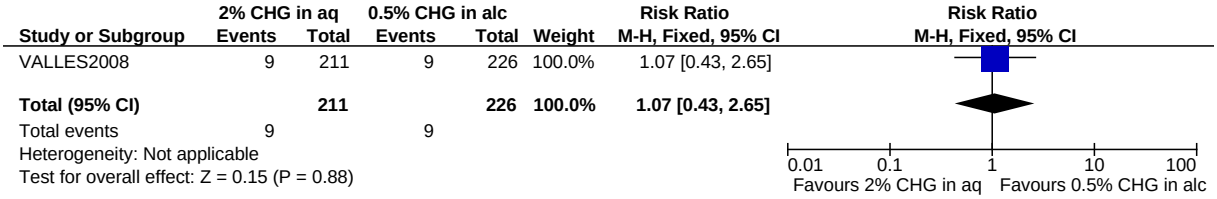


Figure 84: VAD related septicaemia

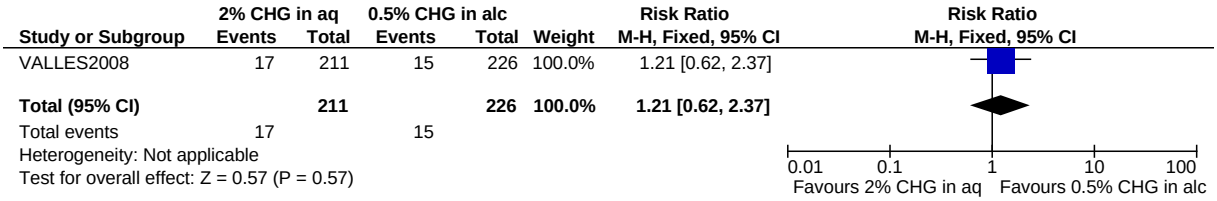
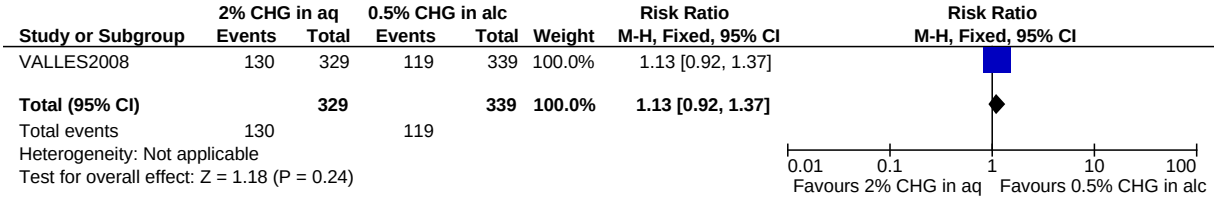


Figure 85: Catheter tip colonisation



0.5% Chlorhexidine gluconate (CHG) in alcohol vs 10% Povidone Iodine (PVP-I) in aqueous

Figure 86: VAD related bacteraemia

Figure 87: VAD related local infection

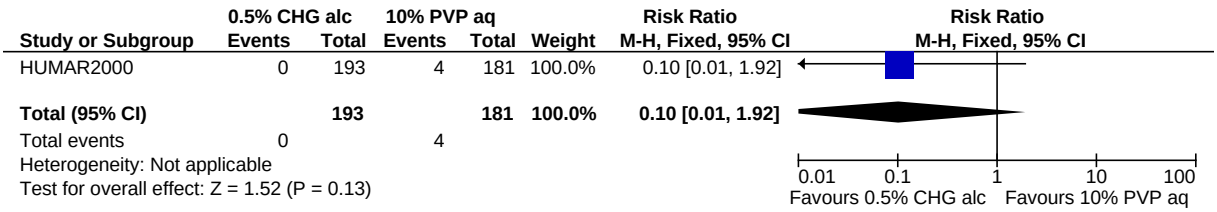
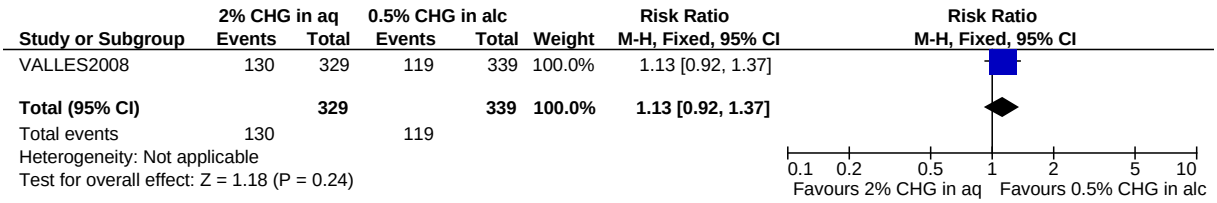


Figure 88: Catheter tip colonisation



10% Povidone Iodine (PVP-I) in aqueous vs 5% Povidone Iodine (PVP-I) in 70% ethanol

Figure 89: VAD related bacteraemia

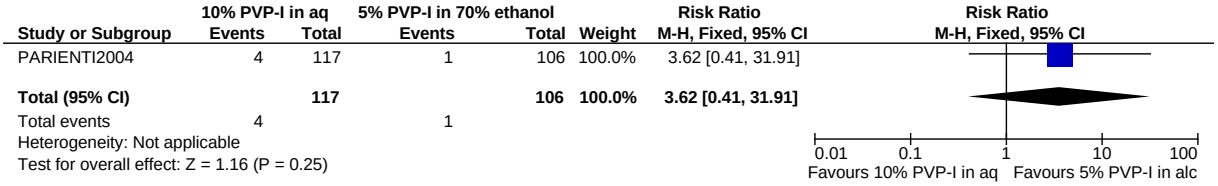
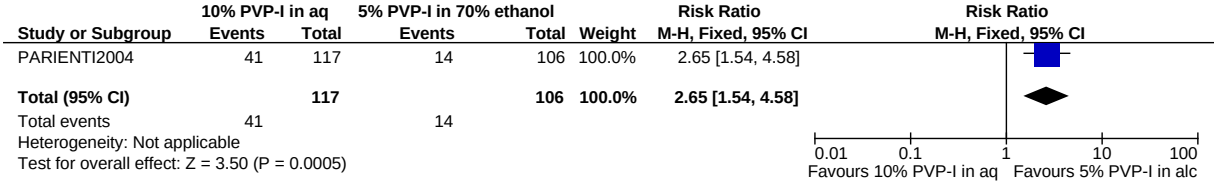


Figure 90: Catheter tip colonisation



10% Povidone Iodine (PVP-I) in aqueous vs 70% Isopropyl alcohol (IPA)

Figure 91: VAD related bacteraemia

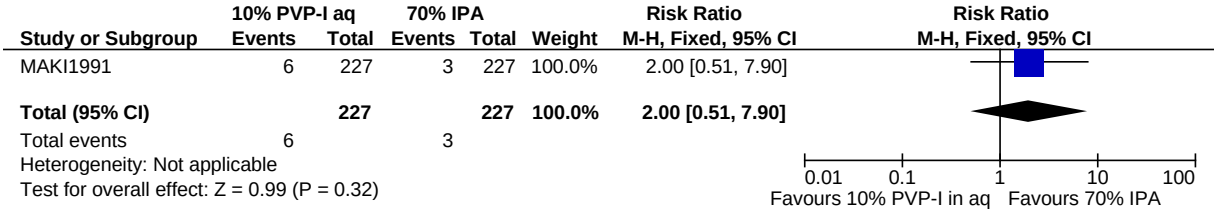
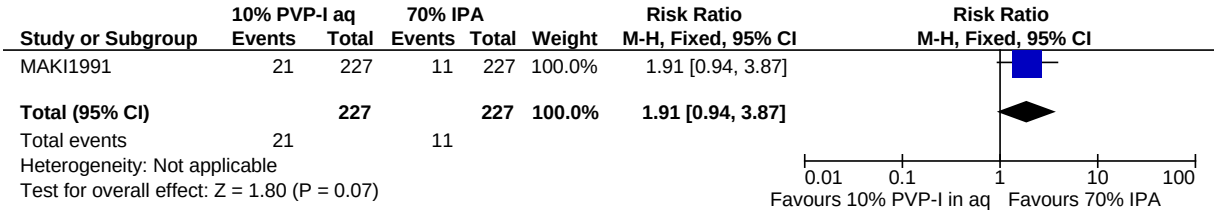


Figure 92: Catheter tip colonisation



0.25% Chlorhexidine gluconate (CHG) in aqueous proprietary solution vs 5% PVP-I in 70% alcohol

Figure 93: VAD related bacteraemia

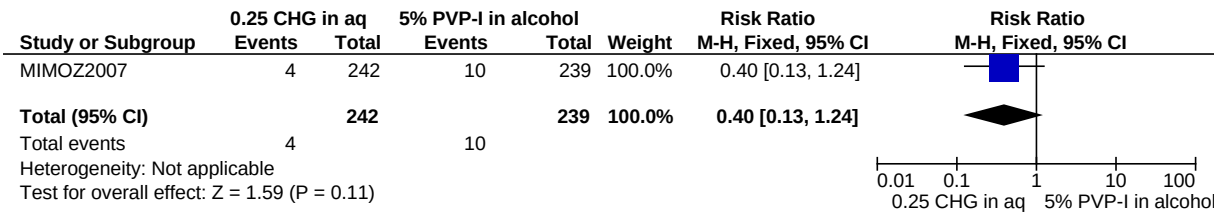


Figure 94: VAD related phlebitis

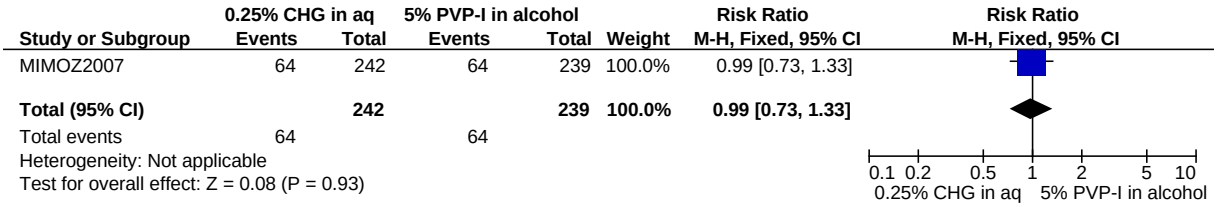


Figure 95: Catheter tip colonisation

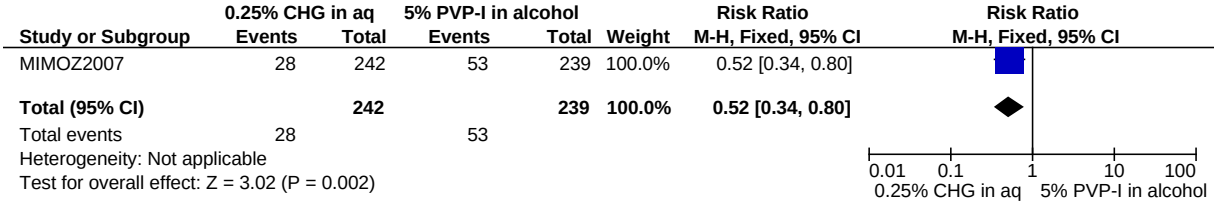
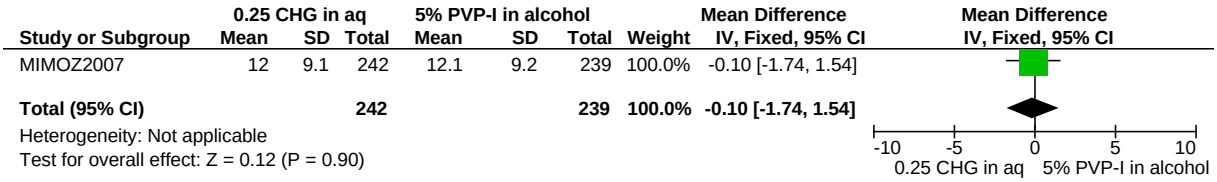


Figure 96: VAD line removal - mean duration of catheter placement (days)



I.6.2.8 Decontaminating peripheral and centrally inserted catheter ports and hubs before access

No clinical evidence was identified.

I.6.2.9 Multi dose vials

No clinical evidence.

Appendix J: Cost-utility analysis: Intermittent self catheterisation

J.1 Introduction

Catheter-associated urinary tract infection (CAUTI) is the most common healthcare acquired infection in the world, accounting for 20% to 45% of all nosocomial infections [376]. While most urinary tract infections (UTIs) are mild and easily resolved with appropriate antibiotic treatment, more severe infections can be devastating, resulting in bacteraemia, sepsis and death. Due to the frequency with which they occur, they also impose a substantial economic burden on the NHS [377].

The most important risk factor for the development of CAUTI is the prolonged use of an indwelling catheter. For this reason, intermittent self catheterisation (ISC) has become the preferred method of catheterisation for patients in which it is clinically indicated [369] [247]. ISC aims to reduce CAUTIs and promote greater independence among people who have bladder emptying problems. Nevertheless, CAUTI remains the most frequent and serious complication of ISC [515].

There are several different approaches to ISC. Patients may use disposable catheters with a hydrophilic polymer surface coating, disposable catheters with pre-packaged water based lubricant (gel reservoir), or non-coated catheters. Non-coated catheters may be discarded after use, or washed and re-used for up to one week. Which material and method constitutes the best approach is an issue of considerable uncertainty.

Our aim in constructing the model was to determine the most cost-effective type of catheter for patients performing ISC in the community. The relative effectiveness of each type of intermittent catheter was based on the results of the randomised controlled trials included in our systematic review. Several different versions of the model were built to reflect the diversity of patient groups using ISC. The model was built probabilistically in order to take into account uncertainty and imprecision around parameter point estimates.

J.2 Methods

J.2.1 Model overview

J.2.1.1 Comparators

There are several types of catheters available for ISC. The catheters included in the model are all those that are available for patients residing in the community:

- Hydrophilic catheters are coated with a hydrophilic polymer coating. Hydrophilic catheters must be immersed in water prior to use or may be packaged in a casing of water or saline. These catheters are designed for single use.
- Gel reservoir catheters are pre-packaged with a small sachet of sterile water-soluble lubricant which must be released and spread over the catheter before use. These catheters are also designed for single use.
- Non-coated catheters do not have a surface coating and patients often apply a water-based or anaesthetic lubricant before use. These catheters may be washed and reused for up to one week, although some patients choose to use them as single use catheters. In the model we chose to explore both methods of non-coated catheter use:
  - Non-coated catheters which are discarded immediately after use – sometimes referred to as ‘sterile’ non-coated ISC.
  - Non-coated catheters which are washed, dried and reused multiple times – sometimes referred to as ‘clean’ non-coated ISC.

The decision to include multiple use non-coated ISC as a treatment alternative was made in consultation with the GDG, expert continence advisor, NICE commissioning managers, Medicines and

Healthcare products Regulatory Agency, British Association of Urological Nurses, staff at Stoke Mandeville Hospital, and the manufacturers of each non-coated catheter listed on the Drug Tariff (Bard, Teleflex Medical, Pennine Healthcare, and Hunter Urology). The conclusion from these conversations was that in the community, clean ISC remains a valid method of catheterisation. However, in settings where facilities are not available, patients are catheterised by others, or patients are below 16 years of age (see below), re-use is not advisable. Therefore, two sets of models were built:

- One for when clean ISC is an option, and
- One for when it is not.

J.2.1.2 Population

There are multiple causes of bladder dysfunction which affect a heterogeneous population. ISC may be used by patients with neurogenic bladder, dysfunctional voiding syndromes, and patients recovering post-operatively for procedures to the urinary tract or reproductive system [219].

Because the majority of the included clinical effectiveness studies were conducted in patients with spinal cord injury (SCI), the base case model considered a population of adult patients with neurogenic bladder due to SCI.

In order to create a model that would be broadly applicable to all individuals using ISC in the community, separate cost-utility analyses were conducted for adult patients with bladder dysfunction caused by a condition other than SCI as part of the sensitivity analysis.

The GDG noted that in children and young people (≤ 16 years old), symptomatic UTI can cause progressive renal scarring which may lead to renal failure later in life. Renal failure carries a high risk of mortality and morbidity, is associated with very high cost and decreased quality of life. The most recent NICE guideline for Urinary Tract Infection in Children [314] concluded that it was not possible to estimate the true risk of renal failure as a result of childhood UTI, did not identify any quality of life values for children with UTI, and did not consider economic modelling a valid option in this population. The current GDG agreed with this decision and noted that none of the studies included in the clinical review which contained symptomatic UTI as an outcome were conducted in children. Given the uncertain risk of harm as a result of symptomatic UTI in childhood, the GDG decided to employ the precautionary principle in their approach to ISC in children. Therefore, only single use catheters were considered an option for ISC in children and modelling was not explicitly undertaken in this population.

J.2.1.3 Time horizon, perspective, discount rates used

The analysis was undertaken from the perspective of the NHS and personal social services, in accordance with NICE guidelines methodology [315]. Relevant costs consisted of the cost of catheters (and lubricant, where applicable) and treatment for UTIs of varying severity at the primary and secondary care level. All costs are reported in 2009/10 British pounds. The primary measure of outcome is the quality-adjusted life-year (QALY). The model was evaluated over a lifetime horizon with both costs and QALYs discounted at a rate of 3.5% per year.

J.2.2 Approach to modelling

Symptomatic UTI is the most meaningful outcome for evaluating the efficacy and costs of intermittent catheterisation. Although asymptomatic bacteriuria is common in patients using ISC over the long term, it has little clinical impact and treatment is not recommended [491]. As in the clinical review, symptomatic UTI was defined one or more symptom suggestive of UTI and/or self-reported UTI requiring treatment.

Current management of symptomatic UTI usually includes a clinical assessment of symptoms and dipstick urinalysis, followed by empiric treatment (referred to as 'first-line antibiotic' treatment throughout the model). The most clinically relevant outcome following treatment is the resolution of symptoms. In the model, this state is referred to as 'clinical cure'.

Although empiric treatment is effective in the majority of cases, a small proportion of these patients will experience persistent symptomatic infection and contact their healthcare provider for further treatment. 'First-line antibiotic resistant UTI' was used to describe patients with symptomatic relapse who require a further antibiotic prescription within 28 days of the initial prescription. Because antibiotic resistance is a key cause of treatment failure, at this point in the treatment pathway the healthcare provider will normally obtain a urine specimen and initiate targeted treatment based on the results of the culture.

UTIs may be caused by a number of different strains of bacteria. Over the past several years, antimicrobial resistant strains have emerged as important causes of UTI in the UK and around the world [370,398]. In order to accurately capture the full impact of UTI on patient morbidity, mortality and cost, the GDG considered it important to incorporate the effects of antibiotic resistance into the model.

