

# **Surgical site infection**

prevention and treatment of  
surgical site infection

**Clinical Guideline**

October 2008

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# **Surgical site infection**

## prevention and treatment of surgical site infection

National Collaborating Centre for Women's  
and Children's Health

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# Guideline Development Group membership and acknowledgements

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Association of NHS Occupational Physicians  
Association of Paediatric Emergency Medicine  
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British Dermatological Nursing Group  
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British Geriatrics Society – Special Interest Group in Diabetes  
British Healthcare Trades Association  
British Hip Society (BHS)  
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Healthcare Commission  
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Help the Aged  
Help the Hospices  
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Infection Control Nurses Association of the British Isles  
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Society of British Neurological Surgeons  
Society of Chiropodists & Podiatrists  
South & Central Huddersfield PCTs  
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Tissue Viability Society (UK)  
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Westmeria Healthcare Ltd  
Whipps Cross University Hospital NHS Trust  
Wiltshire PCT  
Wound Care Society  
York NHS Trust

# Abbreviations

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AAS	aqueous alcohol solution
Ab	antibiotics
AOPW	acidic oxidative potential water
ASA	American Society of Anesthesiologists
BMI	body mass index
BNF	British National Formulary
CABG	coronary artery bypass graft
CDC	Centers for Disease Control and Prevention
CFU	colony-forming unit
CI	confidence interval
COPD	chronic obstructive pulmonary disease
CPPL	closed saline postoperative peritoneal lavage
DAB	a solution containing 0.5 g of neomycin sulfate, 0.1 g of polymyxin B sulfate and 80 mg of gentamicin sulfate per litre of normal saline
FiO <sub>2</sub>	fraction of inspired oxygen in an inhaled gas
GDG	Guideline Development Group
GP	general practitioner
HCAI	healthcare-associated infection
HCHS	Hospital and Community Health Services
IBD	inflammatory bowel disease
ICER	incremental cost-effectiveness ratio
ICU	intensive care unit
IV	intravenous
MBP	mechanical bowel preparation
MRSA	meticillin-resistant <i>Staphylococcus aureus</i>
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NINNS	Nosocomial Infection National Surveillance System
NNIS	National Nosocomial Infection Surveillance
O <sub>2</sub>	oxygen
OR	odds ratio
PSA	probabilistic sensitivity analysis
PU	permeable polyurethane
QALY	quality-adjusted life year
quasi-RCT	quasi-randomised controlled trial
RCT	randomised controlled trial
RTI	respiratory tract infection
SD	standard deviation
SENIC	Study on the Efficacy of Nosocomial Infection Control
SHR	surgical hand rubbing
SHS	surgical hand scrubbing
SSI	surgical site infection
UK	United Kingdom
USA	United States of America
UTI	urinary tract infection
WMD	weighted mean difference

# Glossary of terms

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<b>Absolute risk reduction</b>	The difference between the observed rates of an event (i.e. the proportions of individuals with the outcome of interest) in the groups being compared.
<b>Amorphous</b>	Describes an object that lacks a definitive visible shape or form, such as a gel.
<b>Anaerobes</b>	Organisms that can multiply in atmospheres low in oxygen (facultative anaerobes) or in complete anoxia (strict anaerobes). They are often the cause of surgical site infections (SSIs) and may thrive in synergy with aerobic organisms such as the Gram-negative bacilli (for example, <i>Escherichia coli</i> ).
<b>Anastomosis</b>	An anastomosis is formed when bowel or vessels are joined together during an operation using sutures, or, in the case of bowel, staples as an alternative.
<b>Antibiotic formulary</b>	A local policy document produced by a multi-professional team, usually in a hospital trust or primary commissioning group, combining best evidence and clinical judgement or a simple list of drugs available to a clinician.
<b>Antibiotic prophylaxis</b>	The preoperative use of antibiotics to prevent the development of SSIs.
<b>APACHE</b>	The Acute Physiological and Chronic Health Evaluation provides a score for general patient risk factor assessment for SSI.
<b>ASEPSIS</b>	A scoring system for SSIs that comprises the following factors: Additional treatment (drainage, antibiotics, <b>debridement</b> ), Serous discharge, <b>Erythema</b> , Purulent exudate, Separation of deep tissues, Isolation of bacteria, Stay in hospital > 14 days.
<b>Bias</b>	Influences on a study that can lead to invalid conclusions about a treatment or intervention. Bias in research can make a treatment look better or worse than it really is. It can even make it look as if the treatment works when it actually does not. Bias can occur by chance or as a result of systematic errors in the design and execution of a study. It can occur at different stages in the research process, for example in the collection, analysis, interpretation, publication or review of research data. Good studies recognise potential biases from the beginning and seek to reduce their impact by careful design and by selecting patient subjects appropriately (for example, by allocating equal proportions of patients with and without the possibly biasing factor to each study group, or by accounting for potential bias during statistical analysis). They also acknowledge possible biases in their discussion and conclusions. See <b>blinding or masking</b> and <b>double-blind study</b> .
<b>Blinding or masking</b>	The practice of keeping the investigators or subjects of a study ignorant of the group to which a subject has been assigned. For example, a clinical trial in which the participating patients or their doctors are unaware of whether they (the patients) are taking the experimental drug or a placebo (dummy treatment). The purpose of 'blinding' or 'masking' is to protect against <b>bias</b> . See also <b>double-blind study</b> .
<b>CABG</b>	A coronary artery bypass graft (CABG) is an operation to bypass a diseased and narrowed segment of an artery supplying heart muscle to reduce the risk of a heart attack. Usually undertaken using a segment of vein or a re-routed artery.
<b>Case-control study</b>	A study that starts with the identification of a group of individuals sharing the same characteristics (for example, people with a particular disease) and a suitable comparison ( <b>control</b> ) group (for example, people without the disease). All subjects are then assessed with respect to things that happened to them in the past, for example factors that might have increased their risk of getting the disease under investigation. Such studies are also called <b>retrospective</b> as they look back in time from the outcome to the possible causes.
<b>Case report (or case study)</b>	Detailed report on one patient (or case), usually covering the course of that person's disease and their response to treatment.
<b>Case series</b>	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison ( <b>control</b> ) group of patients, and so the conclusions of such series are subject to possible <b>bias</b> .
<b>Celsian (clinical) signs</b>	Aulus Cornelius Celsus, a Roman gladiatorial surgeon, described these four signs of local inflammation: calor, rubor, dolor, tumor (heat, redness, pain, swelling), to which can be added the mediaeval functio laesa (loss of function; if it hurts, the affected inflamed part is not used and is rested).
<b>Celsian signs of infection</b>	Local heat, <b>erythema</b> (redness), pain and swelling ( <b>oedema</b> ).

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<b>Cholecystectomy</b>	An operation to remove the gallbladder, usually because of symptoms caused by stones. It is undertaken open, with an incision, or by laparoscopic (keyhole) surgery.
<b>Clinical effectiveness</b>	The extent to which an intervention (for example, a device or treatment) produces health benefits (i.e. more good than harm). See <b>cost-effectiveness</b> .
<b>Clinical trial</b>	A research study conducted with patients which tests a drug, or other intervention, to assess its effectiveness and safety. Each trial is designed to answer scientific questions and to find better ways to treat individuals with a specific disease. This general term encompasses <b>controlled clinical trials</b> and <b>randomised controlled trials</b> .
<b>Cochrane Collaboration</b>	An international organisation in which individuals retrieve, appraise and review available evidence of the effect of interventions in health care. The Cochrane Database of Systematic Reviews contains regularly updated reviews on a variety of issues. The Cochrane Library contains the Central Register of Controlled Trials (CENTRAL) and a number of other databases which are regularly updated and is available on CD-ROM and on the internet [www.cochranelibrary.com].
<b>Cohort</b>	A group of people sharing some common characteristic (for example, patients with the same disease), followed up in a research study for a specified period of time.
<b>Cohort study</b>	An <b>observational study</b> that takes a group (cohort) of patients and follows their progress over time in order to measure outcomes such as disease or mortality rates and make comparisons according to the treatments or interventions that patients received. Thus within the study group, subgroups of patients are identified (from information collected about patients) and these groups are compared with respect to outcome, for example comparing mortality between one group that received a specific treatment and one group which did not (or between two groups that received different levels of treatment). Cohorts can be assembled in the present and followed into the future (a 'concurrent' or ' <b>prospective</b> ' cohort study) or identified from past records and followed forward from that time up to the present (a 'historical' or ' <b>retrospective</b> ' cohort study). Because patients are not randomly allocated to subgroups, these subgroups may be quite different in their characteristics and some adjustment must be made when analysing the results to ensure that the comparison between groups is as fair as possible and potential <b>bias</b> is minimised.
<b>Co-interventions</b>	Interventions or treatments, other than the treatment under study, which are applied to the treatment and/or <b>control</b> groups.
<b>Collagen</b>	Protein that is formed during the repair of a wound. It never reaches the pre-wounding strength of tissues and as it matures within a scar it turns white as the reparative blood vessels regress after successful healing.
<b>Colony-forming units (CFUs)</b>	A measurement of viable bacterial numbers present in tissues or body fluids. It has limited value in the description of SSI.
<b>Combine dressing pad</b>	An integral central absorbent material that is attached and part of, not separate to, another wound management material such as a film membrane.
<b>Comorbidity</b>	Disease or diseases in a study population that is present in addition to the condition that is the subject of study, for example diabetes mellitus.
<b>Confidence interval</b>	A way of expressing the degree of certainty about the findings from a study or group of studies, using statistical techniques. A confidence interval describes a range of possible effects (of a treatment or intervention) that is consistent with the results of a study or group of studies. A wide confidence interval indicates a lack of certainty or precision about the true size of the clinical effect and is seen in studies with too few patients. Where confidence intervals are narrow they indicate more precise estimates of effects and a larger sample of patients studied. It is usual to interpret a '95%' confidence interval as the range of effects within which we are 95% confident that the true effect lies – i.e. we would be wrong only once out of 20 occasions with this degree of precision.
<b>Consistency</b>	The extent to which the conclusions of a collection of studies used to support a guideline recommendation are in agreement with each other. See also <b>homogeneity</b> .
<b>Control group</b>	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a <b>placebo</b> (dummy treatment) in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
<b>Controlled clinical trial (CCT)</b>	A study testing a specific drug or other treatment involving two (or more) groups of patients with the same disease. One (the experimental group) receives the treatment that is being tested, and the other (the comparison or <b>control group</b> ) receives an alternative treatment, a <b>placebo</b> (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. A CCT where patients are randomly allocated to treatment and comparison groups is called a <b>randomised controlled trial</b> . See <b>blinding</b> .

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<b>COPD</b>	Chronic obstructive pulmonary disease causes impairment of respiratory reserve and may be caused or worsened by smoking, for example. It is considered to be a major risk factor in major surgery.
<b>Cost–benefit analysis</b>	A type of <b>economic evaluation</b> where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
<b>Cost–consequences analysis</b>	A type of <b>economic evaluation</b> where both outcomes and costs of alternative interventions are described, without any attempt to compare the results.
<b>Cost-effectiveness</b>	Value for money. A specific healthcare treatment is said to be ‘cost-effective’ if it gives a greater health gain than could be achieved by using the resources in other ways.
<b>Cost-effectiveness analysis</b>	A type of <b>economic evaluation</b> comparing the costs and the effects on health of different treatments. When a new treatment is compared with current care, its additional costs divided by its additional benefits is called the cost-effectiveness ratio. Health effects are measured in ‘health-related units’, for example, the cost of preventing one additional surgical site infection.
<b>Cost-minimisation analysis</b>	A type of <b>economic evaluation</b> used to compare the difference in costs between programmes that have the same health outcome.
<b>Costing study</b>	The simplest form of <b>economic evaluation</b> , measuring only the costs of given interventions.
<b>Cost–utility analysis</b>	A special form of <b>cost-effectiveness analysis</b> where benefit is measured in <b>quality-adjusted life years (QALYs)</b> . A treatment is assessed in terms of its ability to both extend life and to improve the quality of life.
<b>Crossover study design</b>	A study comparing two or more interventions in which the participants, upon completion of the course of one treatment, are switched to another. For example, for a comparison of treatments A and B, half the participants are randomly allocated to receive them in the order A, B and half to receive them in the order B, A. A problem with this study design is that the effects of the first treatment may carry over into the period when the second is given. Therefore a crossover study should include an adequate ‘wash-out’ period, which means allowing sufficient time between stopping one treatment and starting another so that the first treatment has time to wash out of the patient’s system.
<b>Cross-sectional study</b>	The observation of a defined set of people at a single point in time or time period – a snapshot. This type of study contrasts with a <b>longitudinal study</b> , which follows a set of people over a period of time.
<b>Cytokines</b>	Cytokines are small molecules released by cells involved in inflammation during the orchestration of the wound healing cascades. If released in excessive amounts they may delay healing and promote infection and sepsis.
<b>Debridement</b>	The excision or wide removal of all dead (necrotic) and damaged tissue that may develop in a surgical wound. In addition, there are currently a number of other accepted methods available for wound debridement: <i>bio-surgery</i> – the use of larvae (sterile maggots) <i>surgery</i> – performed by a surgeon within an operating environment (removes relevant tissue down to healthy bleeding tissue) <i>sharp debridement</i> – performed by a suitably qualified healthcare professional (removes only mobile necrotic or sloughy material within the wound margins and is not as complete as surgical debridement) <i>saline soaks</i> – common practice in the USA but not a recommended debridement technique in the UK the use of <i>wound dressing materials</i> such as <i>hydrocolloids</i> and <i>hydrogels</i> – the use of amorphous hydrogel preparations that moisten and loosen adherent dead tissue to facilitate debridement but need covering with a secondary dressing.
<b>Diapedesis</b>	The movement of white cells out of the circulation into an area of infection or tissue damage where they help to combat infection and start the healing process predominantly under the influence of cytokines.
<b>Discounting</b>	The process of converting future cost and future health outcomes to their present value.
<b>Double-blind study</b>	A study in which neither the subject (patient) nor the observer (investigator or clinician) is aware of which treatment or intervention the subject is receiving. The purpose of blinding is to protect against <b>bias</b> .
<b>Dressings</b>	Materials that are applied directly onto the wound: (a) <b>Passive</b> – such as ‘gauze-like materials’ that simply cover the wound, neither promoting nor intentionally hindering the wound healing process. They have been associated with negative effects on the patient’s quality of life during the 30 day postoperative period.