'Multidrug resistant UTI' was defined as resistance to two or more classes of antimicrobial agents. It was assumed that all patients with a multidrug resistant infection are admitted to hospital for treatment with intravenously administered carbapenem antibiotics. Catheter-associated bacteraemia occurs when a patient's blood and urine cultures reveal growth of the same organism. All patients with catheter-associated bacteraemia were assumed to have symptomatic UTI and it was assumed that they were immediately admitted to hospital upon diagnosis.

Long-term studies have demonstrated that the incidence of urethral complications such as structures and false passages tend to increase over time [515]. Although proponents of hydrophilic catheters often cite the lower surface friction associated with their coating detected by cytological investigation [475] [449] as evidence of a reduction in urethral complications, no comparative clinical studies have been published. Therefore, in the base case analysis it was assumed that the incidence of urethral complications does not vary between the different catheter types. The model was built to allow exploration of this assumption in sensitivity analysis.

J.2.2.1 Key assumptions

The main simplifying assumption of the model is that the probability of antibiotic resistance does not change over time. The decision to build a static model was based on a lack of available data about current and historical resistance rates, the complexity of forecasting antibiotic resistance trends over time and within populations, and a lack of examples on which to base methodological approaches. The GDG deemed the assumption of a static model to be reasonable and the impact of extreme scenarios was explored in sensitivity analysis.

J.2.2.2 Model structure

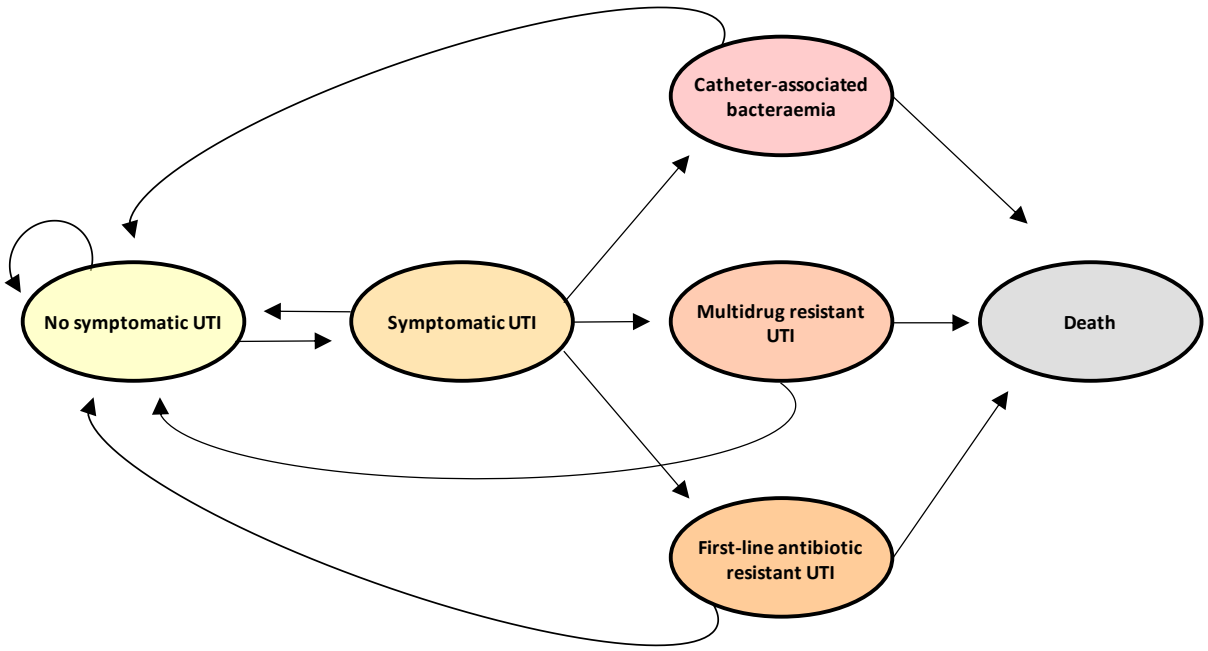
A Markov model was constructed to calculate lifetime costs and QALYs for each comparator. Figure 97 illustrates the key health states in the model and possible transitions between them in each cycle. The model is divided into one year cycles, which was thought to be a reasonable cycle length based on available evidence of clinical efficacy and baseline risk. The model was built in TreeAge Pro 2009.

The hypothetical SCI population entering the model had an average age of 40 years and was 80% male; this is the average age at injury and gender ratio of spinal cord injury patients according to the US National SCI Database [318].

The model structure did not explicitly account for patients who experience more than one UTI within a one year cycle length. Because the data used to inform the clinical effectiveness for each type of catheter measured the occurrence of 'one or more UTI', it was assumed that recurrent infections were implicitly included in the baseline and relative risk estimates. In the absene of more specific randomised evidence of comparative efficacy for recurrent UTI, this was a necessary assumption.

In addition, the analysis also did not explicitly model the transition from first-line or multidrug resistant UTI to bacteraemia. Again, this structural assumption was necessary due to data limitations. A search of the literature only identified the probability of developing bacteraemia after symptomatic UTI of non-specific severity. It was therefore assumed that this value represents the cumulative probability of bacteraemia as a result of all UTI and was only included once in the model.

Figure 97: Markov model structure



Schematic diagram of the Markov model designed to analyse the cost-effectiveness of different types of intermittent catheter. The Markov modelling approach involves a transition between different health states over time. The model is divided into 1 year cycles. At the end of each cycle a transition to another health state is possible unless patients enter into an 'absorbing' health state from which they do not recover. In this model, the absorbing state is death. At each cycle there is also an age-related probability of all-cause mortality; these transitions are not depicted in the diagram.

J.2.2.3 Uncertainty

The model was built probabilistically to take account of the uncertainty surrounding each input parameter. In order to characterise uncertainty, a probability distribution was defined for each parameter based on error estimates from the data sources (e.g. standard errors or confidence intervals). When the model was run, a value for each input was randomly selected from its respective distribution. The model was run repeatedly to obtain mean cost and QALY values.

The number of simulations used to obtain the probabilistic results was chosen according to methods described by Koehler and colleagues [228]. The model was set to ensure that the Monte Carlo error was not more than 1% of the standard error of the mean incremental cost and QALY estimate for each type of catheter. For this model, the number of simulations necessary to obtain this level of accuracy is approximately 10, 000.

Various sensitivity analyses were also undertaken to test the robustness of model assumptions and data sources. In these analyses, one or more inputs were changed and the analysis was rerun in order to evaluate the impact of these changes on the results of the model.

J.2.3 Model inputs

J.2.3.1 Summary table of model inputs

The probability of acquiring a CAUTI was based on clinical evidence identified in the systematic review undertaken for the guideline. All other model inputs were identified by supplementary literature reviews and were validated with members of the GDG. A summary of the probability, cost, and utility inputs used in the base-case analysis is provided in the tables below. More details about sources, calculations and rationale underpinning data selection can be found in the section preceding each summary table.

J.2.3.2 Baseline event rates

Symptomatic UTI

The baseline probability of developing symptomatic UTI was calculated from the studies included in the clinical review (Table 23)[59,95,110,150,224]. The annual rate was obtained by dividing the total number of events observed in patients using single use non-coated catheters by the total number of patient years (Equation 1).

Table 23: Baseline risk of symptomatic UTI in patients with SCI using single use non-coated catheters

Study	Column 1: Patients with one or more UTI	Column 2: Patients without UTI (Total N – Column 1)	Column 3: Follow-up (years)	Column 4: Total person years of observation (Column 1 x Column 3 + Column 2 x Column 3)
Cardenas 2009	14	9	1.00	23.00
de Ridder 2005	51	11	1.00	62.00
Giannatoni 2001	12	42	0.13	7.27
Duffy 1995	35	7	0.17	7.27
King 1992	3	20	0.08	1.77
Total	115	89	N/A	101.31

Equation 1. Rate

$$Rate\ (\lambda) = \frac{number\ of\ events}{total\ person\ years\ of\ observation}$$

$$Rate\ (one\ or\ more\ UTIs\ per\ year) = \frac{115}{101} = 1.14$$

A standard error for the rate was derived using the delta method as described by Kirkwood and Sterne 2003 (Equation 2)[226].

Equation 2. Standard error of the rate

$$\boldsymbol{SE\ of\ the\ rate} = \frac{\boldsymbol{SE\ number\ of\ events}}{\boldsymbol{total\ person\ years\ of\ observation}} = \frac{\sqrt{\boldsymbol{d}}}{\boldsymbol{T}} = \sqrt{\frac{\boldsymbol{\lambda}}{\boldsymbol{T}}}$$

$$\boldsymbol{SE\ of\ the\ rate}\ (\boldsymbol{one\ or\ more\ UTIs\ per\ year}) = \sqrt{\frac{\mathbf{1.14}}{\mathbf{101}}} = \mathbf{0.11}$$

For the purpose of clinical validation, the 95% confidence interval for the rate was derived from the standard error. In order to take account of the constraint that the rate must be greater than or equal to zero, it is preferable to work on the log scale and to derive a confidence interval for the log rate, then calculate the exponential to give a confidence interval for a rate [226]. The formula for the standard error of the log rate is derived using the delta method (Equation 3)[226].

Equation 3. Confidence interval for a rate

$$\mathbf{95\%}\ \boldsymbol{CI}\ (\boldsymbol{rate}) = \mathbf{exp}\left(\boldsymbol{Log}(\boldsymbol{rate}) \pm \mathbf{1.96}\ \times \frac{\mathbf{1}}{\sqrt{\boldsymbol{d}}}\right)$$

$$95\%\ CI\ (rate\ for\ one\ or\ more\ UTIs\ per\ year) = \exp\left(Log\ (1.14) \pm 1.96\ \times \frac{1}{\sqrt{115}}\right)$$
$$= 0.933\ to\ 1.347$$

A gamma distribution was applied to the rate according to the method of moments approach described by Briggs et al 2006 (Equation 4)[51].

Equation 4. Gamma distribution (α, β)

$$\boldsymbol{\alpha} = \frac{\boldsymbol{mean\ value^2}}{\boldsymbol{standard\ error\ of\ the\ mean}^{\mathbf{2}}}$$

$$\boldsymbol{\alpha}\ (\boldsymbol{rate\ for\ one\ or\ more\ UTIs\ per\ year}) = \frac{\mathbf{1.14^2}}{\mathbf{0.11^2}} = \mathbf{115}$$

$$\beta = \frac{standard\ error\ of\ the\ mean^{\,2}}{mean\ value}$$

$$\beta\ (rate\ for\ one\ or\ more\ UTIs\ per\ year) = \frac{0.11^2}{1.14} = 0.0099$$

In order to transform the baseline rate of symptomatic UTI to a probability the following equation was used (Equation 5) [133].

Equation 5. Converting a rate to a probability

$$Probability = 1 - e^{-rate \times time}$$

$$Probability\ (one\ or\ more\ UTIs\ per\ year) = 1 - e^{-1.14(\alpha=115, \beta=0.0099)} = 0.68$$

Therefore, based on the rate of symptomatic UTI observed in the included studies, the baseline probability of symptomatic UTI associated with sterile non-coated catheter use was 68% (Table 24). This is consistent with other epidemiological and observational studies in the literature [515,518].

Urethral complications

In the base case analysis, the baseline probability of developing a urethral complication was derived from an observational study of patients using ISC over an average length of 9.5 years [359]. Over this time, 19% of this group developed urethral strictures. According to the equations described above, this results in a 2.38% annual probability of developing a urethral complication (Table 24).

This value is on the upper end of estimates reported by other papers [515]. It was chosen to represent the possibility of developing urethral complications of any type, whether they are strictures, false passages, urethritis, or any other complication that could be expected as a result of urethral trauma.

J.2.3.3 Relative treatment effects

Symptomatic UTI

The between-strategy differences in costs and QALYs are driven by the relative risk (RR) of symptomatic UTI for each catheter compared to single use non-coated catheters. The RR for each catheter is based on the results of the systematic review and meta-analysis of randomised controlled trials identified in the clinical review (see section I.4), where single use non-coated catheters were used as the baseline comparator.

The probability of symptomatic UTI associated with each catheter strategy was calculated by multiplying the baseline risk of symptomatic UTI by the RR of symptomatic UTI for each catheter. The results of the meta-analysis and the distribution assigned to each RR are reported below in Table 24.

Urethral complications

In the absence of any comparative clinical evidence, it was assumed that the risk of developing urethral complications did not differ between catheters. This assumption was explored in sensitivity analysis.

Table 24: Baseline event rate and relative treatment effects

Input	Point estimate	Confidence interval	Probability distribution	Distribution parameters	Source
Baseline annual event rate					
Baseline rate of UTI (non-coated catheter used once only)	1.14	0.933 -1.347*	Gamma	α = 115.0000 β = 0.0099	Cardenas 2009, de Ridder 2005, Duffy 1995, Giannantoni 2001 & King 1995[59,95,110,150,224]
Baseline probability					
Baseline probability of symptomatic UTI	0.68	See text (Equation 5)			
Baseline probability of urethral complication	0.02	0.01-0.06	Beta	α = 0.5000 β = 20.5000	Prieto-Fingerhut 1997[383]
Relative treatment effect					
RR of UTI with hydrophilic catheter	0.80	0.65 - 0.99	Lognormal	LM = -0.2289 LSD = 0.1073	Cardenas 2009 & de Ridder 2005[59,95]
RR of UTI with gel reservoir catheter	0.33	0.11 - 0.97	Lognormal	LM = -1.2628 LSD = 0.5553	Giannantoni 2001[150]
RR of UTI with non-coated catheter used multiple times	0.98	0.77 - 1.25	Lognormal	LM = -0.0278 LSD = 0.1236	Duffy 1995 & King 1992[110,224]
RR of urethral complications (All catheters)	1.00	N/A	Fixed	N/A	Assumption

** Estimated based on mean rate and standard error according to the delta method and intended for the purpose of clinical validation only (see Equation 3). RR = relative risk, LM = log of the relative risk, LSD = standard deviation of the log of the relative risk.*

J.2.3.4 Cohort probabilities

Antibiotic resistance in UTI

Despite the clinical and political importance of antimicrobial resistant infections, evidence of the prevalence of resistant infections in the urinary tract is scarce. Only one paper which examined the incidence of first-line antibiotic treatment failure among patients with SCI who use ISC was identified [107]. In this Canadian study, patients were randomised to receive either a 3-day or 14-day course of ciprofloxacin. At 23-day follow-up, symptomatic relapse was experienced by 5 out of 30 patients in the 3-day treatment group [107]. The probability of clinical failure after treatment for symptomatic UTI was therefore 15.4%.

Among individuals with SCI, it is thought that prolonged, repeated exposure to healthcare settings and antimicrobial agents increases the risk of infection with multidrug resistant organisms. The most common mechanism of resistance in UTI-causing organisms is the production of extended-spectrum beta-lactamases (ESBL). These enzymes inactivate certain antibiotics. Like all forms of antimicrobial resistance, the prevalence of ESBL varies by geography, healthcare setting, and patient demographic. Recent studies have found that the annual probability of multidrug resistant UTI observed in the SCI population ranges from 4.3% in community dwelling persons using ISC [487] to 9% acute rehabilitation

settings [313]. Based on these estimates, it was assumed that on average, 7% of individuals with catheter-associated UTI are infected with a multidrug resistant pathogen (Table 25); this assumption was further explored in sensitivity analysis.

If on average, 15.4% of patients with SCI who use ISC experience treatment failure for symptomatic UTI and 7% of SCI patients using ISC fail treatment by virtue of having multidrug resistant UTI, it was assumed that the remaining patients experience treatment failure due to first-line antibiotic resistant infections.

Mortality due to multidrug resistant UTI

Patients infected with ESBL-producing bacteria are generally sicker than patients who are not infected with ESBL producing strains. However, there are very few studies of mortality in patients with multi-drug resistant UTI. Even among the few studies that addressed the issue in patients with bacteraemia, the question of whether ESBL-production significantly increases the risk of death remains unclear [391].

A retrospective analysis [201] of ESBL-producing bacteria found an overall mortality rate of 12.1% among patients with UTI caused by ESBL-producing *E.Coli* and *Klebsiella* bacteria. However, there was no control group for this population and it was not clear whether the analysis controlled for the contribution of antibiotic resistance to the reported mortality rates. A recent retrospective study by Klevens et al (2008)[227] determined that 8 out of a total of 43 deaths in patients with UTI caused by ciprofloxacin resistant *E.Coli* were directly caused or contributed to by the resistant organism. Out of a total of 3112 ciprofloxacin resistant isolates collected from 2000 to 2004, 9.8% were UTIs caused by ciprofloxacin-resistant E.coli. Therefore, the mortality rate in patients with UTIs caused by drug-resistant bacteria was 2.6%. The GDG thought this to be a reasonable estimate of mortality to include in the base case analysis.

Bacteraemia

In order to estimate the incidence of bacteraemia following UTI, we looked primarily to the economic evaluations retrieved by our systematic reviews and completed a search of PubMED to identify other data. In 2000 Saint et al[418] published a systematic review of the incidence of bacteraemia in patients with UTI; this was the most recent and comprehensive source of data identied to inform this parameter. Each of the five studies included in this review reported similar estimates ranging from 2.6%to 4.0%. The pooled estimate for the risk of developing bacteraemia as a result of catheter-associated UTI was 3.6% with a 95% CI of 3.4% to 3.8%[418]. The studies included in this review were from a heterogeneous hospital-based population. In the absence of any specific data regarding individuals with SCI, the same probability was assumed to apply to both the SCI and non-SCI population (Table 25).

Mortality due to bacteraemia

There have been few studies of bacteraemia in patients with SCI. Two retrospective analyses of deaths occurring within 30 days of diagnosis of bacteraemia in patients with SCI were identified [303] [488]. The study by Montgomerie and colleagues (1991) reported 4 deaths in 50 bacteraemic episodes were directly related to bacteraemia with a UTI origin (probability of 7.7%), while Wall et al (2003) report a total of 8 deaths in 95 bacteraemic episodes (probability of 8.1%). The former was used to inform the base case analysis as this rate was derived from patients with UTI-associated bacteraemia only. The slightly lower probability of mortality in these patients compared to non-SCI individuals (Table 29) appears to be a well-recognised phenomenon in the literature [303].

Table 25: Overview of baseline probabilities and probability distributions

Parameter description	Point estimate	95% Confidence interval	Beta Distribution parameters	Source
Treatment failure	0.154	0.067-0.330*	α = 4.6055 β = 25.3945	Dow 2004[107]
First-line antibiotic resistant UTI	0.085	See text		
Multidrug resistant UTI	0.070	0.043-0.090*	α = 40.4460 β = 537.3540	Estimate based on Mylotte 2000 & Waites 2000[313,487]
Multidrug resistant mortality	0.026	0.013-0.051*	α = 7.8960 β = 297.1040	Klevens 2008[227]
Bacteraemia	0.036	0.034-0.038	α = 867.5640 β = 23231.436	Saint 2000[418]
Bacteraemia mortality	0.077	0.029- 0.192*	α = 3.8442 β = 46.1558	Montgomerie 2011[303]

** Estimated based on mean rate and standard error according to the delta method and intended for the purpose of clinical validation only (see Equation 3).*

J.2.3.5 Life expectancy

Although there have been dramatic improvements in the care of patients with spinal cord injuries over the past 50 years, life expectancy remains slightly below normal. Mortality rates are significantly higher during the first year after injury than during subsequent years, particularly for more severely injured individuals. For the purposes of this analysis, it was assumed that patients using IC in the community had survived beyond the one-year time point.