**(b) Interactive** – modern (post 1980) dressing materials that are designed to promote the wound healing process through the creation and maintenance of a local, warm, moist environment underneath the chosen dressing, when left in place for a period indicated through a continuous assessment process. Examples are alginates, semi-permeable film membranes, foams, hydrocolloids and fibrous hydrocolloids, non-adherent wound contact materials and combinations of those listed below.

*Alginates* – Alginate dressings are manufactured from salts of alginic acid, a naturally occurring substance in some species of brown seaweed. On contact with wound exudate, an ionic exchange occurs in the alginate and a hydrophilic gel is formed.

*Film Membranes* – Modern film membranes (also known as semi-permeable films) are made of sterile elastic sheets of polyurethane coated with a hypoallergenic acrylic adhesive on one side. They are permeable to air and water vapour but occlusive to fluids and bacteria.

*Foams* – Foam dressings are usually made of polyurethane and are available in a variety of forms, for example simple foam sheets, film-backed foam dressings, polyurethane membranes, polyurethane foam gels (sometimes also referred to as hydro polymers) and silicone foams, the last being used exclusively for filling large but lightly exuding cavities where the margins of the cavity can be seen.

*Hydrocolloids* – Hydrocolloids are designed to absorb small amounts of fluid and consist of a carrier (either a thin sheet of foam or a semi-permeable film) coated with an absorbent mass containing varying amounts of sodium carboxymethylcellulose and other gel-forming agents.

*Hydrogels* – Hydrogels are three-dimensional cross-linked structures made up of hydrophilic homopolymers or copolymers with varying water content dependent on the manufacturing process. Sheet hydrogels retain their physical form and absorb fluid and these tend to be used for the management of burns and scar tissue, whereas amorphous hydrogels have no fixed structure and decrease in viscosity as they absorb fluid, becoming a dispersion or solution of the polymer. The majority of hydrogels contain about 20% propylene glycol that acts as a moisturiser and preservative, and, additionally, most amorphous products contain about 3% of a gel-forming agent, such as carboxymethylcellulose or a starch copolymer.

*Iodine-based materials* – There are two distinct preparations: those of PVP-1 (povidone-iodine) – an iodophor composed of elemental iodine and a synthetic polymer, and cadexomer iodine – a polysaccharide starch lattice containing 0.9% elemental iodine that is released on exposure to wound exudate. They have different physical characteristics that relate to the component parts and the iodine concentration of available iodine that is released when used.

**(c) Active** – Active dressings, through their action, are designed to manipulate or alter the wound healing environment to either re-stimulate or to further promote the wound healing process. Examples include topical negative pressure therapy, larva therapy (sterile maggots), dressing materials that incorporate antimicrobial agents and dressings that contain biomaterials such as **collagen** or hyaluronic acid or cultured keratinocytes or bio-engineered skin.

See Appendix C for further information on wound dressings for SSI prevention.

#### Economic evaluation

The comparative analysis of alternative courses of action by comparing their costs and consequences.

#### Effectiveness

The extent to which interventions achieve health improvements in real practice settings.

#### Efficacy

The extent to which medical interventions achieve health improvements under ideal circumstances.

#### Endogenous infections

Infections caused by the patient's own resident organisms.

#### Endothelium

Endothelium is the single layer of cells that continuously lines the inner side of all blood vessels.

#### Epidemiological study

A study that looks at how a disease or clinical condition is distributed across populations, for example across geographical areas or over time, or between age groups.

#### Epithelialisation

The process that leads to the surface of a skin wound being re-surfaced by new epithelial cells. It is rapid in sutured surgical wounds but can be delayed in open wounds healing by secondary intention, for example when perfusion and tissue oxygenation are not optimal. Epithelium heals by regeneration of damaged cells.

#### Erythema

Abnormal redness of the skin that occurs when there is infection by enzyme- or toxin-producing bacteria (for example,  $\beta$ -haemolytic streptococci). It is one of the **Celsian clinical signs of infection**, the others being heat, pain and swelling.

#### Evidence based

The process of systematically finding, appraising and using research findings as the basis for clinical decisions.

<b>Evidence-based clinical practice</b>	Evidence-based clinical practice involves making decisions about the care of individual patients based on the best research evidence available rather than basing decisions on personal opinions or common practice (which may not always be evidence based). Evidence-based clinical practice therefore involves integrating individual clinical expertise and patient preferences with the best available evidence from research.
<b>Evidence table</b>	A table summarising the results of a collection of studies which, taken together, represent the evidence supporting a particular recommendation or series of recommendations in a guideline.
<b>Exclusion criteria</b>	See <b>selection criteria</b> .
<b>Exogenous infections</b>	Infections caused by external organisms transmitting to the wound from an external source.
<b>Experimental study</b>	A research study designed to test whether a treatment or intervention has an effect on the course or outcome of a condition or disease, where the conditions of testing are to some extent under the control of the investigator. <b>Controlled clinical trials</b> and <b>randomised controlled trials</b> are examples of experimental study designs.
<b>Extrinsic</b>	Features that are external to the individual.
<b>Fibroblasts</b>	Cells involved in the wound repair process which leads to wound repair and the laying down of the scar protein <b>collagen</b> .
<b>FiO<sub>2</sub></b>	The fraction of inspired oxygen in an inhaled gas. When breathing air, the FiO <sub>2</sub> is approximately 20%.
<b>Follow-up</b>	Observation over a period of time of an individual, group or population whose relevant characteristics have been assessed in order to observe changes in health status or health-related variables.
<b>Gold standard</b>	A method, procedure or measurement that is widely accepted as being the best available.
<b>Granulation tissue</b>	Vascular tissue that forms in the base of a wound during the process of healing. It is minimal in surgical incised wounds but can be extensive in open wounds healing by secondary intention. Granulations are composed of new vessels, fibroblasts and white cells that remove dead tissue and microorganisms and prepare the wound for repair by the laying down of the scar protein <b>collagen</b> .
<b>Haematogenous</b>	Spread through the blood stream. Microorganisms and cancer cells can spread by this route.
<b>Haemoglobin saturation</b>	A measurement of the amount of oxygen carried in the blood measured using infrared technology (oximetry). It is maintained as close to 100% as possible during anaesthesia and the postoperative period.
<b>Healing by primary intention</b>	Occurs when a wound has been sutured after an operation and heals to leave a minimal, cosmetically acceptable scar.
<b>Healing by secondary intention</b>	Occurs when a wound is deliberately left open at the end of an operation because of excessive bacterial contamination, particularly by anaerobes or when there is a risk of devitalised tissue, which leads to infection and delayed healing. It may be sutured later within a few days (delayed primary closure), or much later when the wound is clean and granulating (secondary closure), or be left to complete healing naturally without the intervention of suturing.
<b>Health economics</b>	A branch of economics that studies decisions about the use and distribution of healthcare resources.
<b>Healthcare professional</b>	Includes doctors, nurses and allied health professionals such as physiotherapists.
<b>Health Technology Assessment</b>	The process by which evidence on the clinical effectiveness and the costs and benefits of using a technology in clinical practice is systematically evaluated.
<b>Healthcare-associated infection (HCAI)</b>	Infection acquired as a result of the delivery of health care either in an acute (hospital) or non-acute setting.
<b>Hernioplasty</b>	An operation that repairs the defect through which a hernia protrudes.
<b>Heterogeneity or lack of homogeneity</b>	The term is used in <b>meta-analyses</b> and <b>systematic reviews</b> when the results or estimates of effects of treatment from separate studies seem to be very different. This may be in terms of the size of treatment effects, or even to the extent that some indicate beneficial and others suggest adverse treatment effects. Such results may occur as a result of differences between studies in terms of the patient populations, outcome measures, definition of <b>variables</b> or duration of follow-up.
<b>Homeostasis</b>	The maintenance of normal physiological function.
<b>Homogeneity</b>	This means that the results of studies included in a <b>systematic review</b> or <b>meta-analysis</b> are similar and there is no evidence of <b>heterogeneity</b> . Results are usually regarded as homogeneous when any differences between studies could reasonably be expected to occur by chance. See also <b>consistency</b> .
<b>Humectant</b>	A substance that promotes the retention of moisture.

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<b>Hypertrophic</b>	A hypertrophic scar contains an excess of cells (hyperplasia) and also scar tissue that leads to a heaped up, red appearance.
<b>Inflammatory bowel disease (IBD)</b>	Inflammatory bowel disease includes Crohn's disease and ulcerative colitis.
<b>Incise drapes</b>	These are transparent, adhesive polyurethane sheets that adhere to the skin and keep the <b>operative (surgical) drapes</b> in place and isolate the operative area. They may be impregnated with an antiseptic, such as iodophor. They may also be used as a postoperative wound dressing for the first few postoperative days as their transparency facilitates inspection.
<b>Inclusion criteria</b>	See <b>selection criteria</b> .
<b>Incidence</b>	The number of new cases of illness commencing, or of people falling ill, during a specified time period in a given population. Usually expressed as the number of new cases per 100 000 population per year. The incidence of SSI is often expressed as number cases per days of post-operative follow-up or number cases per procedure. See <b>prevalence</b> .
<b>Interactive dressing</b>	See <b>dressings</b> .
<b>Intervention</b>	Healthcare action intended to benefit the patient, for example a surgical procedure.
<b>Intrinsic</b>	Features present within the individual.
<b>Keloid</b>	A keloid scar differs from a hypertrophic scar in extending beyond the margins of a scar. It may lead to extensive disfigurement and is difficult to treat as attempts to remove it are followed by recurrence that may be even more extensive.
<b>Laparotomy</b>	An exploratory, usually emergency, operation of the abdomen.
<b>Leucocyte</b>	The group of white cells (primarily the neutrophils) that are involved in the first defence against infection and are involved in the early wound healing response.
<b>Logistic regression analysis</b>	A statistical method that allows identification of independent variables. For example, this type of analysis may identify risk factors for infection, such as SSI, from a large database of variables.
<b>Longitudinal study</b>	A study of the same group of people at more than one point in time. This type of study contrasts with a <b>cross-sectional study</b> , which observes a defined set of people at a single point in time.
<b>Lymphocyte</b>	White cells involved in the host response to infection. There are many types that confer protection through a hormonal route (B cells) or through the formation of antibodies (T cells).
<b>Macrophages</b>	Macrophages are formed from monocytes that appear in tissues soon after wounding or the presence of infection. They are the principal cells that orchestrate the wound healing process, mostly through cytokine release.
<b>Margination</b>	Prior to <b>diapedesis</b> , white cells become adherent to the <b>endothelium</b> of blood vessels, called margination, through a complicated process involving, for example, intercellular adhesion molecules.
<b>Masking</b>	See <b>blinding</b> .
<b>Meta-analysis</b>	A technique in which the results from a collection of independent studies (investigating the same treatment) are pooled, to allow further statistical techniques to synthesise their findings into a single estimate of a treatment effect. Where studies are not compatible, for example because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to pool results. See also <b>systematic review</b> and <b>heterogeneity</b> .
<b>Metalloproteinases</b>	There are several families of these enzymatic proteins that are released from white cells during the early stages of the wound healing process. Their function is to help with removal of damaged tissue but if excessive may delay healing.
<b>Mitogenic</b>	A substance that can promote cell division.
<b>Monocytes</b>	A type of blood stream white cell. Once in the tissues in the inflammatory process, they become macrophages.
<b>Myofibroblasts</b>	The modified fibroblasts that produce the scar protein <b>collagen</b> and other components of repaired tissue during the wound healing process.
<b>Neonates</b>	Children up to 1 month of age.
<b>Neutrophils</b>	White cells of the leucocyte group.
<b>Non-experimental study</b>	A study in which subjects are selected on the basis of their availability, with no attempt having been made to avoid problems of <b>bias</b> .
<b>Non-pathogenic organisms</b>	Microorganisms that are incapable of causing disease in a host.