To date, there is only one study of mortality among spinal cord injury patients in Britain. Frankel et al (1998) [135] conducted a review of medical records from patients with spinal cord injury of at least one year duration at Stoke Mandeville hospital and the Regional Spinal Injuries Centre in order to calculate standardised mortality ratios (SMRs) for subjects injured between 1973 and 1990. The gender distribution of this cohort (81% male) closely matched that of our baseline demographic and the analysis combined mortality ratios for all levels of disability. Age-dependant annual mortality rates were calculated by multiplying the SMR of 5.41 for patients aged 31-41 at time of injury by central mortality rates obtained from life tables for England and Wales in 2007-2009 [337].

J.2.3.6 Utilities

In accordance with the NICE reference case, health outcomes were estimated using the Quality Adjusted Life Year (QALY). In order to calculate QALYs, it is necessary to quantify both the quality of life of each health state and the time spent in each state. A systematic literature search was performed in order to identify all health related quality of life studies related to UTI and UTI-associated bacteraemia. The results of this review are reported in Appendix K.

The literature search revealed two recent studies which measured the impact of UTI in people with SCI using a validated generic measure of health-related quality of life [174,257,483]. The authors of these studies were contacted for additional information and both replied. Although Haran and co-workers were unable to provide any further data, Vogel and colleagues granted us access to recent patient-level SF-12 responses collected as part of a longitudinal study of adults who sustained SCI as children and adolescents [483,529]. The responses were classified into three groups according to our outcome of interest: no UTI, UTI and severe UTI (requiring intravenous antibiotics or hospitalisation). The recall

period for each group was one year (i.e. patients were asked to describe their health over the past year). Using an algorithm developed by Gray et al 2006 [164], this data was mapped to EQ-5D values for the UK population. Because of the random component contained within this mapping algorithm, a simulation was run 1000 times in order to calculate a mean value, standard error and confidence interval for each of the three health states measured (Table 26).

In order to calculate a utility value for first-line resistant UTI, it was assumed that the quality of life associated with this health state is worse than that for UTI but better than that for multidrug resistant UTI. The mean value of these two health states was taken and the standard error was assumed to be 5% of the mean in order to generate the probability distribution (Table 26).

In the absence of published utility values for UTI-associated bacteraemia, it was assumed that a linear decrease in health-related quality of life applies to those in this health state and that the standard error was 5% of the mean. The implications of this assumption were explored in sensitivity analysis.

The values calculated from the studies by Zebracki et al 2010[529] and Vogel et al 2002[483] were chosen to inform the base case analysis as they better account for the range of health states within the model and were elicited with a recall period that more accurately matches the model cycle length than the data reported by Lee and Harran [174,257].

A recent Cochrane review of procedures for urethral narrowing did not find any quality of life data among patients treated for urethral strictures [512]. A search of the Tufts cost-effectiveness analysis registry [3] also failed to identify any relevant utility weights in the literature. Given that urethral complications would likely involve significant discomfort and stay in hospital, it was assumed that the quality of life associated with this health state would be comparable to that experienced by patients with multidrug resistant UTI.

Table 26: Health state utility weights for people with SCI

Health state	Point estimate (QALY)	95% Confidence interval	Gamma distribution parameters	Source
No symptomatic UTI	0.831	0.809-0.852	α = 5707.1157 β= 0.0001	Vogel 2002 and Zebracki 2010[483,529]
Symptomatic UTI	0.782	0.764-0.799	α = 7549.6790 β = 0.0001	Vogel 2002 and Zebracki 2010[483,529]
First-line resistant UTI	0.760	0.685-0.834*	α = 400.0000 β = 0.0019	Expert opinion
Multidrug resistant UTI	0.738	0.688-0.787	α = 805.6864 β = 0.0009	Vogel 2002 and Zebracki 2010[483,529]
Bacteraemia	0.716	0.645-0.786*	α = 400.0000 β = 0.0018	Expert opinion
Urethral complication	0.738	0.688-0.787	α = 805.6864 β = 0.0009	Assumed to be same as multi-drug resistant UTI

**Estimated based on mean and standard error - intended for the purpose of clinical validation only.*

J.2.3.7 Resource use and cost

Cost of catheters

All catheters available through the NHS Drug Tariff[323] were classified as either hydrophilic, gel reservoir or non-coated with the help of the continence expert and manufacturer information provided on-line. In cases where there was uncertainty about catheter type, manufacturers were contacted by telephone. The average cost of each type of catheter was used as the point estimate; the maximum and minimum listed costs formed the range used to inform each distribution (Table 27).

Most individuals using ISC catheterise between four and six times a day regardless of the type of catheter they use [513]. In order to calculate the annual cost of gel reservoir, hydrophilic and single-use non-coated catheters, it was assumed that patients catheterise an average of 5 times per day. Depending on personal habits and preferences, individuals using non-coated catheters multiple times use a highly variable number of catheters per month. To ensure consistency with prescribing data from the NHS Drug Tariff[323] and the literature[478], an average of 5 catheters per month (ranging from 4 to 6 per month) was used to calculate the annual cost of non-coated catheters used multiple times in the base case analysis. This was varied in sensitivity analysis.

Non-coated catheters require an application of lubricant before use. Although most patients use a water-based lubricant, the GDG estimated that an average of five percent of patients who self catheterise regularly use lidocaine lubricant. This estimate was probabilistically incorporated in the cost of lubricant by assuming a range of between 0% and 10%. Because lubricant is applied to the catheter each time it is used, it was assumed that patients with single use and multiple use non-coated catheters consume equal amounts of lubricant.

In order to accurately capture the cost of catheter use in the community, a monthly prescription dispensing fee was added to the cost of catheters and lubricant (i.e. one prescription charge per month for gel reservoir and hydrophilic catheters and a total of two prescription charges per month for noncoated catheters) .The range used to inform this distribution was based on the highest and lowest dispensing fee scales for authorised dispensing practitioners.

Table 27: Catheter unit costs and annual resource use

	Point estimate	Value range	Gamma Distribution parameters	Source
Mean unit cost per catheter				
Hydrophilic catheter	£1.28	£0.97 - £1.66	α = 56.6920 β = 0.0226	NHS Drug Tariff 2010[323]
Gel reservoir catheter	£1.36	£0.98 - £1.43	α = 184.9600 β = 0.0074	NHS Drug Tariff 2010[323]
Non-coated catheter	£1.19	£0.39 - £1.47	α = 62.9378 β = 0.0189	NHS Drug Tariff 2010[323]
Water-based lubricant (per 5g sachet)	£0.19	£0.18 - £0.19	α = 258.7902 β = 0.0007	NHS Drug Tariff 2010[323]
Lidocaine lubricant (per 8.5g sachet)	£1.20	£0.96 - £1.44*	α = 100.0000 β = 0.0120	NHS Drug Tariff 2010[323]
Dispensing fee (per month)	£1.96	£1.87 - £2.11	α = 61.4656 β = 0.0319	NHS Drug Tariff 2010[323]
Mean number of catheters and lubricant sachets used per year				
Single use hydrophilic, gel	1825	1460 - 2190	α = 102.7970	Woodbury

	Point estimate	Value range	Gamma Distribution parameters	Source
reservoir and non-coated			β = 17.7534	2008[513]
Multiple use non-coated	60	48 - 72	α = 105.1939 β = 0.5703	NHS Drug Tariff 2010[323]
Sachets of lubricant (for both single use and multiple use non-coated catheters)	1825	1460 - 2190	α = 102.7970 β = 17.7534	Assumption based on the number of catheters used per year
Equivalent mean annual cost				
Single use hydrophilic catheter	£2359.40			
Single use gel reservoir catheter	£2505.50			
Single use non-coated catheter	£2657.76			
Multiple use non-coated catheter	£557.35			

**Estimated based on mean and standard error - intended for the purpose of clinical validation only.*

Cost of treatment for infection

CAUTI treatment costs were estimated based on recommended diagnostic and treatment pathways for UTI in adults [474] [181]. Costs regarding contact time with primary healthcare workers were obtained from the 2009/10 Personal and Social Services Research Unit [88] Costs incurred in the community were based on data from the 2010 NHS Drug Tariff [323]. The cost of secondary care was calculated according to 2009/10 NHS Reference costs. A detailed breakdown of the cost of treating catheter-related infections is presented in Table 28.

Please note the following for costing purposes:

- Patients may consult a number of different healthcare professionals for treatment of UTI. It was assumed that the healthcare provider most frequently contacted for UTI was a GP (in 80% of cases), followed by community nurse specialist (in 10% of cases) and hospital emergency room (in 10% of cases) [513]. The cost of GP consultations and community nurse specialist were obtained from the Unit Costs of Health and Social Care 2009/10 [88], the cost of emergency room visit was obtained from the NHS reference costs 2009/10[100]. These costs were incorporated into the model probabilistically according to the following distributions:
  - The average cost of a GP consultation was estimated at £30, based on a 12.6 minute surgery consultation with upper and lower confidence intervals based on the mean cost of home visit (£60) and 10 minute surgery consultation (£23) used to inform the distribution parameters (α = 100.0000, β = 0.3000)
  - The cost of a 20 minute home visit from a community nurse specialist (£20) was used as the mean cost per nurse consultation, with the cost of the same length of visit by a community specialist (£23) and clinical support worker (£8) forming the upper and lower confidence intervals (α = 44.4444, β = 0.4500).
  - The mean national unit cost of an emergency room visit is £62 with an inter quartile range of £37 (α = 4.8985, β = 12.6510).

- First-line therapy for symptomatic UTI in England currently includes the antibiotics trimethoprim, nitrofuratonin, cefalexin, and pivmecillinam; what drug is prescribed varies by region and between practices [13]. In the base case analysis, the model assumes an

average treatment length of 5 days for each drug (with the exception of pivmecillinam), based on an average treatment duration of 3 and 7 days for women and men, respectively [13]. Mean unit cost was calculated as a simple mean based on the following costs listed in the NHS Drug Tariff 2010 [323] and dosages from the prescribing support unit [467] (the most expensive and least expensive course of treatment was used as confidence intervals used to inform the parameter distribution):

- Trimethoprim 200mg twice daily for five days (£0.75)
- Nitrofuratonin 50mg four times daily for five days (£1.91)
- Cefalexin 500mg twice daily for five days (£1.30)
- Pivmecillinam 200mg three times daily for three days (£4.05)

- The same sources and methods were used to calculate the average cost of second-line antibiotics used to treat first-line resistant UTIs. The cost of second-line antibiotics was calculated as a simple mean of the costs of the following individual drugs:
  - Ciprofloxacin 250mg three times daily for seven days (£2.33)
  - Cefaclor 250mg three times daily for seven days (£5.28)
  - Cefixime 200mg once daily for seven days (£13.23)
  - Norfloxacin 400mg twice daily for seven days (£3.81)
  - Ofloxacin 400mg once daily for seven days (£5.82)
  - Pivmecillinam 400mg four times daily for seven days (£50.40).

- In both first- and second-line treatment, it is assumed that patients are fully compliant. Given the short duration of the course of antibiotics, this is considered reasonable [131].

- Increased fluid intake and frequent urination associated with UTI will result in increased catheter use while the patient is symptomatic. Therefore, the cost of additional catheters (and lubricant for non-coated catheters) was added to the cost of each infection treated in the community. The GDG indicated that an average of 12 catheters per infection (and infection exacerbation) would be a reasonable estimation.

- Patients with multidrug resistant infections are usually admitted to hospital for intravenous drug therapy [13]. The cost of treatment for a multidrug resistant infection was calculated as a weighted average reference cost for kidney or urinary tract infection *with intermediate* complications (LA04E; £2,097 (£1, 681 to £2417)) and *without* complications (LA04F; £1, 618 (£1, 203 to £1, 822)). The average excess bed day cost for each HRG is £197 (£154 to £224) and £195 (£154 to £222)[100], respectively. These costs were weighted according to reported activity, with 73% of the total cost attributed to LAO4E, in order to produce a total average cost for people with multi-drug resistant UTI.

- The cost of treatment for bacteraemia secondary to UTI was assumed to be equivalent to the non-elective reference cost for kidney or urinary tract infection *with major* complications (code LA04D) with a national average unit cost of £2938 (£2264 to £3352) and average excess bed day cost of £198 (£152 to £227)[100]. In the UK, bacteraemia caused by resistant organisms does not appear to have a significant impact on length of hospital stay compared to bacteraemia caused by susceptible organisms (Melzer and Petersen 2007)[294].

Cost of treatment for urethral complication

The cost of treating a urethral complication was estimated based on reference cost group LB30B: urethra disorders and intermediate/minor procedures without complications with a national average unit cost of £1,268 and lower and upper quartile unit cost of £908 and £1,399 [100]. The effect of increased treatment cost due to failed or repeat procedures was explored in sensitivity analysis.

Table 28: Cost of treatment

	Point estimate	Value range	Gamma distribution parameters	Source
Symptomatic UTI				
Healthcare consultation	£32.20	See text		PSSRU 2010[88]
Dipstick analysis	£0.07	£0.06 - £0.08	α = 0.5432 β = 0.1357	NHS Drug Tariff 2010[323]
First-line antibiotic treatment	£2.00	£0.75 - £4.05	α = 1.7826 β = 1.1235	NHS Drug Tariff 2010[323]
Dispensing fee	£1.96	£1.87 - £2.11	α = 61.4656 β = 0.0319	NHS Drug Tariff 2010[323]
Additional catheters	Dependant on type of catheter (assumed an average of 12 additional catheters per infection)			NHS Drug Tariff 2010[323]
Equivalent mean total cost	**£36.23 + additional catheters**			
First-line antibiotic resistant UTI				
Healthcare consultation	£32.20	See text		PSSRU 2010[88]
Urine analysis	£7.00	£5.00 - £9.00	α = 5.4444 β = 1.2857	NHS Reference costs
Second line antibiotic treatment	£13.48	£2.33 - £50.40	α = 1.5016 β = 8.9768	NHS Drug Tariff 2010[323]
Dispensing fee	£1.96	£1.87 - £2.11	α = 61.4656 β = 0.0319	NHS Drug Tariff 2010[323]
Additional catheters	Dependant on type of catheter (assumed an average of 12 additional catheters per infection)			NHS Drug Tariff 2010[323]
Equivalent mean total cost	**£54.64 + additional catheters**			
Multidrug resistant UTI				
Healthcare consultation	£32.20	See text		PSSRU 2010[88]
Urine analysis	£7.00	£5.00 - £9.00	α = 5.4444 β = 1.2857	NHS Reference Costs[100]
Non elective inpatient admission (LA04E)	£2, 097	£1, 681 - £2, 417	α = 13.535 β = 154.93	NHS Reference Costs [100]
Non elective inpatient admission (LA04F)	£1, 618	£1, 203 - £1, 822	α = 8.6577 β = 186.92	NHS Reference Costs [100]
Average number of excess bed days (LA04E)	0.92	NA	Fixed	NHS Reference Costs [100]
Average number of excess bed days (LA04F)	1.02	NA	Fixed	NHS Reference Costs [100]
Cost per excess bed day (LA04E)	£197	£154 - £224	α = 12.829 β = 15.355	NHS Reference Costs [100]

	Point estimate	Value range	Gamma distribution parameters	Source
Cost per excess bed day (LA04F)	£195	£154 - £222	α = 14.062 β = 13.866	NHS Reference Costs [100]
Equivalent mean total cost	**£2019.02**			
Bacteraemia				
Healthcare consultation	£32.20	See text		PSSRU 2010[88]
Urine analysis	£7.00	£5.00 - £9.00	α = 5.4444 β = 1.2857	NHS Reference Costs [100]
Blood test	£7.00	£5.00 - £9.00	α = 5.4444 β = 1.2857	NHS Reference Costs [100]
Non elective inpatient admission (LA04D)	£2938	£2, 264 - £3, 352	α = 14.558 β = 201.80	NHS Reference Costs [100]
Average number of excess bed days (LA04D)	0.97	N/A	Fixed	NHS Reference Costs [100]
Cost per excess bed day (LA04D)	£198	£152 - £227	α = 9.2966 β = 21.318	NHS Reference Costs [100]
Equivalent mean total cost	**£3197.83**			
Urethral complication				
Urethral procedure	£1, 268	£908 - £1,399	α = 17.8748 β = 70.9659	NHS Reference Costs [100]

J.2.4 Sensitivity analyses

ISC in people who do not have SCI

In the absence of any clinical data, it was assumed that the relative risk of symptomatic UTI for each type of catheter was the same as that observed in the SCI population. This was a necessary assumption in order to explore the cost-effectiveness of intermittent catheter types across a wider group of people with bladder dysfunction. The GDG indicated that it was also a reasonable assumption as there is no clinical reason to suspect that SCI patients would respond any differently to any one type of catheter than any other patient using ISC.

Cohort probabilities

People with bladder dysfunction not caused by SCI are a highly diverse group of patients, with a wide range of ages, health states, disabilities. Several cohort probabilities were changed to reflect the probability of antibiotic resistance and mortality in a more heterogeneous population. There is very little epidemiological evidence about the prevalence and morbidity of UTI in this population as a whole; young women appear to be the most common subject of UTI-related research in the literature. The GDG indicated that if the sample size were large, this population may represent a sufficiently heterogeneous group from which to draw the parameters to inform probabilities for the sensitivity analysis.

A study of over 75,000 patients from the UK General Practice Research Database was used to estimate the probability of treatment failure in this group of patients. This study found that between 12% and 16% of women treated for UTI return within 28 days for a further course of treatment, regardless of the antibiotic initially prescribed [255]. This is consistent with the findings of a study of a large pharmaceutical database in the Netherlands [158]. Following input from experts at the Health Protection Agency (Neil Woodford and Alan Johnson; personal communication), and review of

several other data sources[10,79,227,294,379,398,514],it seems likely that between 4% to 8% of community acquired urinary isolates in the UK and USA are resistant to ciprofloxacin or contain extended-spectrum beta-lactamase (ESBL) producing bacteria. Therefore, it was assumed that approximately 6% of UTIs in the UK are multidrug resistant (Table 29). The same probability of developing bacteraemia and of dying from multidrug resistant UTI as in the base case analysis was assumed to apply to this analysis. The probability of mortality from bacteraemia was obtained from a meta-analysis by Bryan and Reynolds (1984) [52].