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<b>Number needed to treat (NNT)</b>	Measures the impact of a treatment or <b>intervention</b> . It states how many patients need to be treated with the treatment in question in order to prevent an event that would otherwise occur. For example, if the $NNT = 4$ , then four patients would have to be treated to prevent one bad outcome. The closer the NNT is to 1, the better the treatment is. Analogous to the NNT is the number needed to harm (NNH), which is the number of patients that would need to receive a treatment to cause one additional adverse event.
<b>Observational study</b>	In research about diseases or treatments, this refers to a study in which nature is allowed to take its course. Changes or differences in one characteristic (for example, whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (for example, whether or not they died), without the intervention of the investigator. These studies are easy to perform, but there is a greater risk of <b>selection bias</b> than in <b>experimental studies</b> .
<b>Odds ratio (OR)</b>	Odds are a way of representing probability. In recent years odds ratios have become widely used in reports of clinical studies. They provide an estimate (usually with a <b>confidence interval</b> ) for the effect of a treatment. Odds are used to convey the idea of 'risk' and an odds ratio of 1 between two treatment groups would imply that the risks of an adverse outcome were the same in each group. For rare events the odds ratio and the <b>relative risk</b> (which uses actual risks and not odds) will be very similar. See also <b>relative risk, risk ratio</b> .
<b>Oedema</b>	Swelling due to the accumulation of interstitial tissue fluid and frequently a result of bacterial infection in a wound. It is one of the <b>Celsian signs of infection</b> .
<b>Operative (surgical) drapes</b>	The drapes that are placed around a proposed operative site after skin preparation to protect and isolate the operative field. They may be held in place by towel clips or in higher risk operations by <b>incise drapes</b> . Operative drapes may be reusable or disposable and are usually self-adhesive.
<b>P value</b>	If a study is undertaken to compare two treatments then the <i>P</i> value is the probability of obtaining the results of that study if there really was no difference between the two treatments. (The assumption that there really is no difference between treatments is called the 'null hypothesis'.) Suppose the calculated <i>P</i> value for the study was $P = 0.03$ . This means that, if there really was no difference between treatments, there would only be a 3% chance of achieving the results obtained. Since this chance seems quite low we should question the validity of the assumption that there really is no difference between treatments. We would conclude that there probably is a difference between treatments. By convention, where the value of <i>P</i> is below 0.05 (i.e. less than 5%) the result is seen as statistically significant.
<b>Parenteral</b>	The giving of a drug by an intramuscular or intravenous route (i.e. not given through the gut, principally the oral route).
<b>Pathogenic organisms</b>	Microorganisms that can cause disease in a host.
<b>Peer review</b>	Review of a study, service or recommendations by those with similar interests and expertise to the people who produced the study findings or recommendations. Peer reviewers can include professional and patient/carer representatives.
<b>Perfusion</b>	Blood flow through tissues or organs. If not optimal, this can increase the risk of infectious complications (particularly SSIs).
<b>Pilot study</b>	A small-scale 'test' of the research instrument, for example testing out (piloting) a new questionnaire with people who are similar to the population of the study, in order to highlight any problems or areas of concern, which can then be addressed before the full-scale study begins.
<b>Placebo</b>	Placebos are fake or inactive treatments received by participants allocated to the <b>control group</b> in a <b>clinical trial</b> . They are designed to be indistinguishable from the active treatments being given in the experimental group. They are used so that participants are ignorant of their treatment allocation in order to be able to quantify the effect of the experimental treatment over and above any <b>placebo effect</b> due to receiving care or attention.
<b>Placebo effect</b>	A beneficial (or adverse) effect produced by a <b>placebo</b> and not due to any property of the placebo itself.
<b>POSSUM</b>	The Physiological and Operative Severity Score for Enumeration of Morbidity and Mortality provides an assessment of risk factors associated with SSI. The score can be used to show that patients in different groups have comparable comorbidity.
<b>Post-discharge surveillance</b>	Many SSIs present after discharge from hospital. Comparison of post-discharge surveillance data is difficult as it depends on the methods used to detect SSIs. The method of surveillance should be clear so that comparisons can be made between studies.
<b>Power</b>	See <b>statistical power</b> .

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<b>Predictive validity</b>	A risk assessment tool would have high predictive validity if the predictions it makes (say, of development of SSI in a sample) became true (i.e. it has both high sensitivity and high specificity).
<b>Prevalence</b>	The proportion of patients with a particular disease within a given population at a given time. Point prevalence is the number of patients affected per 100 000 population.
<b>Prospective study</b>	A study in which people are entered into the research study and then followed up over a period of time, with future events recorded as they happen. This contrasts with studies that are <b>retrospective</b> .
<b>Qualitative research</b>	Qualitative research is used to explore and understand people's beliefs, experiences, attitudes, behaviour and interactions. It generates non-numerical data, for example a patient's description of their pain rather than a measure of pain. In health care, qualitative techniques have been commonly used in research documenting the experience of chronic illness and in studies about the functioning of organisations. Qualitative research techniques such as focus groups and in-depth interviews have been used in one-off projects commissioned by guideline development groups to find out more about the views and experiences of patients and carers.
<b>Quality-adjusted life years (QALYs)</b>	A measure of health outcome that combines quantity and quality of life. To each year of life a weight is assigned, ranging from 0 to 1, corresponding to the health-related quality of life. A weight of 1 corresponds to perfect health, and a weight of 0 corresponds to a health state judged as equivalent to death.
<b>Quantitative research</b>	Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the National Census that counts people and households.
<b>Random allocation or Randomisation</b>	Patients are allocated to one (or more) treatments in a research study by using a random numbers table or a computer-generated random sequence. Random allocation implies that each individual (or each unit or group of individuals in the case of cluster randomisation) being entered into a study has the same chance of receiving each of the possible interventions.
<b>Randomised controlled trial (RCT)</b>	A study in which people are randomly assigned to two (or more) groups: one (the experimental group) receiving the treatment that is being tested, and the other (the comparison or <b>control group</b> ) receiving an alternative treatment, a <b>placebo</b> (dummy treatment) or no treatment. The two groups are followed up to compare differences in outcomes to see how effective the experimental treatment was. (Through randomisation, the groups should be similar in all aspects apart from the treatment they receive during the study).
<b>Relative risk (RR)</b>	A summary measure that represents the ratio of the risk of a given event or outcome (for example, an adverse reaction to the drug being tested) in one group of subjects compared with another group. When the 'risk' of the event is the same in the two groups the relative risk is 1. In a study comparing two treatments, a relative risk of 2 would indicate that patients receiving one of the treatments had twice the risk of an undesirable outcome than those receiving the other treatment. Relative risk is sometimes used as a synonym for <b>risk ratio</b> .
<b>Reliability</b>	Refers to a method of measurement that consistently gives the same results. For example, someone who has a high score on one occasion tends to have a high score if measured on another occasion very soon afterwards. With physical assessments it is possible for different clinicians to make independent assessments in quick succession and if their assessments tend to agree then the method of assessment is said to be reliable.
<b>Retrospective study</b>	A study that deals with the present and past and does not involve studying future events. This contrasts with studies that are <b>prospective</b> .
<b>Risk factor</b>	A feature of a patient that is associated with an increased chance that they will suffer a health-related outcome of interest, for example an SSI.
<b>Risk ratio</b>	Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison ( <b>control</b> ) group. The term <b>relative risk</b> is sometimes used as a synonym of risk ratio.
<b>Sample</b>	A part of the study's target population from which the subjects of the study will be recruited. If subjects are drawn in an unbiased way from a particular population, the results can be generalised from the sample to the population as a whole.
<b>Scoring systems and definitions for SSI</b>	There are many different definitions and scoring systems for SSI. The Centers for Disease Control and Prevention (CDC) definition is the one most commonly used.
<b>Screening</b>	The initial identification of a disease or defect by means of usually simple tests, examinations or other procedures that can be applied rapidly. Screening tests differentiate apparently well people who may have a disease from those who probably have not. A screening test is not intended to be diagnostic but should have sufficiently <b>sensitivity</b> and <b>specificity</b> to

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reduce the proportion of false results, positive or negative, to acceptable levels. Screening tests should be sensitive (fewer false negatives), but high specificity (fewer false positives) is less important. Patients with positive or suspicious findings in screening tests should be referred to the appropriate healthcare professional for confirmation of the diagnosis (which often uses tests with higher specificity, but that may be slower or more expensive) and any necessary treatment.

### Selection bias

Selection bias has occurred if:

- the characteristics of the sample differ from those of the wider population from which the sample has been drawn, or
- there are systematic differences between comparison groups of patients in a study in terms of prognosis or responsiveness to treatment.

### Selection criteria

Explicit standards used by guideline development groups to decide which studies should be included and excluded from consideration as potential sources of evidence.

### Sensitivity

In diagnostic testing, this refers to the chance of having a positive test result in patients who actually have the disease. 100% sensitivity means that all those with the disease will test positive, but this is not the same the other way around. A patient could have a positive test result but not have the disease — this is called a ‘false positive’. The sensitivity of a test is also related to its ‘negative predictive value’ (true negatives) – a test with a sensitivity of 100% means that all those who get a negative test result do not have the disease. To judge the accuracy of a test fully, its **specificity** must also be considered. See **screening**.

### Specificity

In diagnostic testing, this refers to the chance of a patient who does not have the disease having a negative test result. 100% specificity means that all those without the disease will test negative, but this is not the same the other way around. A patient could have a negative test result yet still have the disease – this is called a ‘false negative’. The specificity of a test is also related to its ‘positive predictive value’ (true positives) – a test with a specificity of 100% means that all those who get a positive test result definitely have the disease. To fully judge the accuracy of a test, its **sensitivity** must also be considered. See **screening**.

### Statistical power

The ability of a study to demonstrate an association or causal relationship between two **variables**, given that an association exists. For example, 80% power in a **clinical trial** means that the study has a 80% chance of ending up with a **P value** of less than 5% in a statistical test (i.e. a statistically significant treatment effect) if there really was an important difference (for example, 10% versus 5% mortality) between treatments. If the statistical power of a study is low, the study results will be questionable (the study might have been too small to detect any differences). By convention, 80% is an acceptable level of power.

### Surgical site (wound) infection (SSI)

Surgical site infection can be defined as being present when pathogenic organisms multiply in a wound giving rise to local signs and symptoms, for example heat, redness, pain and swelling, and (in more serious cases) with systemic signs of fever or a raised white blood cell count. Infection in the surgical wound may prevent healing taking place so that the wound edges separate or it may cause an abscess to form in the deeper tissues.

The definitions of SSI may vary between research studies but are commonly based on those described by the Centers for Disease Control and Prevention (CDC) although other valid measures have been used, for example the **ASEPSIS** scoring method for postoperative wound infections and some studies that have focused only on the more serious deep and organ/space infections for which less subjective measures are available. Differences in case definitions should be taken into account when comparing reported rates of SSI.

### Surgical wound classification

*Clean* – an incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory, alimentary and genitourinary tracts are not entered.

*Clean-contaminated* – an incision through which the respiratory, alimentary or genitourinary tract is entered under controlled conditions but with no contamination encountered.

*Contaminated* – an incision undertaken during an operation in which there is a major break in sterile technique or gross spillage from the gastrointestinal tract, or an incision in which acute, non-purulent inflammation is encountered. Open traumatic wounds that are more than 12–24 hours old also fall into this category.

*Dirty or infected* – an incision undertaken during an operation in which the viscera are perforated or when acute inflammation with pus is encountered during the operation (for example, emergency surgery for faecal peritonitis), and for traumatic wounds where treatment is delayed, and there is faecal contamination or devitalised tissue present.

<b>Sutures</b>	The 'threads' used by surgeons to close a wound, often in layers, at the end of an operation. They may also be used for other indications such as joining vessels, intestine or ducts, tying off bleeding vessels or repairing damaged organs. The traditional, natural, but unreliable, sutures made of catgut (absorbable) and silk (non-absorbable) have been replaced by synthetic polymers that can be tailor-made for their purpose of use. For example, non-biodegradable polypropylene sutures are used for a permanent anastomosis between arteries, whereas absorbable polyglactin sutures are ideal for suturing bowel together after resection (anastomosis). Modern sutures are all 'swaged' onto the needle, so there is no shoulder, and this allows smooth passage through the tissues.
<b>Systematic review</b>	A review in which evidence from scientific studies has been identified, appraised and synthesised in a methodical way according to predetermined criteria. The review may include a <b>meta-analysis</b> .
<b>Validity</b>	Assessment of how well a tool or instrument measures what it is intended to measure.
<b>Variable</b>	A measurement that can vary within a study, for example the age of participants. Variability is present when differences can be seen between different people, or within the same person over time, with respect to any characteristic or feature that can be assessed or measured.
<b>Vasoconstriction</b>	The shutdown of blood vessels to an organ or tissue. It can lead to poor perfusion, an increased risk of infection or tissue death (gangrene).
<b>Wound classification</b>	See <b>surgical wound classification</b> .
<b>Wound dressings</b>	See <b>dressings</b> .
<b>Wound separation</b>	Separation of the edges of a wound at a time when a sutured wound would be expected to be healing by primary intention is caused by an infectious process or delayed healing or follows surgical drainage of a wound abscess. Healing is delayed because it has to occur via secondary intention but it is usually complete.
<b>Wound dehiscence</b>	After operations in general, wound dehiscence and <b>wound separation</b> are considered to be synonymous. However, in abdominal surgery, wound dehiscence is considered to have occurred when all layers of the wound separate, with evisceration of abdominal contents.