Utilities

The life expectancy and utility values informing the model were also updated. Three studies were identified through our quality of life review (Appendix K:) which allowed a series of multiplicative relationships to be used to calculate utility values per symptom day for patients without SCI. The per-day utility value for patients who recover from symptomatic UTI after empirical treatment was derived from a study by Ellis and Verma (2000) [120], in which the SF-36 questionnaire was administered to a group of otherwise healthy women suffering from UTI and their matched controls. The algorithm suggested by Ara and Brazier (2008) [21] was used to convert SF-36 responses into EQ-5D health state valuations, which were adjusted based on average mapped EQ-5D values for the UK population [207].

A study by Ernst et al (2005)[123] used the Quality of Well Being to evaluate the effect of failed antibiotic treatment compared to clinical cure in patients being treated for UTI. In order to calculate the proportional utility decrease for patients with first line resistant infections, the reported value for patients who failed treatment at 7 days was divided by the score for patients who were cured after 3 days. A multiplicative relationship was assumed to apply to the EQ-5D value derived from Ellis and Verma (2000) in order to estimate the utility value for patients with first-line resistant UTI. The same calculation was applied to patients experiencing treatment failure at 14 days in order to estimate the daily utility value for patients with multidrug resistant UTI. In the absence of any utility values for UTI-associated bacteraemia, a value derived from inpatients with bloodstream infections of unspecified origin was used to inform this health state [428].

The recall period used by Ellis and Verma (2000) asked patients about their quality of life within the past 24 hours. To obtain QALYs, the daily utility value for each health state was multiplied by the duration of the health state, assuming that the rest of the year was lived in a state of full health (Equation 6). For patients who achieve clinical cure after empiric treatment, an average symptom duration of 3.5 days was assumed based on expert opinion. The duration of first-line resistant UTI was assumed to be 8.5 days allowing time for the patient to realise treatment failure, consult a healthcare professional, and begin a second course of antibiotics. Given that patients with multidrug resistant UTI and bacteraemia would be admitted to hospital for treatment, it was assumed that these infections would last an average of 10 days based on expert opinion and NHS Reference Cost data.

Equation 6. QALYs for patients without SCI

$$Utility\ per\ day\ of\ infection\ x\ \left(\frac{symptom\ duration}{365}\right) + Utility\ per\ day\ of\ full\ health\ x\ \left(\frac{365 - symptom\ duration}{365}\right)$$

Resource use and cost

All costs remained the same as in the base case.

Table 29: Summary of probability and utility values for people without SCI

Parameter description	Point estimate	Value range	Probability distribution	Distribution parameters	Source
Cohort probabilities					
Treatment failure	0.14	0.120-0.160	Beta	α = 139.165 β = 854.875	Lawrenson 2001[255]
First-line antibiotic resistant UTI	0.080	See text			See text
Multidrug resistant UTI	0.060	0.040-0.080	Beta	α = 27.9070 β = 437.2088	Expert opinion informed by al Hasan 2010, Cohennahum 2008, Klevens 2008, Melzer 2007, Potz 2006, Reynolds 2009, Woodford 2004[10,79,227,294,379,398,514]
Multidrug resistant mortality	0.026	0.013-0.051*	Beta	α = 7.8960 β = 297.1040	Klevens 2008[227]
Bacteraemia	0.036	0.034-0.038	Beta	α = 867.564 β = 23231.440	Saint 2000[418]
Bacteraemia mortality	0.127	0.091-0.176*	Beta	α = 28.0528 β = 192.9471	Bryan 1984[52]
Utility per *day* of symptoms					
No symptomatic UTI	0.858	0.775 - 0.943*	Beta	α = 55.6619 β = 9.1594	Jenkinson 1999[207]
Symptomatic UTI	0.674	0.608 - 0.741*	Beta	α = 129.5527 β = 62.5388	Ellis 2000[120]‡
First-line resistant UTI	0.630	0.568 - 0.692*	Beta	α = 147.1142 β = 86.1642	Ellis 2000, Ernst 2005[120 123] ‡
Multi-drug resistant UTI	0.617	0.557 - 0.678*	Beta	α = 152.3615 β = 94.3569	Ellis 2000, Ernst 2005[120 123]‡
Bacteraemia	0.530	0.478 - 0.582*	Beta	α = 187.4700 β = 166.2470	Greenwell 2004, Selai 1995[166,428]
Urethral complications	0.617	0.557 - 0.678*	Beta	α = 152.3615 β = 94.3569	Expert opinion
Symptom duration (days)					
Symptomatic UTI	3.5	2.625-4.374*	Gamma	α = 61.5837 β = 0.0568	Expert opinion
First-line resistant UTI	8.5	6.373-10.626*	Gamma	α = 61.3731	Expert

Parameter description	Point estimate	Value range	Probability distribution	Distribution parameters	Source
				β = 0.1385	opinion
Multidrug resistant UTI	10.0	7.493-12.506*	Gamma	α = 61.1306 β = 0.1636	Expert opinion
Bacteraemia	10.0	7.493-12.506*	Gamma	α = 61.1306 β = 0.1636	Expert opinion
Urethral complications	10.0	7.493-12.506*	Gamma	α = 61.1306 β = 0.1636	Expert opinion
Equivalent mean utility per year (QALY)					
No UTI	0.858				
Symptomatic UTI	0.856				
First-line resistant UTI	0.853				
Multidrug resistant UTI	0.852				
Bacteraemia	0.850				
Urethral complications	0.852				

**Estimated based on mean and standard error – intended for the purpose of clinical validation only.*
‡Adapted from reference

Urethral complications

Currently, there is no comparative clinical evidence to suggest that the use of one type of catheter results in fewer urethral complications compared to another. However, there have been animal and laboratory studies suggesting that the coated catheters reduce removal friction and cell adhesion compared to non-coated catheters [275,489]. This is sometimes interpreted as evidence that hydrophilic catheters cause less urethral trauma and may lead to a decrease in urethral complications. The effect of a reduction in urethral complications associated with hydrophilic and gel reservoir catheters was explored in the sensitivity analysis.

Parameter uncertainty

One- and two-way sensitivity analyses were undertaken to evaluate the relative impact of the probability of antimicrobial resistance, mortality, utility, resource use and cost on the outcome of the model.

J.2.5 Value of information analysis

All decisions about the cost-effectiveness of interventions are associated with a certain degree of uncertainty in the evidence base. As a result of this uncertainty there will always be a chance that the wrong decision will be made. A wrong decision would be costly in terms health benefit and resources forgone. The best way to resolve this uncertainty is to gather more information, but this may also be costly and time consuming. Value of information (VOI) analysis provides a framework for determining the expected benefit of future research by taking into account both the probability that further information will change the adoption decision, the sample size necessary to achieve maximal benefit, and the opportunity cost of conducting a research project of this size. VOI aims to answer the question of whether future research should be conducted, and if so, on which uncertain parameters, and provides and estimate of the optimal sample size for each study.

Expected value of perfect information (EVPI)

Per-patient EVPI

The first step of VOI is to estimate the expected value of perfect information (EVPI) per patient. As stated in section J.2.6, the decision rule that we must use when making recommendations is to choose the option that maximises net benefit based on current information. If we had perfect information, we would always choose the correct option and there would be no loss. However, in order to achieve perfect information we would require a study with infinite sample size.

In reality, there will always be a degree of error associated with each data input in the decision problem. The expected cost of uncertainty is determined jointly by the probability that the decision based on based on existing information will be wrong and the consequences of a wrong decision. The expected loss as a result of uncertainty is equivalent to the expected gain from eliminating uncertainty (i.e. the EVPI). Mathematically, the EVPI is the difference between expected maximum net benefit with perfect information and the maximum expected net benefit with current information. The per-patient EVPI for each model was generated directly from the simulated output (over 10 000 iterations) from TreeAge 2009.

Population EVPI

The next step in determining the EVPI is to calculate the upper limit for future research expenditure by taking into account both the current and future patient populations who might be expected to benefit from the intervention in question. Multiplying the per-patient EVPI by the number of current and future people using intermittent catheterisation in England and Wales who will be affected by the decision provides us with an upper boundary for future research expenditure (Equation 7).

Equation 7. Population EVPI

$$Population\ EVPI = per\ patient\ EVPI \times \sum_{t=0}^{T} \frac{Incident\ population\ in\ time\ t}{(1+3.5\%)^t}$$

Current and future patients affected by the decision problem

Several sources of data and a series of assumptions were used to inform the population estimate for the value of information analysis:

- **Prevalence and incidence of traumatic SCI in England and Wales:** There are currently 40,000 people in the UK living with SCI (Kennedy 1998). The majority of these injuries are caused by trauma. The annual incidence of traumatic-SCI is approximately 15 new cases per million per year in Western Europe [86].
- **Prevalence and incidence of non-traumatic SCI in England and Wales:** There is little information about the prevalence of other conditions causing SCI such as spinal stenosis, tumours, ischaemia and inflammation, but it is thought that approximately 36% of spinal cord injuries are non-traumatic[291]. The annual incidence of non-traumatic SCI is estimated at 26.3 cases per million[321,322]
- **Proportion of patients with SCI who use ISC:** Roughly 80% of people with SCI have some degree of difficulty with bladder function[269,269]; it was assumed that 60% of these patients would use ISC. Approximately 90% of individuals with SCI live in private residences following

rehabilitation[318] and 40% are in school or employment[318]. It was assumed that the same proportion applies to those with non-traumatic SCI.

- **Proportion of patients who should not use multiple use non-coated catheters:** It was assumed that people who do not live in a private residence and people who are at work or school do not have regular access to facilities needed to wash and dry catheters. Clean multiple use non-coated ISC was assumed to be an option for the remainder of the SCI population.
- **Lifetime of the technology:** Current guidelines recommend that the selected time horizon should reflect the effective lifetime of the technology. A search of PubMed and Google Scholar did not reveal any evidence of imminent new developments in catheter material research, but there is active work in this field. Ten years was thought to represent a reasonable estimate of time before a new type of intermittent catheter might be expected to be brought to market.
- **Current and future population of England and Wales:** The population of England and Wales is currently 62 million, projected to rise to approximately 67 million over the next 10 years [337].

Given current population and incidence estimates and discounting at a rate of 3.5%, over the next 10 years approximately 13, 437 people will have a choice between using clean or sterile ISC. Approximately 11, 500 will have a choice between different types of sterile ISC.

Expected value of partial parameter information (EVPPI)

It is also possible to identify which type of additional evidence is most valuable to the decision problem by calculating the expected value of partial parameter information (EVPPI). The EVPPI is an estimate of the value of eliminating uncertainty regarding a particular parameter or set of parameters (for example, baseline risks or quality of life). This information can be used to indicate which endpoints should be included in further experimental research, or to focus research on obtaining more precise estimates for values which may not require an experimental design. As with the EVPI, the per-patient EVPPI must also be multiplied by the affected population over the appropriate time period to obtain the population EVPPI. The population EVPPI provides an upper boundary for the cost of research into particular parameters.

The method of calculating EVPPI is conceptually very similar to EVPI. It is the difference between the expected value with perfect and current information about a parameter or group of parameters. The crucial difference is that EVPPI requires a two-level, or 'nested', Monte Carlo procedure. The procedure begins with an outer loop sampling values from the distribution of the parameters of interest, and for each of these, an inner loop sampling the remaining parameters from their conditional distribution.

The per patient EVPPI for the current model was calculated using TreeAge 2011. The outer loop was run 400 times (that is, each parameter of interest was sampled 400 times) and the inner loop was run 5 000 times (that is, for each of the 400 outer samples, the Monte Carlo analysis was run for 5 000 iterations). Given time constraints, this was thought to represent a pragmatic solution to the suggestion that the inner loop should be run 1000 to 10 000 times [335].

Expected value of sample information (EVSI) & expected net benefit of sampling (ENBS)

Although the population EVPI and EVPPI provide an estimate of the maximum budget for research, a positive value does *not* mean that such a budget *should* be set. In order to determine the net benefit of conducting research into a particular topic or specific set of parameters, it is essential to first determine the optimal sample size.

With increasing sample size, the EVSI will reach a ceiling which equals the maximum EVPI/EVPPI (representing an infinite sample size). However, with increasing sample size, the costs of research will also increase. The expected net benefit of sampling (ENBS) is defined as the difference between the expected value of sample information (EVSI) with sample size n and the cost of conducting research with sample size n. The point at which EVBS is maximised is the optimal sample size for the proposed study. If there is no positive sample size for which the EVBS is greater than zero, then additional research is not warranted and the decision should be based on current information only.

The EVSI was calculated by repeatedly running the EVPPI analyses for different n values (outer loops). These analyses were only undertaken for parameters with EVPPI values greater than zero. The analyses were run 5 times for each sample size and an average EVSI obtained for each sample size.

Cost of research

Clinical trial budgets are a mixture of direct, indirect, fixed and variable costs. A search was preformed to identify average research budgets for similar types of trials but no information was identified. It was assumed that a trial of this type would be relatively inexpensive to administer. A fixed cost of £50, 000 was used to account for the estimated full time salary of a study coordinator, to supplement the costs of a clinician/researcher and cover the cost of any additional expertise needed for data analysis. An estimated incremental cost of £500 per patient was also assumed to relate to the costs of administration associated with each patient. It was assumed that the costs of the catheters themselves would be covered by the NHS, not the research grant.

J.2.6 Interpreting results

The results of cost-effectiveness analysis are presented as incremental cost-effectiveness ratios (ICERs). ICERs are calculated by dividing the difference in costs associated with two alternative treatments by the difference in QALYs:

$$\text{ICERs} = \frac{\text{Cost of B} - \text{Cost of A}}{\text{QALY of B} - \text{QALY of A}}$$

Where more than two interventions are being compared, the ICER is calculated according to the following process:

1. The interventions are ranked in terms of cost, from least to most expensive.
2. If an intervention is more expensive and less effective than the preceding intervention, it is said to be 'dominated' and is excluded from further analysis.
3. ICERs are then calculated for each drug compared with the next most expensive non-dominated option. If the ICER for a drug is higher than that of the next most effective strategy, then it is ruled out by 'extended dominance'
4. ICERs are recalculated excluding any drugs subject to dominance or extended dominance.
5. When there are multiple comparators, the option with the greatest average net benefit may also be used to rank comparators.

NICE's report 'Social value judgements: principles for the development of NICE guidance' sets out the principles that GDGs should consider when judging whether an intervention offers good value for money [316].In general, an intervention is considered to be cost-effective if either of the following criteria apply:

- The intervention dominates other relevant strategies (that is, is both less costly in terms of resource use and more clinically effective compared with all the other relevant alternative strategies), or

- The intervention costs less than £20,000 per quality-adjusted life-year (QALY) gained compared with the next best strategy

J.2.7 Validation

The model was developed in consultation with the GDG; model structure, inputs and results were presented to and discussed with the GDG for the purpose of clinical validation and technical interpretation.

The model was systematically checked by the health economist undertaking the analysis; this included inputting null and extreme values and checking that results were plausible given inputs. The model was also peer reviewed by the lead health economist at the NCGC; this included systematic checking of many of the model calculations.

J.3 Results

J.3.1 Base case analysis

For patients who are able to wash and re-use catheters, this represents the most cost-effective option for intermittent self catheterisation. For patients who may not be in a situation that allows them to wash and re-use catheters, gel reservoir catheters are most cost-effective. Results of the base case probabilistic analysis are summarised in Table 30 and shown graphically in Figure 98.

In both scenarios, gel reservoir catheters are the most effective type of catheter (i.e. associated with more QALYs than the other catheter types). However, they are not always the most cost-effective option. According to NICE decision making rules (page 387), an intervention can only be considered cost-effective if its ICER falls below the £20,000 to £30,000 threshold. According to the results of our model, when gel reservoir catheters are compared to multiple-use non-coated catheters, the ICER is £51, 345. In other words, the QALY gain associated with gel reservoir catheters compared to multi-use non-coated catheters is not enough to justify the large difference in cost.

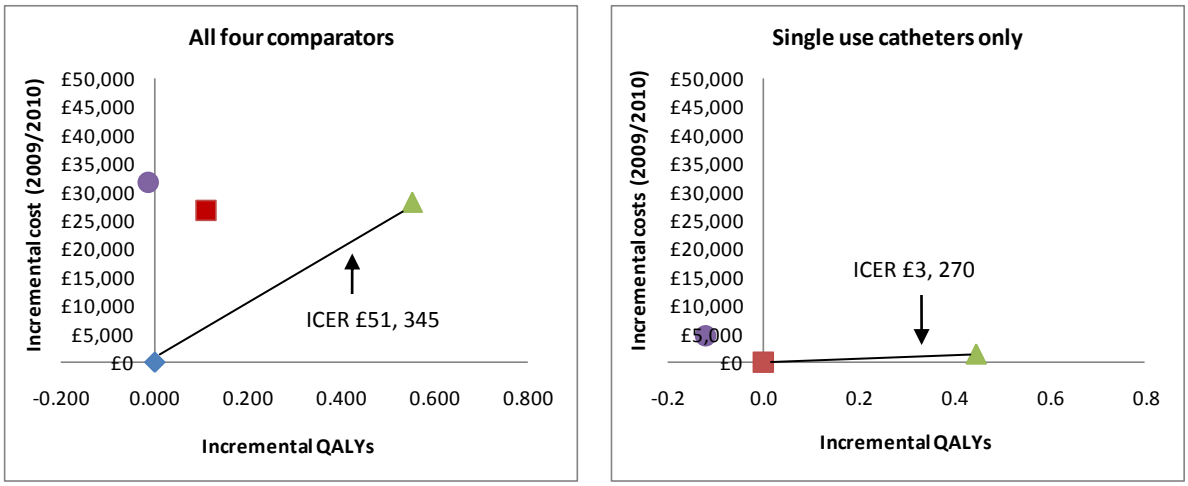
When it is not possible to re-use non-coated catheters, gel reservoir is the most cost-effective type of catheter. Compared to hydrophilic catheters, gel reservoir catheters are more effective and slightly more expensive, with an ICER of approximately £3, 270 per QALY.

Table 30: Base case analysis results (probabilistic)

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

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

Figure 98: Base case analysis results (probabilistic)



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

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

As outlined in Table 31, the main cost driver in the model is the cost of the catheters (and lubricant where applicable). The cost attributed to treating infections is lowest for gel reservoir catheters, however these catheters are associated with the greatest catheter cost. The opposite is true of multiple use non-coated catheters.

Table 31: Discounted total cost per patient with SCI over a lifetime horizon (deterministic)

Cost category	Noncoated multiple use	Gel reservoir	Hydrophilic	Noncoated single use
Catheters	£1, 428	£38, 379	£35, 623	£33, 008
Lubricant (noncoated only)	£6, 956	£0	£0	£6, 953
Symptomatic UTI	£539	£266	£492	£545
First-line resistant UTI	£202	£107	£191	£204
Multi drug resistant UTI	£1, 421	£673	£1, 254	£1, 436
Bacteraemia	£1, 201	£569	£1, 072	£1, 214
Urethral complications	£438	£447	£440	£437

J.3.2 Sensitivity analysis

ISC in people who do not have SCI

The results of the model are unchanged in patients with bladder dysfunction that is not caused by SCI, assuming the same relative effectiveness as observed in the SCI population. Where it is possible to wash and re-use non-coated catheters, gel reservoir catheters are not recommended on the basis

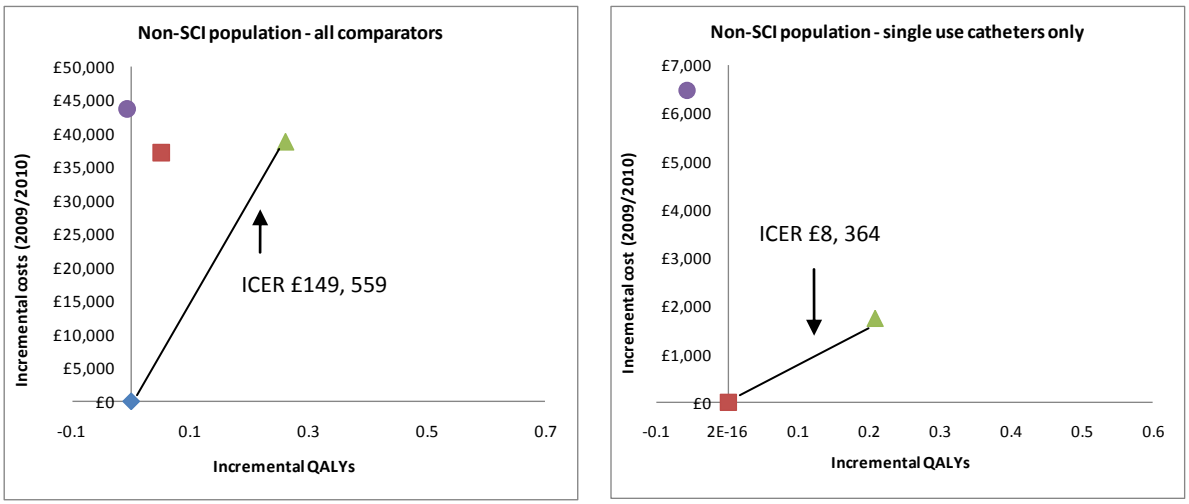
that the ICER is £149, 559. When re-use of non-coated catheters is not an option, gel reservoir catheters represent the most cost-effective option. In both cases, single-use non-coated catheters are excluded from the analysis by dominance.

Table 32: Sensitivity analysis results (probabilistic) – patients without SCI

Catheter	Total cost	Total QALYs	Incremental cost	Incremental QALYs	ICER	Probability CE
In situations where non-coated catheters can be washed and reused						
Non-coated used multiple times	£15, 677	17.774	Baseline	Baseline	Baseline	100.0%
Hydrophilic	£52, 807	17.825	£37, 129	0.051	ED	0.0%
Gel reservoir	£54, 549	18.034	£38, 871	0.260	£149, 559	0.0%
Non-coated used once only	£59, 339	17.767	£43, 661	-0.007	D	0.0%
In situations where catheters cannot be washed and reused						
Hydrophilic	£52, 719	17.822	Baseline	Baseline	Baseline	37.8%
Gel reservoir	£54, 450	18.029	£1, 730	0.207	£8, 364	58.0%
Non-coated used once only	£59, 213	17.764	£6, 493	-0.058	D	4.2%

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

Figure 99: Sensitivity analysis results (probabilistic) – patients without SCI



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

Baseline risk of infection in people without SCI

The baseline risk of infection in people without SCI is likely to differ according to the specific population in question. Older women in particular are likely make up a large proportion of people performing ISC and are very susceptible to UTIs[448]. The baseline probability of infection used in the base case model was 67.8%, based on an annual risk of 1.14; no higher estimates were identified in the literatrure. In exploratory analysis, the baseline risk of UTI was increased to 2 and 4, with an

associated annual probability of 86% and 98%, respectively. In both cases, noncoated multiple use catheters remain the most cost-effective option for ISC.

Table 33: Baseline risk of UTI in people *without* SCI – exploratory analysis (probabilistic)

Sensitivity Analysis	Incr. costs vs. non-coated multiuse		Incr. QALYs vs. non-coated multiuse		Optimal strategy (probability of being CE)
	Gel Res	Hydro	Gel Res	Hydro	
Increased baseline risk of UTI					
Baseline risk of UTI = 2 (baseline probability of UTI = 86%)	£38, 471	£36, 881	0.041	0.283	Non-coated multiple use (100.0%)
Baseline risk of UTI = 4 (baseline probability of UTI = 98%)	£38, 695	£36, 934	0.041	0.212	Non-coated multiple use (99.4%)

In situations where non-coated catheters can be washed and reused (in patients with SCI)

Urethral complications

When the relative risk of urethral complication associated with the use of hydrophilic catheters is half that of other catheters, they are still excluded from the analysis by extended dominance. This remains the case when the probability of urethral complications associated with hydrophilic catheters is eliminated and the cost associated with urethral complications is doubled. The same is true for gel reservoir catheters (i.e. when the risk of urethral complication associated with the use of gel reservoir catheters is reduced by half or eliminated and cost doubled, the ICER remains well above the £20,000 cost-effectiveness threshold). The results of these exploratory analyses are presented in Table 34.

Probability of antimicrobial resistance and mortality

Antimicrobial resistance is dynamic and difficult to predict. The probability of treatment failure, multidrug resistance and mortality were each examined at the upper limit of their confidence intervals in one- and two-way sensitivity analysis. In each case, clean non-coated catheterisation is the most cost-effective strategy (Table 34).

Table 34: Results of one- and two-way sensitivity analyses (probabilistic) –Clean ISC

Analysis	Incr. costs vs. non-coated multiuse		Incr. QALYs vs. non-coated multiuse		Optimal strategy (probability of being CE)
	Gel Res	Hydro	Gel Res	Hydro	
In situations where non-coated catheters can be washed and reused					
Base case					
Base case analysis	£28, 326	£26, 899	0.552	0.109	Non-coated multiple use (99.5%)
Sensitivity analyses					
Urethral complications					
Hydrophilic urethral complications halved (RR = 0.5)	£28, 316	£26, 721	0.552	0.124	Non-coated multiple use (99.5%)
Gel reservoir urethral complications halved (RR = 0.5)	£28, 031	£26, 899	0.574	0.109	Non-coated multiple use (99.4%)
Hydrophilic urethral complications eliminated (RR = 0) and cost doubled	£28, 339	£26, 077	0.552	0.140	Non-coated multiple use

Analysis	Incr. costs vs. non-coated multiuse		Incr. QALYs vs. non-coated multiuse		Optimal strategy (probability of being CE)
	Gel Res	Hydro	Gel Res	Hydro	
(£2, 536)					(99.6%)
Gel reservoir urethral complications eliminated (RR = 0) and cost doubled (£2, 536)	£27, 382	£26, 935	0.586	0.109	Non-coated multiple use (98.6%)
Antibiotic resistance probability & mortality					
Increased probability of treatment failure (33%)	£28, 209	£26, 845	0.577	0.112	Non-coated multiple use (99.2%)
Increased probability of multidrug resistant UTI (9%)	£28, 095	£26, 783	0.575	0.112	Non-coated multiple use (99.3%)
Increased probability of both treatment failure (33%) and multidrug resistant UTI (9%)	£28, 004	£26, 865	0.603	0.117	Non-coated multiple use (99.0%)
Increased probability of mortality from multidrug resistant UTI (5.1%)	£28, 265	£26, 640	0.626	0.122	Non-coated multiple use (98.8%)
Increased probability of mortality from UTI-associated bacteraemia (17.6%)	£28, 108	£26, 372	0.717	0.138	Non-coated multiple use (97.7%)
Increased probability of treatment failure (33%), multidrug resistant UTI (9%), mortality due to multidrug resistant UTI (5.1%), and mortality due to UTI-associated bacteraemia (17.6%)	£27, 751	£25, 871	0.859	0.166	Non-coated multiple use (91.1%)

Threshold analysis – catheter use

The number of clean non-coated catheters used per year was varied between an average of 60 per year (average 5 per *month*) and 1825 per year (average 5 per *day*) in a threshold analysis. Clean ISC ceases to be the most cost-effective option when an average of 208 non-coated catheters is used per year; this equivalent to approximately 4 catheters per week. Therefore, if on average patients use more than four non-coated catheters per week, gel reservoir catheters are the most cost-effective option for ISC.

In situations where non-coated catheters *cannot* be cleaned (in patients with SCI)

Urethral complications

When the probability of urethral complications associated with hydrophilic complications is halved, gel reservoir remain the most cost-effective option in situations where clean ISC is not an option. Gel Reservoir catheters are also the most cost effective option when the probability of urethral complications associated with the use of hydrophilic catheters is eliminated and the cost is doubled.

Table 35: Results of one- and two-way sensitivity analyses (probabilistic) – Probability and cost of urethral complications in situations where non-coated catheters *cannot* be washed and reused

Analysis	Incremental costs Gel reservoir vs. Hydrophilic	Incremental QALYs Gel reservoir vs. Hydrophilic	Optimal strategy (probability of being CE)
Base case			

Analysis	Incremental costs Gel reservoir vs. Hydrophilic	Incremental QALYs Gel reservoir vs. Hydrophilic	Optimal strategy (probability of being CE)
Base case analysis	£1, 393	0.447	Gel reservoir (84.5%)
Sensitivity analyses			
Hydrophilic urethral complications halved (RR = 0.5)	£1, 637	0.430	Gel reservoir (82.5%)
Hydrophilic urethral complications eliminated (RR = 0)	£1, 827	0.413	Gel reservoir (80.0%)
Hydrophilic urethral complications eliminated (RR = 0) and cost doubled (£2, 536)	£2, 328	0.413	Gel reservoir (78.3%)

J.3.3 Value of information analysis

The per-patient and population EVPI is presented in Table 36. At a threshold of £20, 000, the maximum budget for research into the cost-effectiveness of different types of catheter for ISC is approximately £2.5 million. Source/Note: At a threshold of £20, 000 per QALY.

Table 37 presents the EVPPI for each group of parameters. Of the five general parameter groups across each of the two models, only one had a nonzero EVPPI. Note that EVPPI is not expected to sum to EVPI due to interaction between parameters (for example, collecting information about one parameter may affect the value of collecting information on another with which it is closely related). Calculating EVSI and ENBS for the parameter distributions of the relative risk of symptomatic UTI associated with gel reservoir and hydrophilic catheters revealed that under our estimates of the cost of research, conducting additional research into this decision question will not yield a net benefit (Table 36).

Table 36: Expected value of perfect information

	Per patient EVPI	Population over 10 years (discounted at 3.5%)	Population EVPI
Patients with a choice between all four types of ISC	£34.28	13, 437	**£460, 625**
Patients with a choice between types of sterile ISC	£176.83	11, 447	**£2, 024, 075**
Total			**£2, 484, 700**

Source/Note: At a threshold of £20, 000 per QALY.

Table 37: Expected value of perfect parameter information

	Baseline probabilities	Relative effectiveness	Quality of life	Cost of infection	Urethral complications
Patients with a choice between all four types of intermittent catheters					
Per patient EVPPI	£0	£0	£0	£0	£0
Population EVPPI	£0	£0	£0	£0	£0
Patients with a choice between types of single-use intermittent catheters					
Per patient EVPPI	£0	£13	£0	£0	£0
Population EVPPI	£0	£213, 651	£0	£0	£0

Source/Note: At a threshold of £20, 000 per QALY.

Table 38: Expected value of sample information and expected net benefit of sample information: Relative effectiveness of gel reservoir vs. hydrophilic catheters

n	Per-patient EVSI	Population EVSI	Fixed cost of sampling°	Variable cost of sampling ‡	Total cost of sampling	ENBS
0	£0	£0	£0	£0	£0	£0
300	£9	£103, 014	£50, 000	£150, 000	£200, 000	£-96, 986
400	£13	£154, 452	£50, 000	£200, 000	£250, 000	£-95, 548
600	£19	£213, 651	£50, 000	£300, 000	£350, 000	£-136, 349
800	£21	£237, 047	£50, 000	£400, 000	£450, 000	£-212, 953

Source/Note: At a threshold of £20, 000 per QALY. °Assuming that the fixed costs of a clinical trial are £50, 000. ‡Assuming that the variable costs of a clinical trial are £500 per patient.

J.4 Discussion

J.4.1 Summary of results

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

Healthcare workers must also consider other patient-specific situations when deciding which catheter to prescribe. Washing and re-using non-coated catheters may not be an appropriate option for all patients. When clean ISC is not an alternative, gel reservoir catheters may be considered the most cost-effective choice for ISC. If hydrophilic catheters are preferred to gel reservoir catheters, they may also be considered as an option.

J.4.2 Patient preference and compliance

Under the current decision rule, the recommended treatment is identified as that with the highest ICER that falls below the cost-effectiveness threshold. Preferences are incorporated into the cost-utility analysis through the values that are attached to each health state; these values represent the average weight attached to each health state by the general population and are assumed to be independent of factors related to the health care process.

The use of societal values creates the potential for conflict where individual patients hold a strong preference for a particular treatment that is not reflected in the decision made at the societal level[49]. It has been suggested that one way to incorporate individual patient preference into cost-effectiveness decisions would be to adopt a two-part decision process which gives the patient the choice of the most cost-effective treatment plus all cheaper options [103].

Of the five RCTs included in our review of clinical efficacy, three included a measure of patient preference and comfort; none found any difference between catheter types. Nevertheless, it is still possible that patients may find one type of catheter more comfortable or easier to use than another and therefore derive a benefit from the catheter that is not captured in the model[102]. When deciding between gel reservoir and hydrophilic catheters for patients who cannot use multiple non-coated catheters, the GDG did not wish to force the consumption of more costly gel reservoir catheters. If a patient has a strong preference for hydrophilic catheters then the GDG agreed that they should be able to choose this less costly option.

It is important to note that under this rule patients should not be given a choice of therapies that are more expensive and more costly than the most cost-effective treatment [103]. In other words, this line of reasoning *cannot* be extended to patients who are able to use clean multiple use non-coated catheters but prefer not to, nor to patients who prefer single use non-coated catheters to single use gel reservoir or hydrophilic catheters.

J.4.3 Limitations & interpretation

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

The clinical review undertaken as part of this analysis was not designed to evaluate the most effective method of cleaning non-coated catheters. There are many different methods of cleaning advocated in the literature (such as soap and water, boiling, microwave sterilisation, and peroxide application) and no consensus as to which is best. Only two of the manufacturers contacted during the development of this guideline provided any direction as to how to clean and store non-coated catheters – both advised washing with soap and water and leaving to dry in a clean area, using paper towels to absorb excess water if necessary.

J.4.4 Generalisability to other populations / settings

The analysis presented in this report compared all four options for performing ISC from a UK NHS perspective, taking into account a wide range of considerations with extensive sensitivity analyses. It is directly applicable to this guideline and the current UK NHS.

This analysis was designed to assess the cost-effectiveness of different types of intermittent catheters for patients performing intermittent self catheterisation in the community. Outside of the community and primary care setting, there may be other considerations which must be taken into account when considering the cost-effectiveness of each strategy.

The main driver of cost differences in the model is the cost of the catheters themselves. Therefore, the results of this model are only applicable to healthcare systems in which a single payer is responsible for both the cost of the catheter regime and the cost of treatment for UTI and UTI-associated complications.

J.4.5 Comparisons with published studies

Several studies have noted similar effectiveness and lower costs with the use of a clean multiple use non-coated catheters compared to single use catheters [110,182,383]. However, none have attempted to evaluate the costs and quality of life associated with symptomatic UTI or its downstream consequences. To the best of our knowledge, this represents the first cost-utility analysis of

intermittent self catheterisation. By combining the best available evidence about the relative efficacy and costs of the different methods of ISC, this analysis aimed to address an issue which has been a source of debate for many years[516].

Clean intermittent self catheterisation was first introduced in the 1970s as the preferred method of intermittent catheterisation for patients in the community. Lapides et al (1972)[246] proposed that bladder distension was the main contributing factor to UTI rather than the introduction of bacteria to the bladder. Partly on the basis of this theory (which still holds sway within the urological literature) and partly based on non-systematic reviews of the clinical evidence, it is interesting to note that several evidence- and consensus-based guideline groups have recently made recommendations which are very similar to the conclusion reached by our analysis:

- In 2010, the Infectious Diseases Society of America[195] published clinical guidance recommending the use of multiple-use catheters in outpatient and institutional settings, while recognising that multiple use catheters may not always be an option if patients find it inconvenient to clean their catheters when away from home.
- The European Association of Urology Nurses [144] further specifies that catheterisation should be sterile when preformed by someone other than the patient.
- In 1996, the Agency for Healthcare Policy and Research[8] clinical practice guideline on the management of urinary incontinence supported the use of clean intermittent self catheterisation.

J.4.6 Conclusion = evidence statement

Washing and re-using non-coated catheters is the most cost-effective option for intermittent self catheterisation. In situations where it may not be feasible or appropriate to wash and reuse non-coated catheters, gel reservoir catheters appear to be the most cost-effective catheter type. However, if patients prefer hydrophilic catheters to gel reservoir catheters, they may also be considered cost-effective. Single use non-coated catheters are never a cost-effective option for intermittent self catheterisation.

J.4.7 Implications for future research

The expected value of future research is a function of the amount of uncertainty associated with the current adoption decision. Based on best available evidence, the current model reveals that among patients for whom multiple use non-coated catheters are an option, there is very little uncertainty associated with the optimal choice of intermittent catheter. Concequently, the results of our value of information analysis suggest that obtaining more information about this decision would not be a cost-effective use of NHS resources.

Appendix K: Systematic review of health related quality of life for symptomatic UTI

K.1 Introduction

In cost-utility analyses, measures of health benefit are valued in terms of quality adjusted life years (QALYs). The QALY is a measure of a person's length of life weighted by a valuation of their health related quality of life (HRQoL) over that period. The quality of life weighting comprises two elements: the description of changes in HRQoL and an overall valuation of that description.

In order to ensure comparability and consistency across appraisals and reduce bias in the selection of values, the NICE reference case [315] requires that:

- Measurement of changes in HRQoL should be reported directly from patients
- Valuation of changes in patients' HRQoL should be based on public preferences elicited using a choice-based method…such as the time-trade-off or standard gamble, but not rating scale…in a representative sample of the UK population
- Use of utility estimates from published literature must be supported by evidence that demonstrates that they have been identified and selected systematically.

To date, the majority of existing economic evaluations which include urinary tract infection as a health state [131,153,474,500] refer to an analysis by Barry et al (1997) [33] in which the Index of Well Being (IWB) was used to estimate the quality of life experienced by young women with UTI.