# 1 Introduction

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## 1.1 Surgical site infection

Infections that occur in the wound created by an invasive surgical procedure are generally referred to as surgical site infections (SSIs). SSIs are one of the most important causes of healthcare-associated infections (HCAIs). A prevalence survey undertaken in 2006 suggested that approximately 8% of patients in hospital in the UK have an HCAI. SSIs accounted for 14% of these infections and nearly 5% of patients who had undergone a surgical procedure were found to have developed an SSI.<sup>1</sup> However, prevalence studies tend to underestimate SSI because many of these infections occur after the patient has been discharged from hospital.

SSIs are associated with considerable morbidity and it has been reported that over one-third of postoperative deaths are related, at least in part, to SSI.<sup>2</sup> However, it is important to recognise that SSIs can range from a relatively trivial wound discharge with no other complications to a life-threatening condition. Other clinical outcomes of SSIs include poor scars that are cosmetically unacceptable, such as those that are spreading, hypertrophic or keloid, persistent pain and itching, restriction of movement, particularly when over joints, and a significant impact on emotional wellbeing.<sup>3</sup>

SSI can double the length of time a patient stays in hospital and thereby increase the costs of health care. Additional costs attributable to SSI of between £814 and £6626 have been reported depending on the type of surgery and the severity of the infection.<sup>4,5</sup> The main additional costs are related to re-operation, extra nursing care and interventions, and drug treatment costs. The indirect costs, due to loss of productivity, patient dissatisfaction and litigation, and reduced quality of life, have been studied less extensively.

### The wound healing process

The 'normal' wound healing process has been identified as involving three overlapping major phases:

- inflammation, with cascades of processes that can be further subdivided into early (first 24 hours) and late phases (normally up to 72 hours)
- regeneration
- maturation.

The wound healing process is a complex one that involves many interacting cells, cytokines and growth factors, carbohydrates and proteins, all of which cascade into and act within the wound margins and across the wound bed at different rates and at different speeds.

The key cells that are involved in this process have been identified as:

- *inflammation* – platelets, neutrophils, lymphocytes and macrophages
- *regeneration and maturation* – macrophages and fibroblasts, the latter of which are linked with the deposition and regulation of collagen as well as wound contraction (myofibroblasts).

Early inflammation (the first 24 hours) begins with haemostasis through vasoconstriction, thrombin formation and platelet aggregation. Platelets release cytokines and other factors that directly influence leucocyte and monocyte activity. Late inflammation (24–72 hours) involves the release of vasodilators and other agents that increase the permeability of the local capillary bed allowing serum and white cells to be released into the area surrounding the wound, through complex interactions of adhesion molecules, and other systems, in margination and diapedesis. The function of this phase of wound healing is to ensure that the wound bed is free of bacteria

and other contaminants and to create the optimum environment for the production of granulation tissue and for epithelialisation.

Regeneration follows over the next few days to weeks and this phase of the wound healing process is characterised by an increase in fibroblast mitogenic activity and endothelial cell mitotic activity, with epithelial cell migration and the synthesis of collagen and metalloproteinases. This is a very dynamic balance of synthesis and breakdown of effete tissues and cells.

Maturation, which is also known as the remodelling phase, is the final phase of wound healing and can take up to 2 years to complete. Granulation tissue gradually matures into scar tissue, which over time pales (as the neovascularisation required for healing by scar tissue redresses), shrinks and thins. This repair process is governed by fibroblasts and proteases that normally maintain a balance between deposition and degradation of tissue. Over time, immature collagen fibrils are replaced by mature collagen fibres, improving the tensile strength of the scar tissue, but only to 80% of that of normal skin.<sup>6</sup>

### Pathogenesis of surgical site infection

The development of an SSI depends on contamination of the wound site at the end of a surgical procedure and specifically relates to the pathogenicity and inoculum of microorganisms present, balanced against the host's immune response.

The microorganisms that cause SSIs are usually derived from the patient (endogenous infection), being present on their skin or from an opened viscus. Exogenous infection occurs when microorganisms from instruments or the theatre environment contaminate the site at operation, when microorganisms from the environment contaminate a traumatic wound, or when microorganisms gain access to the wound after surgery, before the skin has sealed. Rarely, microorganisms from a distant source of infection, principally through haematogenous spread, can cause an SSI by attaching to a prosthesis or other implant left in an operative site. Practices to prevent SSI are therefore aimed at minimising the number of microorganisms introduced into the operative site, for example by:

- removing microorganisms that normally colonise the skin
- preventing the multiplication of microorganisms at the operative site, for example by using prophylactic antimicrobial therapy
- enhancing the patient's defences against infection, for example by minimising tissue damage and maintaining normothermia
- preventing access of microorganisms into the incision postoperatively by use of a wound dressings.

*Staphylococcus aureus* is the microorganism most commonly cultured from SSIs. When a viscus, such as the large bowel, is opened, tissues are likely to be contaminated by a whole range of organisms. For example, after colorectal surgery enterobacteriaceae and anaerobes are encountered and may act in synergy to cause SSI.

In prosthetic surgery, the presence of the foreign body (for example, a vascular graft after arterial bypass surgery or a prosthetic joint in orthopaedic surgery) reduces the number of pathogenic organisms required to cause an SSI. In this environment, normally non-pathogenic organisms such as *Staphylococcus epidermidis* (coagulase-negative staphylococcus) may also cause an SSI. Operations on sites that are normally sterile ('clean') thus have relatively low rates of SSI (generally less than 2%), whereas after operations in 'contaminated' or 'dirty' sites, rates may exceed 10%.<sup>7</sup>

### Management of surgical site infection

Most SSIs respond to the removal of sutures with drainage of pus if present and, occasionally, there is a need for debridement and open wound care. Many complications of postoperative wounds do not represent infection but exudation of tissue fluid or an early failure to heal, which is common in patients with a high body mass index (BMI). Incomplete sealing of the wound edges can often be managed by using a delayed primary or secondary suture or closure with adhesive tape, but in larger open wounds the granulation tissue must be healthy with a low bioburden of colonising or contaminating organisms if healing is to occur. It is likely that over

15% of postoperative wounds are treated with antibiotics, possibly inappropriately, something which can contribute to the problem of antibiotic resistance.

The appropriate treatment of established SSIs requires careful monitoring and communication between the multidisciplinary postoperative team (surgeons, intensivists, microbiologists, nurses) and the primary care team. If patients are to be returned home early then any SSI needs to be recognised and treated appropriately. Release of pus, debridement and parenteral antibiotics, if indicated, usually requires a return to secondary care. Extensive wound breakdown may need specialist wound management to reduce bacterial burden in the open wound. Wound bed preparation may be required to encourage healing by secondary intention or facilitate secondary suture.

## 1.2 Aim of the guideline

Clinical guidelines have been defined as ‘systematically developed statements which assist clinicians and patients in making decisions about appropriate treatment for specific conditions’. This clinical guideline concerns the prevention and treatment of SSI.

It has been developed with the aim of providing guidance on the patient’s journey throughout the preoperative, intraoperative and postoperative phases of surgery.

## 1.3 Areas outside of the remit of the guideline

This guideline does not address:

- prophylaxis and management of antibiotic-resistant bacteria
- management of the operating theatre environment and environmental factors
- anaesthetic factors relating to SSI.

## 1.4 For whom is the guideline intended?

This guideline is of relevance to those who work in or use the NHS in England, Wales and Northern Ireland, in particular:

- all healthcare professionals who are involved in the care of surgical patients, including GPs, surgeons, nursing and tissue viability staff and pharmacists
- those responsible for commissioning and planning healthcare services, including primary care trust commissioners, and public health, trust and care home managers
- surgical patients, their families and other caregivers.

A version of this guideline for patients, carers and the public, entitled ‘Understanding NICE guidance: Surgical site infection’, is available from the NICE website ([www.nice.org.uk/CG074publicinfo](http://www.nice.org.uk/CG074publicinfo)) or from NICE publications on 0845 003 7783 (quote reference number N1702).

## 1.5 Who has developed the guideline?

The guideline was developed by a multi-professional and lay working group (the Guideline Development Group or GDG) convened by the National Collaborating Centre for Women’s and Children’s Health (NCC-WCH). Membership included:

- two surgeons
- a tissue viability nurse
- two microbiologists
- a theatre nurse
- a surveillance coordinator
- an infection control specialist
- two patient/carer representatives.

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence and health economics modelling and, together with the GDG Chair, wrote successive drafts of the guideline.

During the development of the guideline, the GDG identified a need for expert advice from an anaesthetist and additional clinical representation from a surgeon and a theatre nurse. Expert advisers were appointed by the GDG to advise on each of these issues, although they were not involved in the final decisions regarding formulation of recommendations.

All GDG members' interests were recorded on declaration forms provided by NICE. The form covered consultancies, fee-paid work, shareholdings, fellowships and support from the healthcare industry.

Organisations with interests in SSI were encouraged to register as stakeholders for the guideline, and registered stakeholders were consulted throughout the guideline development process. The process of stakeholder registration was managed by NICE.

### 1.6 Other relevant documents

This guideline is intended to complement other existing and proposed works of relevance, including related NICE guidance:

- This guideline updates NICE Technology Appraisal 24: 'Guidance on the use of debriding agents and specialist wound care clinics for difficult to heal surgical wounds'.
- The effects of maintenance of normothermia are addressed in the 'Inadvertent perioperative hypothermia' guideline (NICE clinical guideline 65), available from [www.nice.org.uk/Guidance/CG65](http://www.nice.org.uk/Guidance/CG65).

### 1.7 Guideline methodology

This guideline was commissioned by NICE and developed in accordance with the guideline development process outlined in the NICE *Technical Manual*.

#### 1.7.1 Literature search strategy

Initial scoping searches were executed to identify relevant guidelines (local, national and international) produced by other development groups. The reference lists in these guidelines were checked against subsequent searches to identify missing evidence.

Relevant published evidence to inform the guideline development process and answer the clinical questions was identified by systematic search strategies. The clinical questions are presented in Appendix B. Additionally, stakeholder organisations were invited to submit evidence for consideration by the GDG provided it was relevant to the topics included in the scope and of equivalent or better quality than evidence identified by the search strategies.

Systematic searches to answer the clinical questions formulated and agreed by the GDG were executed using the following databases via the 'Ovid' platform: Medline (1950 onwards), Embase (1980 onwards) and the Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 onwards). The most recent search conducted for the three Cochrane databases (Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews, and the Database of Abstracts of Reviews of Effects) was undertaken in quarter 1, 2008. Searches to identify economic studies were undertaken using the above databases and the NHS Economic Evaluation Database (NHS EED).

Search strategies combined relevant controlled vocabulary and natural language in an effort to balance sensitivity and specificity. Unless advised by the GDG, searches were not date specific. Language restrictions were applied to searches, and publications in languages other than English were not appraised. Both generic and specially developed methodological search filters were used appropriately.

There was no systematic attempt to search grey literature (conferences, abstracts, theses and unpublished trials). Hand searching of journals not indexed on the databases was not undertaken.

Searches were conducted during a 7 month period between September 2007 and April 2008. Evidence published after this date has not been included in the guideline. September 2007 should thus be considered the starting point for searching for new evidence for future updates to this guideline.

Further details of the search strategies, including the methodological filters employed, are available on the accompanying CD-ROM.

### 1.7.2 Synthesis of clinical effectiveness evidence

Evidence relating to clinical effectiveness was reviewed using established guides and classified using the established hierarchical system presented in Table 1.1. This system reflects the susceptibility to bias that is inherent in particular study designs.

The type of clinical question dictates the highest level of evidence that may be sought. In assessing the quality of the evidence, each study was assigned a quality rating coded as '++', '+', or '-'. For issues of therapy or treatment, the highest possible evidence level (EL) is a well-conducted systematic review or meta-analysis of randomised controlled trials (RCTs; EL = 1++) or an individual RCT (EL = 1+). Studies of poor quality were rated as '-'. Usually, studies rated as '-' should not be used as a basis for making a recommendation, but they can be used to inform recommendations. For issues of prognosis, the highest possible level of evidence is a cohort study (EL = 2). A level of evidence was assigned to each study appraised during the development of the guideline.

For each clinical question, the highest available level of evidence was selected. Where appropriate, for example if a systematic review, meta-analysis or RCT existed in relation to a question, studies of a weaker design were not considered. Where systematic reviews, meta-analyses and RCTs did not exist, other appropriate experimental or observational studies were sought.

Clinical evidence for individual studies was extracted into evidence tables (provided on the accompanying CD-ROM) and a brief description of each study was included in the guideline text. The body of evidence identified for each clinical question was synthesised qualitatively in clinical evidence statements that accurately reflected the evidence. Quantitative synthesis (meta-analysis) was performed for this guideline where sufficient numbers of similar studies were identified to merit such analysis.