The IWB was first introduced in the 1970s as one of the first attempts to develop a generic measurement of health utility. Using medical textbook case descriptions and items from community-wide health surveys, a series of 29 function levels (defined across three dimensions: mobility, physical activity, and social activity) and 42 symptom complexes were described [351]. By randomly combining different functional levels and symptoms complexes across five different age groups, a matrix of 400 case descriptions was developed to represent a wide range of health states that may exist within a population. In order to derive weights or social preferences, a group of 62 American nurses and non-medical graduate students were then asked to rank each case description according to its desirability by placing it on a 16 point scale.

The IWB was the first instrument specifically designed to measure quality of life for the estimation of QALYs. For a long time, it was also one of only a few available measures. However, because it has not been used to elicit health status from patients with UTI and preference-weightings are neither representative of the general population nor elicited according to time-trade-off or standard gamble techniques, it was deemed an unsuitable source for the purposes of our economic evaluation.

The aim of this reviewwas to systematically search the literature for generic preference-based measures of health derived from patients experiencing UTI, severe UTI and UTI-associated bacteraemia in order to identify appropriate utility values for our cost-utility analysis of intermittent self catheterisation.

K.2 Search strategy

We conducted a systematic search of the literature using the electronic databases Medline (Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations and Ovid MEDLINE(R) 1948 to Present) and Embase (Ovid 1980 to 2010 week 47). A list of the search terms used in Medline is provided in Appendix F.2.4. This search strategy was adapted for use in Embase. In addition to these biomedical

databases, the NHS Economic Evaluations Database (NHS EED) and Health Technology Assessment (HTA) databases (via the Centre for Reviews and Dissemination (CRD) interface) and the Health Economics Evaluations database (HEED) were searched for relevant literature. The terms used to search HEED are shown in Appendix F.2.4. These terms were adapted for the CRD interface to search the NHS EED and HTA databases. Both databases were searched from their date of inception to 3rd December 2010.

In February 2011, the Cost-Effectiveness Analysis Registry was searched for utility weights using the keywords 'urinary tract infection', 'bladder infection', 'cystitis', 'pylonephritis', 'kidney infection' and 'bacteraemia/bacteraemia' in the basic search field. The reference search section of the EuroQol website was searched using the same terms.

Studies presenting utility values derived from a generic HRQoL measurement tool or expert opinion were retrieved for full review based on title and abstract sifting. In addition to generic preference-based utility measures such as the EQ-5D, studies using the SF-12 and SF-36 instruments were also included. Although these instruments are not preference-based, there are several established mapping functions which allow the estimation of preference-based utility scores using these descriptive systems.

Studies using disease-specific instruments were excluded. Although mapping techniques could theoretically be extended to disease specific instruments, the use of mapping functions beyond the Short Form questionnaires is currently limited. Also excluded were studies published in a language other than English.

When the method of elicitation or included health states could not be determined from the abstract, full papers were retrieved for further examination. The reference lists of all retrieved studies were also searched for relevant sources.

There is a wide range of clinical manifestations and anatomic levels used to categorise UTI. For the purposes of this review, health states described in the literature were categorised according to the following criteria: 'UTI' was used to refer to an infection confined to the lower urinary tract or bladder; 'severe UTI' to describe an upper urinary tract infection, acute pyelonephritis, or any UTI requiring intravenous treatment or hospitalisation; 'UTI-associated bacteraemia' was used to refer to a blood stream infection with urinary tract origin.

K.3 Results

A total of 529 papers were identified by the MEDLINE and EMBASE search. Excluding duplicates, a further 98 were identified from HEED. The Cost-Effectiveness Analysis Registry returned six results (three of which were identified in the MEDLINE & EMBASE search) and the EuroQol website identified seven studies (none of which were identified in the MEDLINE EMBASE search). One additional relevant publication was uncovered by supplementary citation searching.

Eleven studies (reported in fifteen separate papers) met our inclusion criteria. With the exception of two papers [159,445]which were identified through the Cost-Effectiveness Analysis Registry and citation searching, all were retrieved through MEDLINE and EMBASE. Six studies reported utility values elicited using a method a method other than time-trade-off or standard gamble, or by expert opinion. Five elicited utility values using a validated generic measure of HRQoL; just two of these studies measured quality of life using a generic preference-based measure.

Given the heterogeneity between studies in terms of patient characteristics and elicitation methods, there was no attempt to pool results. Instead, the population, methods and results of each study are reported below. More detailed reports of studies using preference-based measures and non-preference based measures with mapped estimates are presented in Table 39 and Table 40.

The search did not identify any primary studies of quality of life in patients with UTI-associated bacteraemia. Several studies contained utility values for sepsis; however, the infections were not of urinary tract origin and were thought to describe a more severe health state than the one under review.

K.3.1 Health state values derived by a generic measure of health weighted with a method other than time-trade-off or standard gamble, or elicited by time-trade-off or standard gamble alone

As previously discussed, Barry and colleagues (1997) [33] estimated a monthly disutility of 0.2894 for persistent dysuria and a disutility of 0.3732 for patients with pylonephritis using the IWB.

Ackerman et al. (2000) [5] elicited utility values from 13 men with moderate to severe benign prostatic hyperplasia (BPH). A series of BPH-specific health states were described according to three treatments, five short-term clinical events, and 17 possible long-term outcomes. In order to assign preference weights to each health state, the standard gamble was administered to patients by a trained interviewer. Results were reported according to patients' risk attitudes. Risk-averse individuals (n = 6) reported an average utility value of 97.2 (SE 1.1; range 94-99) for severe UTI, while non-risk-averse patients (n = 7) reported an average value of 89.3 (SE 4.6; range 77-99).

In 1998, Gold et al [159] published a catalogue of 130 health state values developed using the Health and Activity Limitation Index (HALex). The HALex score was derived from the answers to two questions asked in the US National Health Interview Survey about activity limitations and self-rated health. Between 1987 and 1992, 84 443 people were included in the survey; at the time of each survey, a total of 384 people reported having a bladder infection and 387 reported having a kidney infection. Based weights developed from a correspondence analysis and multi-attribute utility model, bladder infections were assigned a mean HRQoL value of 0.73 (median 0.84; IQR 0.4) and kidney infection a value of 0.66 (median 0.63; IQR 0.36).

K.3.2 Health state values based on expert opinion

Unable to find relevant utility data for patients with acute pylonephritis, Yen and colleagues (2003) [525] asked a panel of six emergency physicians and internists to develop utility weights using the standard reference gamble technique. Based on the results from the expert panel, pylonephritis was assigned a QALY of 0.90, 0.87 for pylonephritis with mild side effects, and 0.81 for pylonephritis with serious side effects.

Sonnenberg et al (2004) [445] elicited the utility associated with UTI from 'a convenience sample of female members of the research team and advisor pannel' using the time-trade-off technique. They report a short-term disutility of 0.0192 associated with UTI. Similarly, Lawler and colleagues (1991) [254] used their own judgement to arrive at an estimated utility value of 0.99 for patients suffering from UTI.

K.3.3 Health state values elicited using a generic preference-based measure of health or generic measure of health with validated mapping algorithm

Two studies measured the impact of UTI on quality of life among otherwise healthy adult women. In 2000, Ellis and Verma [120] conducted a case-control study to evaluate the effect of UTI on quality of life in women using the SF-36. Although the authors mentioned that quality of life was lower in patients with severe UTI, these results were not reported. The authors of this study were contacted for further information; a reply was received but additional data was not available. The algorithm published by Ara and Brazier (2008) [21] was used to map the mean reported SF-36 dimension scores to EQ-5D health state values (Table 40).

More recently, Ernst et al (2005) [123] conducted a study to evaluate quality of life among 157 women with acute cystitis and the impact of treatment on quality of life. Patients were randomised to receive either trimethoprim/ sulfamethoxazole for 3 days or nitrofuratonin for 7 days. The Quality of Well Being (QWB) questionnaire was administered at baseline and 3, 7, 14, and 28 days after the initial visit. The QWB value at baseline (i.e. suffering from UTI) was 0.68 (SD 0.03) and 0.81 (SD 0.11) at 28 day follow-up (i.e. cured from UTI). Patients who experienced clinical cure had significantly better quality of life scores at days 3 (0.77 vs. 0.72), 7 (0.82 vs. 0.71) and 14 (0.83 vs. 0.76) compared to those who failed treatment; this difference was not due to treatment assignment. To our knowledge, this is the only study to examine the effect of treatment failure on quality of life in patients with UTI.

Maxwell et al (2009) [286] measured quality of life in older adults living in care homes using the Health Utilities Index Mark 2 (HUI2). Results were reported according to the presence or absence of several different clinical conditions, including urinary tract infection. The HUI2 was scored according to the published Canadian preference weights.

Two different research groups have used the Short Form questionnaires to evaluate the effect of UTI on individuals with spinal cord injury. Haran and colleagues have published a series of articles reporting the use of the SF-36 in individuals with spinal cord injury [174,257,258]. The 2005 paper specifies that individuals suffering UTI have worse general health, vitality, and mental health domain scores than those who do not have UTI, but does not report specific domain values for these groups. This paper cites a website containing SF-36 data stratified by age, sex, and impairment group, but at the time of press this link was not functional. The authors were contacted but were unable to provide additional information. In 2008, the group published mapped SF-6D values derived from both the full SF-36 and the recalculated SF-12 scores [257].

A long-term cohort study of individuals with spinal cord injury (SCI) by Vogel and co-workers (2002)[483] was identified in the literature search. This study reported a statistically significant difference in SF-12 scores for subjects suffering from UTI and severe UTI compared to patients who did not experience UTI. However, SF-12 values for these groups were not reported. Upon request, the research group provided us with anonymised patient-level SF-12 responses from their most recent follow-up [482,529]. Five of the 415 cases contained missing data; they were assumed to be missing completely at random and were omitted from the analysis. Using an algorithm developed by Gray et al (2006) [164] and the accompanying spreadsheet available on the Health Economics Research Centre website [180], EQ-5D values were estimated based on raw SF-12 data. Because the Gray algorithm contains random number generators, it was necessary to run a simulation (10 000 times) in order to obtain mean EQ-5D estimates for each health state. All calculations were performed using Microsoft Excel 2007. The results of the mapping, as well as the physical and mental component summary scores are presented in Table 40.

Table 39: Sample characteristics and data collection methods of studies using validated generic health state utility measures

Study	Country of respondents	Respondents	Recruitment and selection	Sample characteristics	Health state description system and valuation technique
Ernst et al (2005)[123]	USA	Women suffering from UTI n: 146 Mean age (SD): 34 (12) Male: 0%	Patients with diagnosed UTI were recruited from two family medicine clinics and randomised to receive one of three different antibiotics. The QWB was administered in-person at baseline and over the telephone by a trained interviewer at 3, 7, 14 and 28 days after the initial visit.	**No UTI** n: 146 Mean age (SD): 34 (12) **UTI** n: 146 Mean age (SD): 34 (12)	**Descriptive system:** QWB **Valuation technique:** Original scoring algorithm developed by an American population using a visual analogue rating scale
Ellis and Verma (2000)[120]	Canada	Women suffering from UTI and healthy age-matched controls Total n: 118 Mean age (SD): NR Male: 0%	The SF-36 was administered to women with diagnosed UTI attending a family medicine clinic, student health services or urology outpatient clinic. A group of healthy undergraduate women were recruited to act as the control population.	**No UTI** n: 71 Mean age (SD): 34.0 (12.8) **UTI** n: 47 Mean age (SD): 32.3 (12.5)	**Descriptive system:** SF-36 **Valuation technique:** Not applicable
Maxwell et al (2009)[286]	USA and Canada	Older adults living in care homes Total n: 514 Mean age (SD): 80.5 (8.4) Male: 28%	Adults age 65+ living in two care homes (Calgary, Canada and Michigan, USA) that were able to communicate and provide informed consent were invited to participate. A trained interviewer administered the HUI2 and MSD-HC.	**No UTI** n: 496 Mean age (SD): NR **UTI:** n: 18 Mean age (SD): NR	**Descriptive system:** HUI2 **Valuation technique:** Original Canadian weights as calculated using multi-attribute utility theory
Vogel et al (2011)[482] and Zebracki et al (2010)[529]	USA and Canada	Individuals with SCI Total n: 415 Mean age (SD): 30.9 (5.3) Male: 63% Mean time since SCI (SD): 16.6 years (6.2)	Eligible participants were former patients enrolled in SCI programs at Shriners Hospitals for Children and were located using the hospitals' databases, White Pages directories, and a professional search service. Subjects were administered the SF-12 by	**No UTI** n: 134 Mean age (SD): 31.3 (5.4) **UTI** n: 238 Mean age (SD): 30.7 (5.2)	**Descriptive system:** SF-12 **Valuation technique:** Not applicable

Study	Country of respondents	Respondents	Recruitment and selection	Sample characteristics	Health state description system and valuation technique
		Aetiology of SCI: Trauma 89% Medical 9% Other 2% Tetraplegia: 54%	telephone. Information about medical complications was also obtained.	**Severe UTI** n: 42 Mean age (SD): 29.5 (4.3)	
Haran et al (2005)[174], Lee et al (2008)[257]	Australia	Individuals with SCI predominantly living in the community Total n: 305 Mean age (SD): 44 (14) Male: 83% Mean time since SCI (SD): 15.7 years (11.6) Aetiology of SCI: NR Tetraplegia: 55%	Subjects were identified from a register comprised of a state-wide database and admissions records for two acute spinal units. They were invited to participate in a clinical trial of antiseptic agents for the prevention of UTI. Subjects completed the SF-36 at enrolment and again on development of UTI. If no UTI was experienced, the SF-36 was completed at 6 month follow-up.	**No UTI** n: 167 Mean age (SD): NR **UTI** n: 138 Mean age (SD): NR	Descriptive system: SF-36 Valuation technique: Australian factor SF-6D utility scores were derived using two algorithms developed by Brazier et al [47,48]

Table 40: Generic preference-based health utility values for patients experiencing UTI and severe UTI

Respondents	Study	Recall period	Method		No UTI		UTI		Severe UTI	
			Measure	Domain	Mean	SE	Mean	SE	Mean	SE
Adult women	Ellis and Verma (2000)[120]	1 day	SF-36	GH	78.90	NR	63.30	NR	NR	NR
				PF	87.60	NR	76.60	NR		
				RP	93.00	NR	53.80	NR		
				RE	88.30	NR	67.40	NR		
				VT	64.90	NR	43.00	NR		
				MH	80.20	NR	64.40	NR		
				BP	91.50	NR	58.70	NR		
				SF	90.40	NR	60.40	NR		

Respondents	Study	Recall period	Method		No UTI		UTI		Severe UTI	
			Mapped EQ-5D°		0.922	----	0.724	----		
	Ernst et al (2005) [123]	28 days	QWB		0.81	0.11	0.68	0.03	NA	NA
Older adults	Maxwell et al (2009) [286]	1 week	HUI2		0.49	0.01¥	0.40	0.04¥	NA	NA
Adults with spinal cord injury	Vogel et al (2011) [482] and Zebracki et al (2010) [529]	1 year	SF-12	MCS-12	53.73	7.58	52.56	9.40	52.12	9.79
				PCS-12	47.39	10.13	43.53	10.64	42.73	10.92
			Mapped EQ-5D‡		0.831	0.01	0.782	0.01	0.738	0.03
	Haran et al, 2005[174] and Lee et al 2008 [257]	6 months (no UTI)	SF-36	NR	NR	NR	NR	NR	NA	NA
			Mapped SF-6Dα		0.68	0.01¥	0.58	0.01¥		
		1 week (UTI)Δ	Mapped SF-6Dβ		0.70	0.01¥	0.60	0.01¥		

Abbreviations: SF-36 = Short-Form 36-item questionnaire; SE = standard error; GH = general health; PF = physical functioning; RP = role physical; RE = role emotional; VT = vitality; MH = mental health; BP = bodily pain; SF = social functioning; ; EQ-5D = EuroQol 5-Dimension; HUI2 = Health Utilities Index Mark 2; MCS = mental component summary; PCS = physical component summary; NR = not reported; N/A= not applicable.

° Mapped based on algorithm developed by Ara and Brazier (2008)[21]

¥Calculated as SD/SQRT(n)

‡ Mapped based on algorithm developed by Gray et al (2006)[164]

α Derived from SF-36 responses using algorithm developed by Brazier et al (2002)[48]

β SF-12 values were calculated from SF-36 scores and mapped to SF-6D based on an algorithm developed by Brazier and Roberts (2004)[47]

Δ For subjects who developed UTI, follow-up assessments were completed on development of UTI. Specific recall time not reported; we assumed the assessment occurred within one week. For subjects who did not develop UTI, follow-up assessments were completed at 6 months.

K.4 Discussion

Health state utility values are key parameters in economic decision models. Values for equivalent health states can vary substantially depending on the measure used and method of valuation [46]. This has a direct impact on the results of economic analyses.

This review identified utility values elicited from adult women, older adults and adults with spinal cord injuries using generic preference-based measured compatible with the NICE reference case. Currently, similar health related quality of life values do not appear to to have been elicited from chidren experiencing UTI. By performing this review we were able to systematically identify and select the most appropriate utility values with which to populate the economic model and identify important gaps in the literature.

K.4.1 Acknowledgements

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Appendix L: Excluded studies

L.1 Excluded clinical studies

L.1.1 Standard principles

L.1.1.1 Patient information

Ref Id	Reason for exclusion
Allison 2010 [15]	Focused on feasibility of implementation of hand gel and masks in a school. Conducted in the UK, but only teachers (not students) were surveyed about the acceptabilty of implementing the interventions on students.
Banfield 2005 [31]	A review of literature (not systematic review).
Cochrane2003 [78]	UK study of availability of handwashing facilities in a non-acute hospital.
Lee 2005 [260]	Focused on the transmission of respiratory and gastrointestinal illnesses among families with children attending child care, and the the link of alcohol hand gel use and respiratory or gastrointestinal illnesses.
Lopez-Quintero 2009 [272]	Focused on hand washing behaviour in relation to availablility of basic hand washing facilities, illnesses and personality trait among school children in Bogota.
Ray 2009 [393]	Focused on frequency of hand washing, methods and when hand washing was done rather than on factors which affect hand washing behaviour in urban and rural West Bengal, India.
Vivas 2010 [481]	Ethiopian study conducted among school children. Focused on quantitative data on when or how hands are washed, no explanatory information. Looks at practices and facilities availabilty
Xiang 2010 [519]	Most of the content of the survey focused on poultry to human transmissions, including handling of food
Yalcin 2004 [521]	Conducted in adolescents Turkey. Survey of frequency of hand washing in 6 conditions, and how hand washing was done.