**Table 1.1** Levels of evidence for intervention studies

Level	Source of evidence
1++	High-quality meta-analyses, systematic reviews of randomised controlled trials (RCTs), or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews of RCTs, or RCTs with a low risk of bias
1-	Meta-analyses, systematic reviews of RCTs, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case-control or cohort studies; high-quality case-control or cohort studies with a very low risk of confounding, bias or chance and a high probability that the relationship is causal
2+	Well-conducted case-control or cohort studies with a low risk of confounding, bias or chance and a moderate probability that the relationship is causal
2-	Case-control or cohort studies with a high risk of confounding, bias or chance and a significant risk that the relationship is not causal
3	Non-analytical studies (for example, case reports, case series)
4	Expert opinion, formal consensus

### 1.7.3 Health economics

The aims of the economic input to the guideline were to inform the GDG of potential economic issues relating to the prevention and treatment of SSI and its complications, and to ensure that recommendations represented cost-effective use of healthcare resources.

The GDG prioritised a number of clinical questions where it was thought that economic considerations would be particularly important in formulating recommendations. A systematic search for published economic evidence was undertaken for these questions. For economic evaluations, no standard system of grading the quality of evidence exists and included papers were assessed using a quality assessment checklist based on good practice in decision-analytic modelling.<sup>8</sup> Reviews of the very limited relevant published economic literature are presented alongside the clinical reviews or as part of appendices detailing original economic analyses (see below).

Health economic considerations were aided by original economic analysis undertaken as part of the development of the guideline where robust clinical effectiveness data were available and UK cost data could be obtained. For this guideline, the areas prioritised for economic analysis were:

- hair removal (Section 5.2)
- nasal decontamination (Section 5.6)
- wound dressings (Section 6.12).

The results of each economic analysis are summarised briefly in the guideline text with full cost-effectiveness models presented in Appendices D–G.

### 1.7.4 Forming and grading recommendations

For each clinical question, recommendations for clinical care were derived using, and linked explicitly to, the evidence that supported them. In the first instance, informal consensus methods were used by the GDG to agree clinical and cost-effectiveness evidence statements. Statements summarising the GDG's interpretation of the evidence and any extrapolation from the evidence used to form recommendations were also prepared. In areas where no substantial clinical research evidence was identified, the GDG considered other evidence-based guidelines and consensus statements or used their collective experience to identify good practice. The health economics justification in areas of the guideline where the use of NHS resources (interventions) was considered was based on GDG consensus in relation to the likely cost-effectiveness implications of the recommendations. The GDG also identified areas where evidence to answer their clinical questions was lacking and used this information to formulate recommendations for future research.

Towards the end of the guideline development process, formal consensus methods were used to consider all the clinical care recommendations and research recommendations that had been drafted previously. The GDG identified ten key priorities for implementation (key recommendations), which were those recommendations expected to have the biggest impact on care and outcomes for adults and children undergoing surgical incisions through the skin.

The GDG also identified five key priorities for research, which were the most important research recommendations.

### 1.7.5 External review

This guideline has been developed in accordance with the NICE guideline development process. This has included giving registered stakeholder organisations the opportunity to comment on the scope of the guideline at the initial stage of development and on the evidence and recommendations at the concluding stage.

## **1.8 Schedule for updating the guideline**

Clinical guidelines commissioned by NICE are published with a review date 4 years from date of publication. Reviewing may begin earlier than 4 years if significant evidence that affects guideline recommendations is identified sooner. The updated guideline will be available within 2 years of the start of the review process.

# 2 Summary of recommendations

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## 2.1 Key priorities for implementation (key recommendations)

### Chapter 4 Information for patients and carers

Offer patients and carers clear, consistent information and advice throughout all stages of their care. This should include the risks of surgical site infections, what is being done to reduce them and how they are managed.

### Chapter 5 Preoperative phase

#### *Hair removal*

Do not use hair removal routinely to reduce the risk of surgical site infection.

If hair has to be removed, use electric clippers with a single-use head on the day of surgery. Do not use razors for hair removal, because they increase the risk of surgical site infection.

#### *Antibiotic prophylaxis*

Give antibiotic prophylaxis to patients before:

- clean surgery involving the placement of a prosthesis or implant
- clean-contaminated surgery
- contaminated surgery.

Do not use antibiotic prophylaxis routinely for clean non-prosthetic uncomplicated surgery.

Use the local antibiotic formulary and always consider potential adverse effects when choosing specific antibiotics for prophylaxis.

Consider giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia. However, give prophylaxis earlier for operations in which a tourniquet is used.

### Chapter 6 Intraoperative phase

#### *Antiseptic skin preparation*

Prepare the skin at the surgical site immediately before incision using an antiseptic (aqueous or alcohol-based) preparation: povidone-iodine or chlorhexidine are most suitable.

#### *Wound dressings*

Cover surgical incisions with an appropriate interactive dressing at the end of the operation.

### Chapter 7 Postoperative phase

#### *Dressings for wound healing by secondary intention*

Refer to a tissue viability nurse (or another healthcare professional with tissue viability expertise) for advice on appropriate dressings for the management of surgical wounds that are healing by secondary intention.



## 2.2 Summary of recommendations

### Chapter 4 Information for patients and carers

Offer patients and carers clear, consistent information and advice throughout all stages of their care. This should include the risks of surgical site infections, what is being done to reduce them and how they are managed.

Offer patients and carers information and advice on how to care for their wound after discharge.

Offer patients and carers information and advice about how to recognise a surgical site infection and who to contact if they are concerned. Use an integrated care pathway for healthcare-associated infections to help communicate this information to both patients and all those involved in their care after discharge.

Always inform patients after their operation if they have been given antibiotics.

### Chapter 5 Preoperative phase

#### *Preoperative showering*

Advise patients to shower or have a bath (or help patients to shower, bath or bed bath) using soap, either the day before, or on the day of, surgery.

#### *Hair removal*

Do not use hair removal routinely to reduce the risk of surgical site infection.

If hair has to be removed, use electric clippers with a single-use head on the day of surgery. Do not use razors for hair removal, because they increase the risk of surgical site infection.

#### *Patient theatre wear*

Give patients specific theatre wear that is appropriate for the procedure and clinical setting and that provides easy access to the operative site and areas for placing devices, such as intravenous cannulas. Consider also the patient's comfort and dignity.

#### *Staff theatre wear*

All staff should wear specific non-sterile theatre wear in all areas where operations are undertaken.

#### *Staff leaving the operating area*

Staff wearing non-sterile theatre wear should keep their movements in and out of the operating area to a minimum.

#### *Nasal decontamination*

Do not use nasal decontamination with topical antimicrobial agents aimed at eliminating *Staphylococcus aureus* routinely to reduce the risk of surgical site infection.

#### *Mechanical bowel preparation*

Do not use mechanical bowel preparation routinely to reduce the risk of surgical site infection.

#### *Hand jewellery, artificial nails and nail polish*

The operating team should remove hand jewellery before operations.

The operating team should remove artificial nails and nail polish before operations.

#### *Antibiotic prophylaxis*

Give antibiotic prophylaxis to patients before:

- clean surgery involving the placement of a prosthesis or implant
- clean-contaminated surgery
- contaminated surgery.

Do not use antibiotic prophylaxis routinely for clean non-prosthetic uncomplicated surgery.

Use the local antibiotic formulary and always consider potential adverse effects when choosing specific antibiotics for prophylaxis.

Consider giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia. However, give prophylaxis earlier for operations in which a tourniquet is used.

Before giving antibiotic prophylaxis, consider the timing and pharmacokinetics (for example, the serum half-life) and necessary infusion time of the antibiotic. Give a repeat dose of antibiotic prophylaxis when the operation is longer than the half-life of the antibiotic given.

Give antibiotic treatment (in addition to prophylaxis) to patients having surgery on a dirty or infected wound.

Inform patients before the operation, whenever possible, if they will need antibiotic prophylaxis, and afterwards if they have been given antibiotics during their operation.

### **Chapter 6 Intraoperative phase**

#### *Hand decontamination*

The operating team should wash their hands prior to the first operation on the list using an aqueous antiseptic surgical solution, with a single-use brush or pick for the nails, and ensure that hands and nails are visibly clean.

Before subsequent operations, hands should be washed using either an alcoholic hand rub or an antiseptic surgical solution. If hands are soiled then they should be washed again with an antiseptic surgical solution.

#### *Incise drapes*

Do not use non-iodophor-impregnated incise drapes routinely for surgery as they may increase the risk of surgical site infection.

If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy.

#### *Use of sterile gowns*

The operating team should wear sterile gowns in the operating theatre during the operation.

#### *Gloves*

Consider wearing two pairs of sterile gloves when there is a high risk of glove perforation and the consequences of contamination may be serious.

#### *Antiseptic skin preparation*

Prepare the skin at the surgical site immediately before incision using an antiseptic (aqueous or alcohol-based) preparation: povidone-iodine or chlorhexidine are most suitable.

If diathermy is to be used, ensure that antiseptic skin preparations are dried by evaporation and pooling of alcohol-based preparations is avoided.

#### *Diathermy*

Do not use diathermy for surgical incision to reduce the risk of surgical site infection.

#### *Maintaining patient homeostasis*

Maintain patient temperature in line with 'Inadvertent perioperative hypothermia' (NICE clinical guideline 65).

Maintain optimal oxygenation during surgery. In particular, give patients sufficient oxygen during major surgery and in the recovery period to ensure that a haemoglobin saturation of more than 95% is maintained.

Maintain adequate perfusion during surgery.

Do not give insulin routinely to patients who do not have diabetes to optimise blood glucose postoperatively as a means of reducing the risk of surgical site infection.

*Wound irrigation and intracavity lavage*

Do not use wound irrigation to reduce the risk of surgical site infection.

Do not use intracavity lavage to reduce the risk of surgical site infection.

*Antiseptic and antimicrobial agents before wound closure*

Do not use intraoperative skin re-disinfection or topical cefotaxime in abdominal surgery to reduce the risk of surgical site infection.

*Wound dressings*

Cover surgical incisions with an appropriate interactive dressing at the end of the operation.

## **Chapter 7 Postoperative phase**

*Changing dressings*

Use an aseptic non-touch technique for changing or removing surgical wound dressings.

*Postoperative cleansing*

Use sterile saline for wound cleansing up to 48 hours after surgery.

Advise patients that they may shower safely 48 hours after surgery.

Use tap water for wound cleansing after 48 hours if the surgical wound has separated or has been surgically opened to drain pus.

*Topical antimicrobial agents for wound healing by primary intention*

Do not use topical antimicrobial agents for surgical wounds that are healing by primary intention to reduce the risk of surgical site infection.

*Dressings for wound healing by secondary intention*

Do not use Eusol and gauze, or moist cotton gauze or mercuric antiseptic solutions to manage surgical wounds that are healing by secondary intention.

Use an appropriate interactive dressing to manage surgical wounds that are healing by secondary intention.

Refer to a tissue viability nurse (or another healthcare professional with tissue viability expertise) for advice on appropriate dressings for the management of surgical wounds that are healing by secondary intention.

*Antibiotic treatment of surgical site infection and treatment failure*

When surgical site infection is suspected (i.e. cellulitis), either *de novo* or because of treatment failure, give the patient an antibiotic that covers the likely causative organisms. Consider local resistance patterns and the results of microbiological tests in choosing an antibiotic.

*Debridement*

Do not use Eusol and gauze, or dextranomer or enzymatic treatments for debridement in the management of surgical site infection.

*Specialist wound care services*

Although there is no direct evidence to support the provision of specialist wound care services for managing difficult to heal surgical wounds, a structured approach to care (including preoperative assessments to identify individuals with potential wound healing problems) is required in order to improve overall management of surgical wounds. To support this, enhanced education of healthcare workers, patients and carers, and sharing of clinical expertise will be required.

## 2.3 Key priorities for research

### Nasal decontamination

Is it cost-effective to use mupirocin for nasal decontamination? In which patients is it most effective?

#### *Why this is important*

This is important as it is not clear how many surgical site infections would be prevented by treating all patients with nasal mupirocin, or whether only patients who are nasally colonised with meticillin-resistant *Staphylococcus aureus* should be treated. The use of mupirocin and its application is cost- and time-sensitive, apart from the concern that excessive use of mupirocin may lead to resistance. There should be further research involving large numbers of study participants undergoing different operations.

### Maintaining patient homeostasis – oxygenation

What is the value of supplemented oxygenation in the recovery room in the prevention of surgical site infection? What are the likely mechanisms of action?

#### *Why this is important*

There have been several randomised control trials (RCTs) that show a contradictory effect of supplemental oxygenation in the recovery room period, some showing benefit, some not. Two separate trials indicate that surgical site infection rates can be halved simply by increasing the amount of inspired oxygen. However, a fraction of inspired oxygen (FiO<sub>2</sub>) of 0.8 cannot be achieved using a face mask, and all patients already receive an increased FiO<sub>2</sub> to give a haemoglobin saturation of at least 95% by their anaesthetist during the operation and in the immediate postoperative period. The mechanism for improved blood oxygen carriage due to increased FiO<sub>2</sub> is physiologically not clear. However, this simple, cheap intervention deserves further investigation.

### Maintaining patient homeostasis – perioperative blood glucose control

What are the possible benefits of improved postoperative blood glucose control on the incidence of surgical site infection?

#### *Why this is important*

There have been several large cohort studies in cardiac surgery which indicate that tight postoperative blood glucose control can reduce the risk of surgical site infections, and the serious complication of sternal incision infection in particular. A blood glucose level above the normal range is typical after major trauma and has been considered part of the 'normal' metabolic response. Further studies should be adequately powered RCTs covering a wide range of surgical procedures to show unequivocally that tight blood glucose control is acceptable (even if it lowers the risk of surgical site infections in general) as the lowering of glucose in the immediate postoperative period may have unwanted complications and will require added careful surveillance. Again, the physiological mechanisms that reduce the risk of surgical site infection are not entirely clear.

### Closure methods

What types of closure method will reduce the risk of surgical site infection?

#### *Why this is important*

Although there are many studies in the field of wound closure, there are still several areas in which questions remain unanswered. Natural suture materials such as catgut and silk have been replaced by tailor-made absorbable and non-absorbable polymers. However, more research is needed to convince surgeons to stop using mass closure of the abdominal wall or subcuticular sutures for skin closure, as these methods have become standard practice. The use of monofilaments or braids also depends on personal preference and further trials are unlikely to show differences in

surgical site infection. There are data to show some techniques can allow more rapid closure, such as the use of staples or adhesive acrylate glues. Again, these have other disadvantages that could only be proven in what would be large, single-intervention RCTs. Further research is required on use of different suture materials and skin adhesives and their effect on the rate of surgical site infection. Research should be multi-centred, adequately powered, single-intervention RCTs. Studies should also include the cost-effectiveness of different closure methods.

### **Wound dressings**

What is the benefit and cost-effectiveness of different types of post-surgical interactive dressing for reducing the risk of surgical site infection?

#### *Why this is important*

There are a huge number of dressings available for chronic wound care that could also be used for incisional sites. The use of island dressings compared with simple adhesive polyurethane transparent dressings is an example of a study that could be undertaken with outcomes of reductions in surgical site infections and also reductions in skin complications and improvements in final cosmetic outcomes. However, current studies are not adequate to show convincing differences. Research is also required on the effects of antiseptic-bearing dressings, placed at the end of an operation or at dressing changes. These antiseptics could include povidone-iodine, biguanides (such as chlorhexidine) or silver.

### **Dressings for wound healing by secondary intention**

What are the most appropriate methods of chronic wound care (including alginates, foams and hydrocolloids and dressings containing antiseptics such as antimicrobial honey, cadexomer iodine or silver) in terms of management of surgical site infection as well as patient outcomes?

#### *Why this is important*

There are many small cohort studies which have examined the use of the wide range of dressings in surgical site infection management after an infected wound has been opened or after there has been separation of the wound edges after a surgical site infection. Differences are hard to see because the trials often include other wounds that are healing by secondary intention, such as chronic venous or diabetic ulcers and pressure sores. Specific studies using antiseptics (povidone-iodine, biguanides such as chlorhexidine, or silver) and other agents such as antimicrobial honey need to address this in powered randomised trials, specifically in the management of surgical site infection of an open wound. Similar questions need to be asked for the use of topical negative pressure, which has become widely used with or without antiseptic irrigation.

## **2.4 Summary of research recommendations**

### **Chapter 3 Definitions, surveillance and risk factors**

#### *Risk factors*

Would a risk assessment tool developed by consensus methodology help predict the risk of surgical site infection?

### **Chapter 5 Preoperative phase**

#### *Nasal decontamination*

Is it cost-effective to use mupirocin for nasal decontamination? In which patients is it most effective?

### **Chapter 6 Intraoperative phase**

#### *Disposable or reusable drapes and gowns*

What is the cost-effectiveness of new materials used in reusable and disposable operative drapes and gowns in reducing the incidence of surgical site infection?

### *Maintaining patient homeostasis – oxygenation*

What is the value of supplemented oxygenation in the recovery room in the prevention of surgical site infection? What are the likely mechanisms of action?

### *Maintaining patient homeostasis – perioperative blood glucose control*

What are the possible benefits of improved postoperative blood glucose control on the incidence of surgical site infection?

### *Wound irrigation*

Does irrigation with modern antiseptics and saline under pressure with or without added antiseptics in a broader range of surgery allow the development of a strategy less dependent on antibiotic prophylaxis to reduce the incidence of surgical site infection?

### *Antiseptic and antimicrobial agents before wound closure*

Does the use of antiseptic products applied to the wound prior to closure in elective clean non-prosthetic surgery reduce the reliance on antibiotic prophylaxis to reduce the incidence of surgical site infection?

What is the cost-effectiveness of collagen implants with antibiotics or antiseptics in the reduction in the incidence of surgical site infection?

### *Closure methods*

What types of closure method will reduce the risk of surgical site infection?

### *Wound dressings*

What is the benefit and cost-effectiveness of different types of post-surgical interactive dressing for reducing the risk of surgical site infection?

## **Chapter 7 Postoperative phase**

### *Dressings for wound healing by secondary intention*

What are the most appropriate methods of chronic wound care (including alginates, foams and hydrocolloids and dressings containing antiseptics such as antimicrobial honey, cadexomer iodine or silver) in terms of management of surgical site infection as well as patient outcomes?

### *Debridement*

What is the effectiveness of modern methods of debridement in surgical wounds healing by secondary intention?

# 3 Definitions, surveillance and risk factors

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## 3.1 Defining surgical site infection

Since skin is normally colonised by a range of microorganisms that could cause infection, defining an SSI requires evidence of clinical signs and symptoms of infection rather than microbiological evidence alone. SSIs frequently only affect the superficial tissues, but some more serious infections affect the deeper tissues or other parts of the body manipulated during the procedure. The majority of SSIs become apparent within 30 days of an operative procedure and most often between the 5th and 10th postoperative days. However, where a prosthetic implant is used, SSIs affecting the deeper tissues may occur several months after the operation.

Although the outcome measure for SSI used by many studies is based on standard definitions such as those described by the Centers for Disease Control and Prevention (CDC)<sup>9</sup> or the Surgical Site Infection Surveillance Service,<sup>10</sup> other valid measures based on clinical signs and symptoms have been described such as the Southampton<sup>11</sup> and ASEPSIS<sup>12</sup> methods.

The CDC definition<sup>7</sup> describes three levels of SSI:

- *superficial incisional*, affecting the skin and subcutaneous tissue. These infections may be indicated by localised (Celsian) signs such as redness, pain, heat or swelling at the site of the incision or by the drainage of pus.
- *deep incisional*, affecting the fascial and muscle layers. These infections may be indicated by the presence of pus or an abscess, fever with tenderness of the wound, or a separation of the edges of the incision exposing the deeper tissues.
- *organ or space infection*, which involves any part of the anatomy other than the incision that is opened or manipulated during the surgical procedure, for example joint or peritoneum. These infections may be indicated by the drainage of pus or the formation of an abscess detected by histopathological or radiological examination or during re-operation. Organ infection is not included within the scope of this guideline.

In addition, there may also be microbiological evidence of wound infection from cultures obtained aseptically from wound fluid or tissue. However, since skin sites are normally colonised by a variety of organisms, positive wound cultures in the absence of clinical signs are rarely indicative of SSI.

Some studies report infections that affect any part of the incision, whereas other studies focus only on those that affect the deeper tissues as these may be considered to be more important and their definition less subjective. Variation introduced by the definition of SSIs and the methods used to detect them need to be taken account when combining or comparing evidence from different studies. This variation has been an important limiting factor in reviewing evidence for this guideline.

## 3.2 Surveillance for surgical site infection

Surveillance of SSI provides data that can both inform and influence practice to minimise the risk of SSI, as well as communicate more clearly the risks of infection to patients.<sup>13</sup> Surveillance was first recognised as an important tool in reducing rates of infection in the 1980s.<sup>14</sup> The Study on the Efficacy of Nosocomial Infection Control (SENIC) showed that surveillance and infection control programmes that included the collection, analysis and feedback of data on infection rates to surgeons were associated with significant reductions in rates of SSI.<sup>15</sup> Since then, many

national surveillance systems have been established and have reported reductions in rates of SSI in association with surveillance, feedback of data to clinicians and benchmarking of rates of SSI.<sup>7,10–13</sup> Consumer demand for information about the performance of healthcare providers has also led to compulsory public reporting of data on HCAs, including SSIs. In England, reporting of rates of SSI following orthopaedic surgery became compulsory in April 2004 and the other UK countries also have mandatory programmes of SSI surveillance after several types of operative procedure.

National surveillance systems, such as the Surgical Site Infection Surveillance System in England and similar schemes in Wales and Northern Ireland, provide standardised surveillance methods that enable hospitals to benchmark their rates of SSI. Such benchmarking can be a powerful driver for change but requires participating hospitals to use uniform methods of finding and defining cases of SSI that are likely to reliably identify a large proportion of the infections, and a reliable approach to analysing rates of SSI that takes account of variation in risk associated with different procedures and risk factors in the patients undergoing surgery. Most national surveillance systems target surveillance towards defined groups of patients undergoing similar operative procedures, following each case up to identify those that develop an SSI, although the sensitivity of case-finding will be influenced by the methods employed.<sup>16</sup> This enables rates of SSI to be calculated using the number of procedures as the denominator. Feedback of rates to individual surgical teams and comparisons with the benchmark rate are essential components of effective surveillance.<sup>15</sup> The risk index developed by the CDC in the USA, which takes account of the underlying illness of the patient, the duration of the operation and the wound classification of the procedure, is commonly used to adjust rates of SSI and improve the validity of comparisons where case-mix may vary over time or between centres.<sup>17</sup> However, comparisons between different surveillance systems is complicated because of variation in both the methods of surveillance and the application and interpretation of case definitions.<sup>18</sup>

Since some SSIs may take many days to develop, evidence of infection may not become apparent until after the patient has been discharged from hospital. Surveillance focused on detecting SSI during the inpatient stay is thus likely to underestimate the true rate of SSI, a problem that is exacerbated by the increasing trend towards shorter lengths of postoperative hospital stay and day surgery.<sup>19</sup> Therefore, systems that enable cases of SSI to be identified after discharge from hospital enhance the value of surveillance. However, there are a number of practical difficulties in reliably identifying SSI in community settings and methods that systematically and accurately identify SSI are required if valid comparisons of rates are to be made.<sup>20</sup>

### 3.3 Risk factors

The risk of SSI is increased by factors that:

- increase the risk of endogenous contamination (for example, procedures that involve parts of the body with a high concentration of normal flora such as the bowel)
- increase the risk of exogenous contamination (for example, prolonged operations that increase the length of time that tissues are exposed)
- diminish the efficacy of the general immune response (for example, diabetes, malnutrition, or immunosuppressive therapy with radiotherapy, chemotherapy or steroids) or local immune response (for example, foreign bodies, damaged tissue or formation of a haematoma).

Randomised controlled trials, which require the assessment of comparability between groups, have not been undertaken for risk factors. While data on risk factors for SSI are available from observational studies using regression analyses, factors that are significant in one type of surgery may not be generalisable to other surgical procedures.

#### 3.3.1 Age

Five studies were identified.<sup>10,21–24</sup>

One prospective observational study using logistic regression to analyse data collected from 142 medical centres identified age as an independent risk factor for SSI.<sup>21</sup> [EL = 2+] Trained nurses gathered data on inherent and operative risk factors for SSI in patients undergoing general and vascular surgery. Of 163 624 patients who were included in the study, 7035 developed SSI



within 30 days of surgery. Patients aged over 40 had a statistically significantly increased risk of developing SSI compared with those under 40 years (OR 1.24, 95% CI 1.07 to 1.44).

Another prospective observational study examined SSI in patients undergoing total hip replacement, hemiarthroplasty or revision procedures as part of SSI surveillance in England.<sup>10</sup> [EL = 2+] Trained personnel collected clinical and operative data throughout the duration of the hospital stay. Detected cases of SSI were thus classified as occurring in the immediate postoperative period. Age over 75 was found to be a significant risk factor (compared with a baseline of age under 65) when all types of hip replacement were considered together (for age 75–79 years OR 1.56, 95% CI 1.16 to 2.10, for age  $\geq$  80 years OR 1.66, 95% CI 1.24 to 2.21).

A retrospective observational study conducted in the USA included patients who underwent general surgery with antibiotic prophylaxis at a community hospital.<sup>22</sup> [EL = 2–] Demographic and clinical information was extracted from the database including readmission up to 28 days post-surgery. Regression techniques were used to identify independent risk factors for SSI detected early (between 2 and 7 days postoperatively), necessitating readmission or causing death. Age was found to be a statistically significant risk factor for early SSI incidence (SSI incidence for each decade increase in age OR 1.22,  $P < 0.01$ ).

One large prospective study ( $n = 23\,649$  wounds) including children and adults undergoing procedures on mostly clean wounds stratified results by age group.<sup>23</sup> [EL = 2–] Observations of SSI were made for 28 days postoperatively and a broad trend of increasing SSI incidence with increasing age was reported.

A prospective cohort study of adult surgical patients ( $n = 144\,485$ ) from 11 hospitals reported an SSI incidence rate of 1.2%.<sup>24</sup> [EL = 2+] A direct linear trend of increasing risk of deep or organ space SSI from age 17 until age 65 (1.1% for each year of age,  $P < 0.002$ ) was reported. However, for patients aged over 65 the risk of SSI decreased by 1.2% for each extra year of life ( $P = 0.008$ ).