L.1.2 Hand decontamination

L.1.2.1 When to wash hands

Ref Id	Reason for exclusion
Alemagno 2010[12]	No relevant outcomes.
Aragon 2005[22]	Based on local hospital hand hygiene policy (not based on published guidelines).
Ebnother 2008[115]	Based on local hospital hand hygiene policy (not based on published guidelines).
Gill 2009[152]	Based on local hospital hand hygiene policy (not based on published guidelines).
Grayson 2008[165]	Based on local hospital hand hygiene policy (not based on published guidelines).
Johnson 2005[209]	Based on local hospital hand hygiene policy (not based on published guidelines).
Helder 2010[185]	Based on local hospital hand hygiene policy (not based on published guidelines).
Lam 2004[244]	Based on local hospital hand hygiene policy (not based on published guidelines).
Makris 2000[284]	Based on local hospital hand hygiene policy (not based on published guidelines).
Owusuofori 2010[345]	No control or baseline data reported.
Pessoasilva 2007[361]	Based on local hospital hand hygiene policy (not based on published guidelines).
Sharek 2002[431]	Based on local hospital hand hygiene policy (not based on published guidelines).
Won 2004[511]	Based on local hospital hand hygiene policy (not based on published guidelines).

L.1.2.2 Cleaning preparation

Ref Id	Reason for exclusion
Barbut 2007[32]	Prospective cohort. Higher quality study data (RCT) available.
Cardoso 1999[60]	Laboratory study. Volunteers artificially contaminated.
Dharan 2003[101]	Laboratory study. Volunteers artificially contaminated.
Chamorey 2011[69]	Not relevant to review question.
Dyer 1998[114]	Laboratory study. Volunteers artificially contaminated.
Gaonkar 2005[140]	Laboratory study. Volunteers artificially contaminated.
Guilhermetti 2001[169]	Laboratory study. Volunteers artificially contaminated.
Herruzocabrera 2001[190]	Implementation study, introduction of alcohol gel in acute setting.
Kampf 2003B[215]	Laboratory study. Volunteers artificially contaminated.
Kampf 2005A[213]	Laboratory study. Volunteers artificially

Ref Id	Reason for exclusion
	contaminated.
Larson 2000[249]	Intervention is a surgical scrub.
Larson 2005A[251]	Non randomised trial
Moadab 2001[300]	Laboratory study. Volunteers artificially contaminated.
Moralejo 2003[308]	Commentary on Girou 2002 (included RCT).
Nhung 2007[325]	Laboratory study. Volunteers artificially contaminated.
Oughton 2009[343]	Laboratory study. Volunteers artificially contaminated.
Paulson 1999[352]	Laboratory study. Volunteers artificially contaminated.
Pietsch 2009[368]	Laboratory study. Volunteers artificially contaminated.
Rupp 2008[411]	Implementation study, introduction of alcohol gel in acute setting.
Seal 2005[427]	Laboratory study. Volunteers artificially contaminated.
Sickbertbennett 2005[436]	Laboratory study. Volunteers artificially contaminated.

L.1.2.3 Bare below the elbow

Ref Id	Reason for exclusion
Jeans 2010[206]	Cross-sectional study. Higher quality study data (RCT) available.
Ward 2007[490]	Non-systematic review.
Willis-Owen 2010[504]	Observational study. Higher quality study data (RCT) available.

L.1.3 Sharps

L.1.3.1 Safety needles and cannulae

Ref Id	Reason for exclusion
Adams 2006[7]	Before and after observational studies. Mixed interventions (not just 1 safety needle or cannulae introduced).
Bouza 2003[42]	Not relevant to review question, connector not a sharps device.
Casey 2007A[63]	Not relevant to review question, connector not a sharps device.
Casey 2003[64]	Not relevant to review question, connector not a sharps device.
Esteve 2007[124]	Not relevant to review question, connector not a sharps device.
Moorjani 2008[307]	Reciprocating procedure device with safety needle. Intervention is the syringe device, not the safety needle. Does not answer review question.

Ref Id	Reason for exclusion
Oto 2007[342]	Not relevant to review question, connector not a sharps device.
Reddy 2001[394]	Before and after observational studies. Mixed interventions (not just 1 safety needle or cannulae introduced).
Schilling 2006[423]	Not relevant to review question, connector not a sharps device.
Sohn 2004[444]	Before and after observational studies. Mixed interventions (not just 1 safety needle or cannulae introduced).
Whitby 2008[498]	Before and after observational studies. Mixed interventions (not just 1 safety needle or cannulae introduced).
Yebenes 2004[524]	Not relevant to review question, connector not a sharps device.
Yebenes 2008A[523]	Not relevant to review question, connector not a sharps device.

L.1.4 Personal protective equipment

L.1.4.1 Gloves

Ref Id	Reason for exclusion
Korniewicz 2003[232]	Laboratory study. Does not meet our inclusion criteria.
Lierman 2007[266]	Laboratory study. Does not meet our inclusion criteria.
Wittmann 2010[510]	Laboratory study. Does not meet our inclusion criteria.

L.1.4.2 Gowns and aprons

Ref Id	Reason for exclusion
Bischoff 2004[40]	Lab study investigating whether they are contaminated when wearing different outfits. The outfits do not include either gowns or aprons
Chiang 2008[71]	Focus on cardiopulmonary resuscitation and use of PPE (not only aprons and gowns, but also masks and gloves)
Huntley 1998[200]	Previous guideline ref. Does not answer our review question. Microbiological sampling of long sleeved scrub jackets worn during routine dental hygiene procedures.
Ishihama 2008[205]	No control. Aim was to evaluate incidence of blood exposure during oral surgery, when HCW wore gown and visor.
Morgan 2010[309]	Does not answer our review question. Focus on colonisation of PPE with multi drug resistant organisms. Samples gloves/gowns hands for contamination. No comparison of with/without gowns/aprons.
Orji 2003[340]	Just looks at whether gowns became infected with

Ref Id	Reason for exclusion
	microorganisms during work rather than whether gowns had a protective effect. No comparison
Perry 2001[360]	Previous guideline ref. Does not answer our review question. Microbiological sampling of uniforms before and after duty.
Safdar 2006[417]	MRSA outbreaks. Intervention is enhanced pre-emptive barrier precautions (microbiological surveillance and full barrier precautions; gowns and gloves). Mixed intervention
Wilson 2007[506]	Does not answer our review question. Focus on laundering uniforms and HCAI adherence to different types of fabric.

L.1.5 Long term urinary catheters

L.1.5.1 Antibiotics

Ref Id	Reason for exclusion
Leone 2007[264]	Short term urinary catheters.
Nicolle 2005[327]	Review/ clinical summary.
Nielweise 2005[328]	Short term urinary catheters.
Nielweise 2005A[329]	Included daily antibiotics and intermittent self catheterisation.
Pfefferkorn 2009[364]	Short term urinary catheters. 6-7 days
Pfefferkorn 2009B[363]	Editorial comment.
Qazi 2005[388]	Comment on Wazait 2004.
Romanelli 1990[407]	Population unclear. Patients most likely had a urethral catheter inserted for the first time.
Saint 1999[419]	Non systematic review.
Salomon 2006[421]	Historical comparison.
Schaeffer 2006[422]	Review/opinion.
Tenke 2008[462]	Summary of European/ Asian guidelines.
Wazait 2004[494]	Short term urinary catheters.

L.1.5.2 Catheter type

Ref Id	Reason for exclusion
Cindolo 2004[75]	Short term urinary catheters.
Crabtree 2003[83]	No relevant outcomes
Day 2003[94]	No relevant interventions. Investigating closed vs. open system.
Erickson 2008[122]	Short term urinary catheters. 14-21 days
Quigley 1993[389]	No relevant interventions. Investigating closed vs. open system.
Roadhouse 2004[401]	Retrospective case-control. Short term urinary catheters.
Seymour 2006[429]	Audit. Short term urinary catheters.
Srinivasan 2006[446]	Prospective crossover. Short term indwelling catheters.

Ref Id	Reason for exclusion
Witjes 2009[509]	PVC vs. polyvinyl chloride free. Not prioritised in the protocol

L.1.5.3 Instillations and washouts

Ref Id	Reason for exclusion
Al-Juburi 1989[11]	comparison of a drainage system not instillations or washouts
ANON 1982[1]	Not a comparison of instillations or washouts. Outcomes not relevant
Bastable 1977[34]	Post-op irrigation
Dudley 1981[109]	review - antimicrobial irrigations
Getliffe 1994A[148]	In vitro study using artificial urine
Getliffe 2000[149]	In vitro study using artificial urine
Kirk 1979[225]	Short term catheterisation
Maizels 1980[280]	Short term catheterisation
Stickler 1987[450]	in vitro study - assessing antiseptic properties
Thompson 1984[469]	Short term catheterisation
Warren 1978 [492]	Short term catheterisation
Zacharias 2009[526]	Not long term catheter - duration of up to 29 days only.

L.1.6 Percutaneous endoscopic gastrostomy

Ref Id	Reason for exclusion
Kenny 2010[221]	Non systematic review. Single vs. reusable syringes not covered.
Phillips 2008[365]	Systematic review. Single vs. reusable syringes not covered.
Reising 2005[397]	Non systematic review. Single vs. reusable syringes not covered.

L.1.7 Vascular access devices

L.1.7.1 Dressing type

Ref Id	Reason for exclusion
Callaghan 2002[58]	Primary outcome is securement of dressing
Carrer 2005[61]	Intensive care setting – identified as exclusion criteria
Garland 2001[141]	Intensive care setting – identified as exclusion criteria
Giles 2002 [151]	Mixed intervention. investigates type of decontamination and dressing type
Khattak 2010[222]	No relevant outcomes. Investigating systemic silver absorption
Hill 2010[192]	Intensive care setting – identified as exclusion criteria
Levy 2005[265]	Intensive care setting – identified as exclusion criteria

Ref Id	Reason for exclusion
Little 1998[268]	Intensive care setting – identified as exclusion criteria
Livesley 1993[270]	Primary outcome is securement of dressing
Madeo 1998[278]	Intensive care setting – identified as exclusion criteria
Maki 1994[283]	Intensive care setting – identified as exclusion criteria
Nikoletti 1999[330]	Intensive care setting – identified as exclusion criteria
Ruschulte 2009[413]	High dependency unit – identified as exclusion criteria
Sheppard 1999[433]	Primary outcome is securement of dressing
Sivasangari 2005[440]	Primary outcome is securement of dressing

L.1.7.2 VAD decontamination

Ref Id	Reason for exclusion
Adams 2007[6]	Study design, non systematic review.
Assadian 2004[25]	Study design, letter.
Balamongkhon 2007[30]	Study design, implementation study.
Carson 2004[62]	Study design, non systematic review.
Chaiyakunapruk 2003[68]	Study design, decision analysis.
Garland 2009[142]	Population, neonates.
Inwood 2007[204]	Study design, discussion paper.
Reichel 2009[396]	Population, healthy volunteers.
Richardson 2006[399]	Study design, non systematic review.
Traore 2000[471]	Population, healthy volunteers.

L.1.7.3 Multidose vials

Ref Id	Reason for exclusion
Archibald 1998[23]	No relevant intervention or comparison
Harnett 2001[176]	No relevant intervention or comparison
Krause 2003[236]	No relevant intervention or comparison
Montenegro 2000[302]	No relevant intervention or comparison
Pugliese 2000[385]	No relevant intervention or comparison
Silini 2002[438]	No relevant intervention or comparison
Widell 1999[501]	No relevant intervention or comparison
Wiersma 2010[502]	No relevant intervention or comparison

L.2 Excluded economic studies

L.2.1 Hand decontamination

L.2.1.1 When to wash hands

Ref Id	Reason for exclusion
Pittet 2000[372]	Wrong intervention (posters and performance feedback; no guidance as to hand hygiene policy)
Pittet 2004[374]	Wrong intervention (posters and performance feedback; no guidance as to hand hygiene policy)
MacDonald 2004[277]	Wrong intervention (posters and performance feedback; no guidance as to hand hygiene policy)
NPSA 2004[317]	Wrong intervention (multimodal hand hygiene promotional campaign)
Kampf 2003[212]	Review of economic evaluations

L.2.1.2 Cleaning preparation

Ref Id	Reason for exclusion
Harrison 2003[177]	No costs or economic considerations
Huber 2006[198]	Inadequate sample size (n = 2)
Gleich 2004[155]	Cost study with no consideration of comparative effectiveness
Larson 2001[248]	Wong comparison (surgical scrub)
Nicolay 2006[326]	Review, wrong comparison (surgical scrubs)
NPSA 2010[317]	Wrong comparison (implementation study rather than comparative study of hand decontamination products)
Nthumba 2010[331]	Wong comparison (surgical scrub)
Ritchie 2005[400]	Review
Tavolacci 2006[460]	Wong comparison (surgical scrub)

L.2.1.3 Bare below the elbow

No economic evidence was identified.

L.2.2 Sharps

L.2.2.1 Safety needles and cannulae

Ref Id	Reason for exclusion
Drain 2003[108]	Wrong comparison; wrong settting
Glennard 2009[156]	National cost analysis specific to Sweden
Lee 2005A[261]	Review
Lee 2005[262]	Review
Leigh 2007[263]	Review
Nwokolo 2002[333]	Review

L.2.3 Personal protective equipment

L.2.3.1 Gloves

Ref Id	Reason for exclusion
Akridge 2009[9]	Review of US glove industry requirements
Danchaivijitr 2005[91]	Wrong comparison and setting (surgical glove recycling in Thailand)
Fritzsche 2008[138]	Wrong comparison and setting (cut-resistant gloves in pathology)
Gottrup 2001[161]	
Hampton 2002[173]	Review. Some discussion of economic considerations but no comparative analysis.
Korczak 2010[231]	Review
Lamont 2004[245]	Wong setting (neonatal intensive care), no cost considerations.
Latza 2005[253]	Review of latex allergy insurance claims
Reed 2003[395]	Review of latex allergy
Thomas-Copeland 2009[468]	Wrong comparison and setting (Double gloving in surgery)
Trick 2004[472]	Wrong comparison (glove use in contact-isolation procedures)

L.2.3.2 Gowns and aprons

Ref Id	Reason for exclusion
Baykasoglu 2009[35]	Societal perspective with incomparable costing method. Not relevant to UK NHS perspective.
Bischoff 2007[39]	No costs or economic considerations.
Conterno 2007[80]	Multiple interventions; not possible to separate effects
Hu 2004[197]	Wrong comparison and setting (maximal sterile barriers for inserting central VADs)

L.2.4 Long term urinary catheters

L.2.4.1 Antibiotics

Ref Id	Reason for exclusion
Sutkin 2009[456]	Wrong comparison (prophylactic antibiotics for intermittent self catheterisation); decision model with no cost considerations

L.2.4.2 Catheter type

Ref Id	Reason for exclusion
Karchmer 2000[216]	Short term catheterisation
Kovindha 2004[233]	Non-OECD country; observational non-comparative study of non-coated catheters used over 3 years
Lai 2002[243]	Short term catheterisation; retrospective study
Platt 1989[375]	Wrong comparison (sealed catheters vs. antibiotics)
Plowman 2001[376]	Short term catheterisation; wrong comparison

Ref Id	Reason for exclusion
	(sealed catheters vs. antibiotic prophylaxis vs. selective catheterisation)
Rupp 2004[410]	Short term catheterisation
Saint 2000[418]	Short term catheterisation

L.2.4.3 Instillations and washouts

No economic evidence was identified.

L.2.5 Percutaneous endoscopic gastrostomy

No economic evidence was identified.

L.2.6 Vascular access devices

L.2.6.1 Dressing type

Ref Id	Reason for exclusion
Ho 2006 [193]	Wrong setting (neonatal ICU)
Salles 2007 [420]	Wrong comparison (micro porous dressings vs. transparent dressings – micro porous dressings described as 'water-permiable and non-sterile' and therefore assumed to be similar to common plasters)
Gallieni 2004[139,139]	Review
Keene 2009[218,218]	Wong intervention (CVC dressing security)

L.2.6.2 Decontamination

Ref Id	Reason for exclusion
Chaiyakunapruk 2003[68]	Wrong intervention/population (5/7 studies informing the clinical evidence were for insertion of CVCs and 3 appear unpublished). The GDG made a consensus decision to exclude.
Bakke 2010[26,29]	Multiple interventions (chlorhexidine skin and port/hubdecomtamination, hand washing, aseptic technique for dressing change, and BSI monitoring); not possible to separate effect.
Halton 2010[171,172]	Multiple interventions (CVC 'bundle')
Maenthaisong 2006[279,279]	Non OECD setting (Thailand)

L.2.6.3 Multidose vials

Ref Id	Reason for exclusion
Tarricone 2010 [459]	Wrong comparison (intravenous infusion containers); wrong setting (intensive care)

Appendix M: High priority research recommendations

M.1 Standard Principles of infection prevention and control

M.1.1 What are the barriers to compliance with standard principles of infection prevention and control that patients and carers experience in their own homes?

Why is this important?

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

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

What are the barriers to compliance with standard principles of infection prevention and control that patients and carers experience in their own homes?	
PICO/SPICE question	Population and setting: Patients and people who care for a family or friend in their own homes Focus of Interest: Barriers or factors that promote the ability and/or likelihood of adherence to the standard principles of infection prevention and control. This includes knowledge or understanding of these principles. Comparison: None Evaluation: The following areas should be explored through qualitative studies (interviews, focus groups, observations) or surveys • Hand decontamination • Use of personal protective equipment • Use and disposal of sharps
Importance to patients or the population	It is important to understand compliance with the standard principles of infection prevention and control which could potentially increase patient safety through decreasing healthcare associated infections. Given that much care is provided by lay people in the community it would be important to highlight the barriers to compliance with standard principles of infection prevention and control in order that these issues can be addressed.
Relevance to NICE guidance	This research recommendation is relevant to all chapters within this guideline. It is also relevant to any other guidance where patient/carer information delivery and the risk of infection are particular concerns.
Relevance to the NHS	The prevention and control of infection within the patients' own home (including care homes) will reduce hospital admissions/re-admissions, morbidity and mortality, reduce the amount of antibiotics prescribed and reduce the number of community staff visits, e.g. GP, District Nurses. It will also reduce carer and patient stress, and have a large impact on quality of life both for the patient and the carer.
National priorities	Reduce demand for emergency/urgent care (in National Operating Framework for the NHS).
Current evidence base	The existing evidence base was systematically reviewed for literature related to barriers to hand decontamination. There was a lack of evidence of patient/carer education in a UK community setting.
Study design	Qualitative study of a range of carers regarding the education they received regarding infection control, their understanding of hand decontamination, supplies and use of protective equipment and disposal. The focus should be on barriers to compliance.
Economic considerations	When training is delivered in an ineffective or inappropriate manner it represents an inefficient use of NHS resources. By determining the factors with the greatest influence on the efficacy of training provided to patients and carers, more targeted and cost-effective training packages can be delivered. If more effective training packages lead to a reduction in healthcare associated infections, this will also have an impact the cost of treating infections, quality of life and mortality rates among patients. Outcomes with economic consequences (such as the cost and resource use associated with training interventions and associated infection rates) should be recorded.
Feasibility	The GDG thought that it would be feasible to conduct a qualitative study in this area, so long as it was designed to be focused and specific. The time scale of such as study would ideally be designed to feed into the development and implementation of educational initiatives, but a three to six month impact study should be sufficient.