### 3.3.2 Underlying illness

The American Society of Anesthesiologists' (ASA) classification of physical status score is used to assess a patient's preoperative physical condition and provides a simple measure of the severity of the underlying illness. Four studies were identified that found ASA score to be an indicator of SSI development.<sup>10,17,21,24</sup>

A prospective cohort study of adult surgical patients ( $n = 144\,485$ ) from 11 hospitals reported an SSI incidence rate of 1.2%.<sup>24</sup> [EL = 2+] A statistically significantly higher SSI incidence for those with an ASA score of 3 or greater compared with those with an ASA score of 1 or 2 (OR 3.0, 95% CI 2.6 to 3.2) was reported.

This effect was also demonstrated in a prospective observational study examining SSI in patients undergoing total hip replacement, hemiarthroplasty or revision procedures.<sup>10</sup> [EL = 2+] Cases of SSI occurring in the immediate postoperative period were included. Overall, the SSI incidence rate was 3.07% ( $n = 24\,808$  procedures, cases of SSI = 761). Multivariate analysis showed ASA score of 3 or greater to be an independent risk factor for SSI (OR 1.55, 95% CI 1.29 to 1.88).

A prospective observational study using logistic regression to analyse data collected from patients undergoing general or vascular surgery in 142 medical centres also identified ASA score as an independent risk factor for SSI.<sup>21</sup> [EL = 2+] The SSI incidence rate was 4.3%. Compared with an ASA score of 1, a score of 3 and a score of 4 or 5 were found to be statistically significantly associated with SSI (OR 1.97, 95% CI 1.53 to 2.54 and OR 1.77, 95% CI 1.34 to 2.32, respectively).

In one retrospective observational study, analysis of data from the National Nosocomial Infections Surveillance System ( $n = 84\,691$  operations) found an overall SSI incidence of 2.8%.<sup>17</sup> [EL = 2–] The majority of patients (94%) were undergoing clean or clean-contaminated surgery. The strength of association between ASA score and SSI development risk was estimated (Goodman–Kruskal  $G$  statistic = 0.34, standard error (SE) = 0.01) and stratification of results by ASA score demonstrated that the rate of SSI increased by a factor of 4.7 as ASA score ranged between 1 (1.5 SSIs per 100 operations) to 5 (7.1 SSIs per 100 operations).

In addition, there are some specific underlying diseases or conditions that are independently associated with an increased risk of SSI.

A number of studies in cardiac, spinal, vascular and general surgery and have shown that diabetes is strongly associated with an increased risk of SSI.<sup>21,23,25–29</sup> Studies report a two- to three-fold increase in risk of developing an SSI in patients with diabetes. This may be related to altered cellular immune function.

A prospective cohort study (with a parallel case–control analysis) of 1044 cardiothoracic surgery patients demonstrated evidence that the rate of SSI is independently associated with postoperative hyperglycaemia (OR 2.02, 95% CI 1.21 to 3.37) and that the risk of SSI correlated with the degree of hyperglycaemia during the postoperative period (for patients with postoperative glucose levels of 200–249 mg/dl, 250–299 mg/dl and  $\geq 300$  mg/dl, SSI ORs were 2.54, 2.97 and 3.32, respectively).<sup>27</sup> [EL = 2+]

One large prospective study of procedures on mostly clean wounds in children and adults reported that malnourishment increased the incidence of SSI from 1.8% to 16.6% (univariate analysis).<sup>23</sup> [EL = 2–]

Two studies were identified that found low serum albumin to be an indicator of SSI development.<sup>21,22</sup>

In a large prospective cohort study of general and vascular surgery patients ( $n = 163\ 624$  patients), multivariate analysis demonstrated that those with a low preoperative serum albumin ( $\leq 3.5$  g/dl) were more likely to develop SSI (OR 1.13, 95% CI 1.04 to 1.22), compared with those with normal serum albumin levels.<sup>21</sup> [EL = 2+]

The results of a retrospective observational study of patients undergoing general surgery with antibiotic prophylaxis ( $n = 9016$ ) further suggested that low serum albumin was associated with the development of SSI within the first 2–7 days postoperatively (OR 2.27,  $P < 0.01$ , per gram percent decrease).<sup>22</sup> [EL = 2–]

One study was identified that found treatments associated with anti-cancer therapy to be indicators of SSI development.<sup>21</sup> The prospective cohort of general and vascular surgery patients also found that radiotherapy within 90 days prior to surgery (OR 1.37, 95% CI 1.08 to 1.74) and use of steroids (OR 1.39, 95% CI 1.18 to 1.63) independently predicted development of SSI.<sup>21</sup> [EL = 2+]

### 3.3.3 Obesity

Adipose tissue is poorly vascularised and the consequent effect on oxygenation of the tissues and functioning of the immune response is thought to increase the risk of SSI. In addition, operations on patients who are obese can be more complex and prolonged.<sup>30</sup> The effect of obesity on the risk of SSI has been investigated in cardiac and spinal surgery and in caesarean section. Studies report ORs of between 2 and 7 for SSI in patients with a body mass index of 35 kg/m<sup>2</sup> or more.<sup>23,25–31</sup>

### 3.3.4 Smoking

The wound healing process may be affected by the vasoconstrictive effects and reduced oxygen-carrying capacity of blood associated with smoking cigarettes. Four studies were identified that investigated the association of smoking with SSI development.<sup>21,26,29,32</sup>

One prospective observational study, using logistic regression to analyse data collected from patients ( $n = 163\ 624$ ) undergoing general and vascular surgery in 142 medical centres, identified smoking as an independent risk factor for SSI.<sup>21</sup> [EL = 2+] Smokers had a statistically significantly greater risk of developing SSI compared with non-smokers (OR 1.23, 95% CI 1.04 to 1.22).

A case–control study of adults undergoing cardiac surgery ( $n = 117$ ) examined risk factors for SSI.<sup>29</sup> [EL = 2+] Statistically significantly more patients who developed an SSI smoked compared with uninfected controls (28.2% versus 14.1%) and, following logistic regression analysis, smoking remained an independent risk factor for SSI (OR 3.27, 95% CI 1.04 to 10.20)

A prospective observational study investigated SSI in patients undergoing breast reduction surgery.<sup>32</sup> [EL = 2+] Participants ( $n = 87$ ) were instructed to stop smoking at least 4 weeks prior to surgery. Twenty-four patients developed SSI, which occurred 8 days postoperatively on average. Statistically significantly more smokers developed SSI than non-smokers (37.2% versus 18.2%,  $P < 0.05$ ). Sixteen of 43 smokers developed SSI. Those who smoked more cigarettes were more

likely to develop SSI (estimated cigarettes smoked mean 146 000 range 29 200–228 125 versus mean 10 950 range 9125–54 750,  $P < 0.001$ ) and those who had smoked for a longer time also experienced statistically significantly more infections (mean pack years 20, range 4–31 versus mean pack years 2, range 1–8,  $P < 0.001$ )

A retrospective observational study of cardiac surgery ( $n = 3008$ ) investigating risk factors for SSI, using logistic regression techniques, found that smokers developed statistically significantly more sternal SSIs (OR 1.39, 95% CI 1.05 to 1.86) and deep sternal SSIs (OR 2.41, 95% CI 1.42 to 4.10) than non-smokers and that peripheral vascular disease was also an independent risk factor for the development of deep SSI (OR 2.11, 95% CI 1.09 to 4.09).<sup>26</sup> [EL = 2+]

A further prospective study of cardiac surgery patients reported 199 SSIs occurring within 2345 included participants.<sup>28</sup> [EL = 2+] Multivariate analysis also demonstrated that generalised peripheral vascular disease statistically significantly increased the risk of SSI (OR 1.64, 95% CI 1.16 to 2.33).

### 3.3.5 Wound classification

The significance of the microbial flora normally colonising the operative site in the subsequent risk of SSI has been recognised for many decades. The wound classification developed by the National Academy of Sciences in the 1960s distinguishes four levels of risk, from clean, where the procedure involves a sterile body site, to dirty, where the procedure involves a heavily contaminated site (see Glossary of terms).

Three studies were identified that examined the association of wound classification with SSI incidence.<sup>17,21,24</sup>

In a retrospective analysis of a large infection surveillance data set, the SSI incidence rate per 100 operations was 2.1, 3.3, 6.4, 7.1 for clean, clean-contaminated, contaminated and dirty wound classes, respectively.<sup>17</sup> [EL = 2–]

Another study of general and vascular procedures reported that wound class was an independent predictor of SSI (clean surgery SSI OR 1, SSI ORs for clean-contaminated, contaminated and dirty wound classes were 1.04, 1.7 and 1.5, respectively,  $P < 0.0001$ ),<sup>21</sup> [EL = 2+] while a third prospective study found that SSI was statistically significantly increased in contaminated and dirty wounds (wound class  $> 2$  OR 2.3, 95% CI 2.0 to 2.7).<sup>24</sup> [EL = 2+]

### 3.3.6 Site and complexity of procedure

For many types of surgery there is evidence that the risk of SSI is affected by the specific site of the operation, for example cervical laminectomy is associated with a lower risk of SSI than laminectomy performed at other levels (OR 6.7, 95% CI 1.4 to 33.3).<sup>25</sup> Complexity of the procedure is also indicated as an SSI risk factor. One study of general and vascular surgery estimated that there was a two- to three-fold increased risk of SSI with increasing surgical complexity measured as work relative value units.<sup>21</sup> However, complex surgery is more often distinguished by prolonged duration of the procedure. In studies of cardiac<sup>28</sup> and hip replacement surgery,<sup>10</sup> there was a 1.5- to 1.75-fold increased risk of SSI associated with longer duration of surgery.

While some of these patient characteristics, such as obesity, hyperglycaemia, malnutrition and smoking, may be modified prior to surgery, others, such as the complexity of the procedure and the underlying illness in the patient, cannot. Mechanisms of accounting for variation in intrinsic characteristics of patients or procedures that influence the risk of SSI are important for surveillance systems in order to enable valid comparisons of rates among surgeons, among hospitals, or across time. Early surveillance systems<sup>23</sup> used the basic wound classification to adjust for risk of SSI but analyses of large data sets on a range of operative procedures identified a few key risk factors that were associated with an increased risk of SSI and that when used in combination provided a better indicator of risk of SSI than the wound classification.<sup>21,25</sup> This National Nosocomial Infection Surveillance (NNIS) system risk index is based on the presence of the following risk factors:

1. a patient with an ASA preoperative assessment score of 3, 4 or 5 (a simple measure of the severity of the patient's underlying illness)
2. an operation classified as contaminated or dirty-infected

3. an operation lasting over  $T$  hours, where  $T$  depends on the operative procedure being performed.<sup>3,17</sup> The  $T$  time is the 75th percentile of the distribution of operation time for a particular category of procedures rounded to the nearest hour.<sup>17</sup>

While this NNIS risk index does not measure all the factors that contribute to the risk of developing an SSI, it does provide a practical way of adjusting rates for the major patient and operative risk factors and it is used to stratify rates of SSI by most national surveillance systems. Other more complex risk stratification systems to predict the risk of SSI have also been developed.<sup>21,26</sup>

### 3.3.7 Evidence statements on risk factors

#### *Age*

The age of the patient is a significant independent predictor of the risk of SSI development generally and for early SSI development. [EL = 2+]

Moreover, in adults a direct linear trend of increasing risk of SSI until age 65 has been demonstrated. [EL = 2-]

For those aged over 65, an inverse linear trend of SSI risk was found, although this finding may be subject to selection bias (i.e. only those who are fit enough undergo surgery). [EL = 2+]

#### *Underlying illness*

Those patients with an ASA score of 3 or more have a severe systemic disease and have been found to have a significantly higher risk of SSI. [EL = 2+]

Studies have repeatedly shown that diabetes is strongly associated with an increased risk of SSI. [EL = 2+]

Malnutrition has been implicated as a risk factor for SSI. [EL = 2-]

There is evidence from a prospective [EL = 1+] and a retrospective [EL = 2-] study that the risk of SSI is increased in patients with a low serum albumin.

Radiotherapy and steroid use have both been linked to an increased risk of SSI. [EL = 2+]

#### *Obesity*

Studies have repeatedly shown that obesity is strongly associated with an increased risk of SSI. [EL = 2+]

#### *Smoking*

Smoking, duration of smoking and number of cigarettes smoked are associated with an increased risk of SSI. [EL = 2+]

Peripheral vascular disease has been demonstrated to increase SSI risk in a prospective [EL = 1+] and a retrospective [EL = 2-] study.

#### *Wound classification*

There is consistent evidence that the risk of infection increases with level of wound contamination. [EL = 2+]

### **GDG interpretation**

The observational studies described have identified the factors that confer a significant increase in the risk of the patient developing an SSI. Apart from the ASA scoring system, there has been no systematic assessment of risk factors to provide an overall 'risk score' to assess the likelihood of SSI for an individual patient undergoing a specific operative procedure. There is insufficient information to make any specific recommendations.

#### **Research recommendation on risk factors**

Would a risk assessment tool developed by consensus methodology help predict the risk of surgical site infection?

# 4 Information for patients and carers

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## 4.1 Information for patients and carers

### *Clinical question*

When, how and what information should be provided for patients for the prevention of surgical site infection?

### **Overview of evidence**

Searches were run with no study-design filters.