What are the barriers to compliance with standard principles of infection prevention and control that patients and carers experience in their own homes?	
Equalities	Education needs to be tailored to the needs of patients and carers. This is particularly important for patients with specific cultural, religious, linguistic, or educational needs. Mental ability and physical capability should also be considered. It should also be remembered that some people, particularly the elderly, have very little money to spare on purchasing items such as handrub.
Other comments	This area is of potential interest to psychosocial and educational research institutes, in addition to health and social care researchers. The GDG highlighted that education around the cleaning of reusable equipment was an important theme that could be incorporated in the study.

M.2 Hand decontamination

M.2.1 When clean running water is not available what is the clinical and cost effectiveness of using wipes, gels, handrubs or other products to remove visible contamination?

Why is this important?

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

When clean running water is not available what is the clinical and cost effectiveness of using wipes,gels, handrubs or other products to remove visible contamination?	
PICO question	Population: Community based healthcare workers Intervention: All types of hand wipes, hand rinses, gels and handrubs used on physically dirty hands without running water. Comparison: Each other Outcomes: Colony forming units (CFUs) based on the Adenosine triphosphate (ATP) surface test or swabbing on agar plates. Compliance with different methods and acceptability to healthcare workers.
Importance to patients or the population	Need to know which products are effective and what healthcare workers should be using when running water is not available.
Relevance to NICE guidance	Particularly relevant to community based healthcare workers, especially the ambulance service.
Relevance to the NHS	As more care is being provided in the community and at patient's residence setting, the evidence behind maintaining hand decontamination with no running water will be of vital importance to inform healthcare workers, patients, carers and patients undertaking care treatments what to do in this situation.
National priorities	No relevant national priorities
Current evidence base	No RCT evidence was identified in the clinical review for hand decontamination without running water for the removal of blood and /or body fluid.
Study design	RCT. Power calculations should be conducted to establish the required sample size of the trial. It is important that the study is adequately powered to detect a clinically important effect size.
Economic considerations	Yes, this study would affect a large number of the population, including patient groups and community based healthcare workers.
Feasibility	This proposed research should be able to be carried out within a realistic timescale and cost. There may be technical issues around conducting this as an RCT as compared to in laboratory settings.
Equalities	None identified.
Other comments	None.

M.3 Long term urinary catheters

M.3.1 In patients performing intermittent self catheterisation over the long term, what is the clinical and cost-effectiveness of single use non-coated versus single use hydrophilic versus single use gel reservoir versus re-useable non-coated catheters on symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality, patient comfort & preference, quality of life, and clinical symptoms of urethral damage?

Why is this important?

Long-term (more than 28 days) intermittent self catheterisation (ISC) is performed by a large number of people living in the community. It is important that the choice between intermittent catheters is informed by robust clinical and cost-effectiveness evidence.

The cost-effectiveness model developed for this guideline combined evidence of clinical effectiveness, costs, and quality of life of symptomatic UTI and its associated complications. The results of this analysis show that non-coated catheters used multiple times are the most cost-effective option for ISC. However, the clinical evidence informing this model is of low to very low quality.

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

Currently, non coated catheters are considered single use devices by the MHRA. In order to make an 'off-licence' recommendation, better quality evidence is needed. The results of this research could lead to the current recommendation being considered for a rapid update.

In patients performing intermittent self catheterisation over the long term, what is the clinical and cost-effectiveness of single use non-coated vs. single use hydrophilic vs. single use gel reservoir vs. re-used non-coated catheters on symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality, patient comfort & preference, quality of life, and clinical symptoms of urethral damage?	
PICO question	Population: People performing intermittent self catheterisation in the community. This heterogeneous population should include: People aged 16 and over, wheelchair users, people with spinal cord injuries, older people, males and females. This population should not include: People living in residential care Interventions: Multiple-use non-coated catheters, single use non-coated catheters, single use gel reservoir catheters and single use hydrophilic catheters. Comparisons: Multiple-use non-coated catheters, single use non-coated catheters, single use gel reservoir catheters and single use hydrophilic catheters. Outcomes: Symptomatic urinary tract infection, bacteraemia, mortality, patient comfort & preference, clinical symptoms of urethral damage quality of life and costs . Trial duration: Follow-up should be a minimum of 1 year
Importance to patients or the population	Catheter-associated UTIs are the most common type of healthcare-acquired infection in the world. While most urinary tract infections (UTIs) are mild and easily resolved with appropriate antibiotic treatment, more severe infections can be devastating, resulting in bacteraemia, sepsis and death. ISC is an intimate procedure which is often associated with anxiety and discomfort; compliance and patient acceptability are key considerations informing the choice of catheter. It is important that high quality clinical evidence is available to determine which type of intermittent catheter is the most effective for preventing catheter-associated infections and urethral damage and which represents the most acceptable option for patients.
Relevance to NICE guidance	Currently, the MHRA has designated all non-coated intermittent catheters as single use devices. This is in contrast to the Department of Health, who recommend that five non coated catheters represents one month's supply and require that manufacturers provide

In patients performing intermittent self catheterisation over the long term, what is the clinical and cost-effectiveness of single use non-coated vs. single use hydrophilic vs. single use gel reservoir vs. re-used non-coated catheters on symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality, patient comfort & preference, quality of life, and clinical symptoms of urethral damage?	
	instructions for cleaning these items. Due to the uncertain legal status of these devices, concerns raised by stakeholders, and the low to very low quality clinical evidence base, non coated catheters were not recommended for multiple-use in the current guideline. NICE consider the reuse of these items to be 'off-licence'. In order to make an 'off-licence' recommendation, NICE requires sound clinical and cost-effectiveness evidence. The current clinical evidence base is of low to very low quality and better quality evidence is needed. If the results of the proposed research are found to contradict the current recommendation, the recommendation may be put forward for rapid update.
Relevance to the NHS	The uncertainty inherent in the current recommendation represents a large opportunity cost for patients within the NHS. The results of this trial have the potential to change this recommendation. A change in this recommendation would represent a significant cost savings and would result in a more efficient use of resources across the NHS.
National priorities	This research is relevant to two key national priority areas: reducing healthcare-associated infections and identifying efficiency savings as set out in the Operating Framework for the NHS in England in 2010/11.
Current evidence base	The current clinical evidence base consists of five randomised controlled trials: one comparing single use gel reservoir to single use non-coated catheters; two comparing single use hydrophilic to single use non-coated catheters; and two comparing re-used single use catheters to single use non-coated catheters. These studies varied in length of follow up between patients and had unclear randomisation, allocation concealment, and blinding. All were assigned a GRADE rating of low to very low quality. The cost-effectiveness model developed for this guideline combined evidence of clinical effectiveness, costs, and quality of life of symptomatic UTI and its associated complications. The results of this analysis showed that in 100% of model simulations, non-coated catheters used multiple times are the most cost-effective option for ISC. This conclusion was robust to a wide range of sensitivity analyses, including exploratory analysis of the impact of urethral strictures to cost and quality of life and varying levels of use of non-coated catheters.
Study design	This research should be a randomised controlled trial with a minimum follow-up of one year. Although blinding will not be possible, the trial should have good randomisation and allocation concealment. Sample size should be calculated using appropriate statistical methods. It is important that the study is adequately powered to detect a clinically important effect size. ISC technique (including the use of lubricant for non coated catheters) and patient characteristics should be clearly reported. The trial should include a diverse community-based population who regularly self catheterise. The primary outcome measures should be symptomatic urinary tract infections, UTI-associated bacteraemia, mortality, patient comfort & preference, quality of life, clinical symptoms of urethral damage, and costs. Clinical results should be fully reported and uncertainty surrounding cost-effectiveness should be explored using appropriate bootstrap analyses. The criteria for symptomatic UTI, UTI-associated bacteraemia and mortality should be clearly defined, consistently applied and clearly reported. Clinical symptoms of urethral damage could include stricture, epididymitis and urethritis; these outcomes should be

In patients performing intermittent self catheterisation over the long term, what is the clinical and cost-effectiveness of single use non-coated vs. single use hydrophilic vs. single use gel reservoir vs. re-used non-coated catheters on symptomatic urinary tract infections, urinary tract infection-associated bacteraemia, mortality, patient comfort & preference, quality of life, and clinical symptoms of urethral damage?	
	confirmed in a clinically appropriate manner and be clearly described. Patient comfort and preference should be measured using a validated score or scale. At a minimum, quality of life should be captured using the EQ-5D. If other measures of quality of life are also thought to be appropriate these could also be included. Costs should be measured from the NHS and personal social services perspective and should include both the cost associated with each type of catheter (and lubricant for non-coated catheters) and costs associated with treating UTI, urethral damage and any other catheter-associated complications. In order to 'future proof' this research, cost data could also be collected from a societal perspective; however these costs should be reported and analysed separately.
Economic considerations	See "current evidence base" above. There is a proportion of the community that require long-term intermittent catheterisation. The net gain of finding the most cost effective catheter that minimises the risks of catheter associated urinary tract infection and bacteraemia would be of ongoing benefit.
Feasibility	It should be possible to undertake this trial within a realistic timescale and at reasonable cost.
Equalities	Equality considerations apply regarding patients' physical abilities, such as problems with manual dexterity or mobility, including wheelchair users. Other equality issues such as cognitive and visual impairment would be taken into consideration prior to selecting an intermittent catheter.
Other comments	The research is of high priority. The results of this research have the potential to alter future guidance on the use of intermittent urinary catheters. If the results of this research are found to contradict the current recommendation, the recommendation may be put forward for rapid update.

M.3.2 In patients using long-term indwelling urinary catheters what is the clinical and cost effectiveness of impregnated versus hydrophilic versus silicone catheters in reducing symptomatic urinary tract infections, encrustations and/or blockages?

Why is this important?

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

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

In patients using long-term indwelling urinary catheters what is the clinical and cost effectiveness of impregnated versus hydrophilic versus silicone catheters on reducing symptomatic urinary tract infections, encrustations and/or blockages?	
PICO question	Population: Patients with indwelling LTUC in the community Intervention: Impregnated silver or antimicrobial catheters, hydrophilic catheters (both urethral and suprapubic) Comparison: Silicone catheters Outcomes: Symptomatic urinary tract infections, encrustations, blockages, mean no of days catheter in situ/mean dwell time and patient comfort.
Importance to patients or the population	The impact would be that future guidance could recommend the most appropriate long-term urinary catheter type to minimise catheter associated urinary tract infection, bacteraemia and unnecessary urinary catheter changes due to blockage and encrustations. Patients will benefit from preventive measures that are appropriate.
Relevance to NICE guidance	The results would ensure that long-term catheter choice is informed by evidence to ensure the best patient outcome.
Relevance to the NHS	The study results would ensure the minimisation of catheter associated urinary tract infection and bacteraemia in patients with long-term urinary catheterisation with inherent cost savings on treatment and additional service delivery due to morbidity. The minimisation of additional professional resources involved in unscheduled urinary catheter changes, due to encrustations and blockage. Minimisation of patient discomfort would also lead to reduced costs generated by catheter changes. Patients will benefit from preventive measures that are appropriate and reduce variation in clinical practice and patient care.
National priorities	This study is in line with national antibiotic prescribing, reducing the variation in practice thereby supporting the patient safety agenda.
Current evidence base	No evidence was identified in the clinical review for any impregnated catheters (silicone vs. hydrogel only).
Study design	RCT. Power calculations should be conducted to establish the required sample size of the trial. It is important that the study is adequately powered to detect a clinically important effect size. The study should be in non-hospitalised patients but could include residential/nursing homes.
Economic considerations	There is a proportion of the community that require long-term catheterisation. The net gain of finding the most cost effective catheter that minimises the risks of catheter associated urinary tract infection and bacteraemia would be of ongoing benefit.
Feasibility	This research could be completed within a reasonable timescale. There are technical issues over trial design but it is unlikely there would be ethical problems as both types of catheter are already in widespread clinical use and there is no denial of treatment or placebo involved.
Equalities	No specific equality issues identified
Other comments	None.

M.3.3 When recatheterising patients who have a long-term indwelling urinary catheter, what is the clinical and cost effectiveness of single-dose antibiotic prophylaxis in reducing symptomatic urinary tract infections in patients with a history of urinary tract infections associated with catheter change?

Why is this important?

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

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

When recatheterising patients who have long term indwelling urinary catheters what is the clinical and cost effectiveness of single-dose antibiotic prophylaxis in reducing symptomatic urinary tract infections in patients with a history of urinary tract infections associated with catheter change?	
PICO question	Population: Patients with long term indwelling urinary catheters Intervention: single dose antibiotic prophylaxis Comparison: no antibiotic prophylaxis Outcomes: symptomatic urinary tract infections.
Importance to patients or the population	The importance would be: to avoid the use of unnecessary antibiotic prescribing to minimise the development of antibiotic resistance organisms to minimise the risk of infective antibiotic diarrhoea e.g. *clostridium difficile* to minimise symptomatic urinary tract infections.
Relevance to NICE guidance	A recommendation on using antibiotic prophylaxis has been made in the current guideline but the quality of evidence was low and the decision largely made on consensus. RCT/cohort evidence would be important to inform update of this guideline.
Relevance to the NHS	This has the potential to produce cost savings either through reduced prescribing or, if the research concludes that antibiotics are effective, by reducing the associated costs from catheter associated urinary tract infection.
National priorities	This research would have impacts in the reduction of catheter associated urinary tract infection, reduction in antibiotic resistant bacteria and the risk of infective antibiotic diarrhoea e.g. *clostridium difficile*.
Current evidence base	Low quality evidence that supports the current recommendation. One small RCT was identified in the clinical review that had serious limitations.
Study design	The most feasible design would be a cohort study, however an RCT study design would be preferable in terms of study quality.
Economic considerations	Economic considerations include appropriate use of antibiotics, reducing the risk of infective antibiotic diarrhoea e.g. clostridium difficile, reducing the risk of antibiotic resistant bacteria.
Feasibility	Although an RCT is preferable there are likely to be ethical issues over withholding antibiotics from high risk groups, therefore a cohort study is more feasible.
Equalities	None identified.
Other comments	None.

M.4 Vascular access devices

M.4.1 What is the clinical and cost effectiveness of 2%chlorhexidine in alcohol versus 0.5% chlorhexidine in alcohol versus 2% chlorhexidine in aqueous solution versus 0.5% chlorhexidine in aqueous solution for cleansing skin (beforeinsertion of peripheral vascular access devices [VADs] and during dressing changes of all VADs) in reducing VAD-related bacteraemia and VAD site infections?

Why is this important?

The effective management of vascular access devices (VADs) is important for reducing phlebitis and bacteraemia. In the community, compliance is improved when a single solution is used for all aspects of VAD-related skin care. There is no direct evidence comparing different percentages of chlorhexidine in aqueous and alcohol solutions, and little evidence looking at the use of such solutions in the community. A randomised controlled trial is required to compare the clinical and cost effectiveness of the different solutions available. The trial should enrol patients in the community with a VAD. The protocol would need to follow the same skin preparation technique regardless of solution, and could also investigate the effects of decontamination technique and drying time. The primary outcome measure should be rates of VAD-related bacteraemia, rate of VAD site infections, mortality, cost and quality of life. Secondary outcomes measures should include Visual Infusion Phlebitis (VIP) score, insertion times and skin irritation.

It was recognised that decontamination of VAD hubs would be another important alternative to skin. The GDG wanted to design the study to include these but concluded that this would probably require another research study.

What is the clinical and cost effectiveness of 2%chlorhexidine in alcohol versus 0.5% chlorhexidine in alcohol versus 2% chlorhexidine in aqueous solution versus 0.5% chlorhexidine in aqueous solution for cleansing skin (beforeinsertion of peripheral vascular access devices [VADs] and during dressing changes of all VADs) in reducing VAD-related bacteraemia and VAD site infections?	
PICO question	Population: Patients in the community with a VAD. Interventions: 2% chlorhexidine in alcohol vs. 0.5% chlorhexidine in alcohol vs. 2% chlorhexidine aqueous solution vs. 0.5% chlorhexidine aqueous solution. The method and technique used for cleaning need to be clearly defined and reported in the protocol. Comparison: Each other Outcomes: VAD related bacteraemia and VAD site infection.
Importance to patients or the population	It is clinically easier to have one solution for everything. It is currently unknown which solution is best to use – knowing could help reduce VAD related bacteraemia and VAD site infections.
Relevance to NICE guidance	This study would provide evidence with regard to the specificity of the recommendation of correct skin cleansing agent. There would be potential to recommend a standard across skin cleansing for insertion and site care.
Relevance to the NHS	It would be more cost effective buying a standard solution across the NHS (both secondary and primary care). There would be greater compliance by staff where there is certainty in practice, inherent cost savings on treatment and additional service delivery due to morbidity. The minimisation of additional professional resources involved in unscheduled VAD changes, delayed treatment or treatment of acquired infection, hospitalisation. The minimisation of patient discomfort associated with VAD infections.
National priorities	This study has a direct bearing on the prevention of infection agenda. Saving Lives: reducing infection, delivering clean and safe care (Department of Health, 2007)[99].
Current evidence base	There is no direct evidence looking at percentages of chlorhexidine in randomised controlled trials and little evidence looking at the use of solutions for cleansing skin prior to insertion of peripheral VADs and during dressing changes of all VADs in the community.
Study design	RCT. Power calculations should be conducted to establish the required sample size of the trial. It is important that the study is adequately powered to detect a clinically important effect size.
Economic considerations	The specific evidence base to inform practice would ensure that patients are properly protected against HCAI in relation to VAD insertion thereby reducing both the risks and costs of acquiring an infection.
Feasibility	Currently, all the proposed solutions are available and in use in practice, therefore it should be feasible to carry out the research in a realistic timescale at a reasonable cost.
Equalities	There are no specific equality issues.
Other comments	An ongoing concern is the possibility of chlorhexidine resistant microorganisms.

What is the clinical and cost effectiveness of 2%chlorhexidine in alcohol versus 0.5% chlorhexidine in alcohol versus 2% chlorhexidine in aqueous solution versus 0.5% chlorhexidine in aqueous solution for cleansing skin (beforeinsertion of peripheral vascular access devices [VADs] and during dressing changes of all VADs) in reducing VAD-related bacteraemia and VAD site infections?	
	It was recognised that decontamination of VAD hubs would be another important alternative to skin decontamination. The GDG wanted to design the study to include these but concluded that this would probably require a separate research study.

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