The searches failed to identify any studies investigating the role of patient information in prevention of SSI. They did, however, identify one RCT<sup>33</sup> that examined the accuracy of SSI self-diagnosis among post-surgical patients who received information on signs and symptoms of SSI before discharge.

The RCT<sup>33</sup> ( $n = 588$  participants) examined the effects of providing patients with education on how to self-recognise an SSI event during the post-discharge recovery period. The study compared a group of 'educated' patients with a 'non-educated' group in assessing the performance of SSI self-diagnosis. [EL = 1+] Participants were surgical patients who had undergone a range of interventions. The main outcome of the study was the number of SSI events. There was no statistically significant difference ( $P = 0.399$ ) in the proportion of SSI diagnosed by the infection control professional between the 'educated' group (12.3%, 95% CI 8.8% to 16.7%) and the 'non-educated' group (10.1%, 95% CI 6.9 to 14.1). The 'educated' group correctly self-diagnosed 83.3% of those wounds that were infected. This result was the same for the 'non-educated' group, where 83.3% of infected wounds were also correctly identified. On the other hand, the 'educated' group correctly identified 93.7% of the non-infected wounds while for the 'non-educated' group the percentage of non-infected wounds correctly identified was 98.1%. So, even if both groups correctly identified the same proportion of true SSI, the educated group over-estimated the number of SSI events.

### **Evidence statement**

There is evidence from a single RCT to suggest that education provided before discharge does not improve patient self-diagnosis.

### **GDG interpretation**

There is insufficient evidence about the specific information that should be given and how this should be provided for patients and carers to reduce their risk of SSI. Even if there is evidence from an RCT suggesting that educating patients on the recognition of SSI might lead to more false-positive SSI diagnoses, the GDG consensus was that it is preferable to deal with an overestimation of cases than with missing ones. The GDG considered that, as a minimum, patients and carers should be provided with information and advice about the risk of SSI associated with their particular type of procedure.

### **Recommendations on information for patients and carers**

Offer patients and carers clear, consistent information and advice throughout all stages of their care. This should include the risks of surgical site infections, what is being done to reduce them and how they are managed.

Offer patients and carers information and advice on how to care for their wound after discharge.

Offer patients and carers information and advice about how to recognise a surgical site infection and who to contact if they are concerned. Use an integrated care pathway for healthcare-associated infections to help communicate this information to both patients and all those involved in their care after discharge.

Always inform patients after their operation if they have been given antibiotics.

# 5 Preoperative phase

## 5.1 Preoperative showering

*Clinical question*

What is the clinical effectiveness of preoperative showering to reduce surgical site infection?

### Introduction

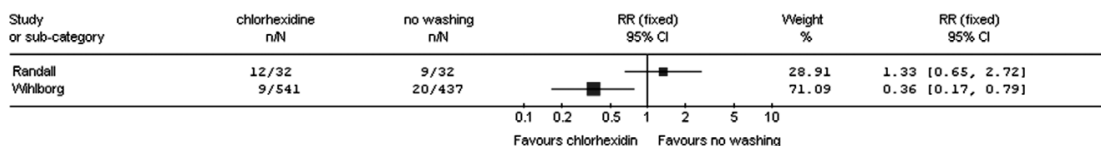
When the skin is incised, microorganisms colonising the surface may contaminate the exposed tissues and subsequently proliferate and lead to an SSI. Interventions that reduce the number of microorganisms on the skin surrounding the incision may therefore decrease the risk of SSI. The microbial flora on the skin comprises transient microorganisms that are acquired by touch and easily removed by washing with soap, and resident flora that normally live in the skin appendages such as hair follicles. The resident flora are generally not pathogenic but are not so readily removed by soap although their numbers can be reduced by antiseptics. The purpose of the review was to determine the clinical effectiveness of preoperative bathing or showering with antiseptics for the prevention of SSI.

### Overview of evidence

One systematic review was identified.

One well-conducted systematic review<sup>34</sup> (six RCTs,  $n = 10\,007$  participants) examined the evidence for preoperative bathing or showering with antiseptics for the prevention of SSI. [EL = 1+] Patients were undergoing orthopaedic, vascular, biliary tract, inguinal hernia, breast, vasectomy and other general surgical operations. The incidence of SSI was the primary outcome measure in all studies although definitions varied among studies. Four studies had two treatment arms and two had three treatment arms. The only antiseptic used in the included studies was chlorhexidine.

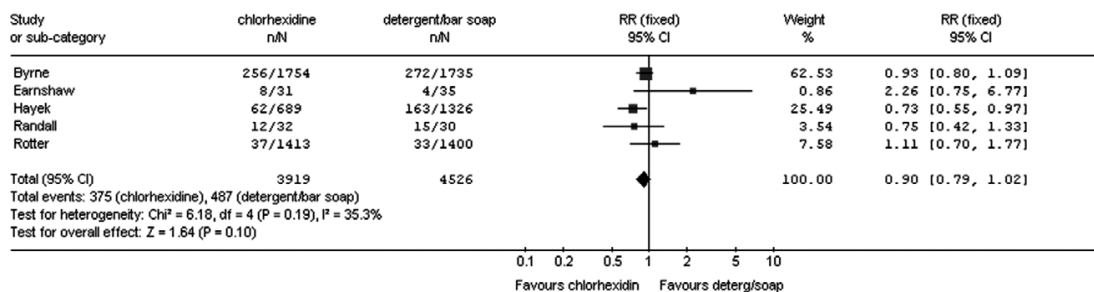
Two RCTs (Figure 5.1) compared the effect on SSI of showering with 4% chlorhexidine against no showering. The smaller trial ( $n = 64$  participants) found no difference in the SSI rate between the two groups (RR 1.33, 95% CI 0.65 to 2.72), while the larger trial ( $n = 978$ ) found statistically significantly fewer SSIs in the group that used chlorhexidine (9/541) than in the group that did not shower (20/437) (RR 0.36, 95% CI 0.17 to 0.79).



**Figure 5.1** Comparison of showering with 4% chlorhexidine versus no showering on SSI incidence in two trials

Five studies in the systematic review examined the effect of preoperative showering or bathing with 4% chlorhexidine solution compared with a detergent or bar soap. Three RCTs ( $n = 7691$  participants) used a detergent and three RCTs ( $n = 1443$ ) used bar soap as a comparator. It should be noted that one of these studies<sup>35</sup> used a detergent that was subsequently discovered to have antimicrobial properties.

A meta-analysis (Figure 5.2) of these five RCTs ( $n = 8445$  participants) demonstrated that the incidence of SSIs was not statistically significantly different between groups showering with chlorhexidine (375/3919) and with detergent or bar soap (487/4526) (RR 0.90, 95% CI 0.79 to 1.02,  $I^2 = 35.3\%$ ).



**Figure 5.2** Meta-analysis of five trials comparing the effect of showering with chlorhexidine versus showering with detergent or bar soap on SSI incidence

One included RCT ( $n = 1093$ ) found that total body washing with chlorhexidine produced a statistically significant reduction in SSI incidence compared with partial body washing where only the skin area at the site of incision was washed (RR 0.40, 95% CI 0.19 to 0.85).

#### *Clinical question*

What is the contribution to clinical effectiveness of the timing and number of preoperative washing for the prevention of surgical site infection?

#### Overview of evidence

One systematic review<sup>34</sup> that examined the evidence for preoperative bathing or showering with antiseptics for the prevention of SSI made reference to an analysis comparing 'one wash against more than one wash' that had been published in a previous Cochrane Library issue, but which had been subsequently withdrawn. [EL = 1+]

This analysis was removed because no trial specifically randomised patients by number of washes and the methodology was deemed insufficiently rigorous for publication.

Similarly, no trials were identified that specifically randomised patients by timing of washes.

#### *Clinical question*

Are preoperative showers with antiseptics cost-effective?

#### Health economics overview of evidence

One RCT was identified.

One RCT<sup>36</sup> compared a chlorhexidine detergent shower three times before elective surgery with three showers using detergent. This study did not find that chlorhexidine was associated with a statistically significant reduction in wound infection. The average cost of both non-infected and infected patients was found to be higher in the chlorhexidine than in the detergent group. The average cost of a non-infected chlorhexidine-treated patient was £847.95 compared with £804.60 for a non-infected patient treated with detergent alone, whereas the average cost of an infected patient was £1,459.70 (chlorhexidine) and £1,414.22 (detergent). The authors concluded that preoperative whole-body disinfection with a chlorhexidine detergent was not a cost-effective treatment for reducing wound infection, being more costly and showing no statistically significant clinical benefit.

#### Evidence statements

There is evidence from one RCT that showering or bathing using chlorhexidine significantly reduces the rate of SSI compared with no showering. [EL = 1+]



There is evidence of no difference in SSI incidence when chlorhexidine or detergent/bar soap is used for preoperative showering or bathing. [EL = 1+]

There is no (systematic review or RCT) evidence that examines the clinical effectiveness of the timing or number of preoperative showers to prevent SSI.

### Health economics evidence statement

There is evidence to indicate that preoperative showering with a chlorhexidine detergent is not a cost-effective intervention to prevent SSIs when compared with preoperative showering with a detergent or bar soap.

### GDG interpretation

One study demonstrated a significant reduction in SSI associated with a chlorhexidine preoperative shower compared with no showering or a partial body wash, and, in one study, whole-body showering with chlorhexidine was compared with a partial wash. In a separate meta-analysis, chlorhexidine was demonstrated to be no more effective than bar soap or detergent in the prevention of SSI and one RCT found it not to be a cost-effective intervention.

Therefore, while there is evidence to support the efficacy of preoperative showering as a measure to reduce the rate of SSI, there is evidence of no difference of effect on SSI rate between chlorhexidine as a cleansing agent and plain detergent or soap. In addition, chlorhexidine has been found not to be cost-effective.

None of the studies provided evidence to indicate whether the number and timing of preoperative showers affected the rate of SSI but the GDG view was that showering should take place as close to or on the day of surgery.

### Recommendation on preoperative showering

Advise patients to shower or have a bath (or help patients to shower, bath or bed bath) using soap, either the day before, or on the day of, surgery.

## 5.2 Hair removal

### *Clinical question*

What is the clinical effectiveness of preoperative hair removal from the operative site to reduce surgical site infection?

### Introduction

The removal of hair may be necessary to adequately view or access the operative site and it is sometimes undertaken because of a perceived increased risk of microbial contamination of the operative site from the presence of hair. However, micro-abrasions of the skin caused by shaving using razors may support the multiplication of bacteria, within the skin and on the skin surface, particularly if undertaken several hours prior to surgery. An increase in the number of microorganisms colonising the skin surrounding the operative site may facilitate contamination of the wound and subsequent development of SSI. Therefore, when hair removal is indicated, the method used should minimise damage to the skin. The purpose of the review was to determine the clinical effectiveness of preoperative removal of hair from the operative site to prevent SSI.

### Overview of evidence

One systematic review and one additional RCT were identified.

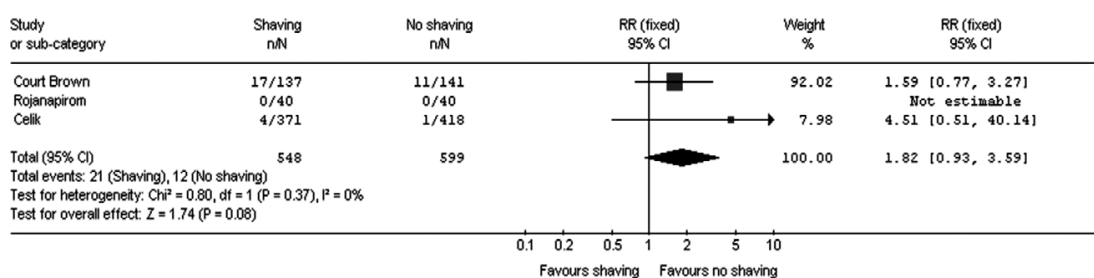
One well-conducted systematic review<sup>37</sup> (11 RCTs,  $n = 4627$  participants) was identified that examined the evidence for preoperative hair removal for the prevention of SSI. [EL = 1+] RCTs were included where adult patients undergoing any surgery in a designated operating theatre

were allocated to groups comparing any hair removal schedule. Methods of hair removal included were shaving using razors, clipping and depilatory cream.

Two RCTs reported in the systematic review compared the effect of shaving using razors with no hair removal (total  $n = 358$  adults). No SSIs were found in either group in the smaller study ( $n = 80$ ) whereas, in the larger study ( $n = 278$ ), 9.6% of people who were shaved developed an SSI compared with 6% people who were not shaved (RR 1.59, 95% CI 0.77 to 3.27).

A recent RCT<sup>38</sup> compared the effect of shaving using razors with no hair removal in spinal surgery patients in Turkey. [EL = 1+] There was no statistically significant difference between the two groups (RR 4.51, 95% CI 0.51 to 40.14).

Adding this latest study to the Cochrane meta-analysis and using a fixed effects model shows that there was no statistically significant difference in SSI incidence between shaving using razors and no hair removal (RR 1.82, 95% CI 0.93 to 3.59) (Figure 5.3).



**Figure 5.3** Meta-analysis of three trials comparing the effect of shaving and no hair removal on SSI incidence

One trial ( $n = 267$  adults) reported in the systematic review compared SSI incidence in two groups randomised to either hair removal with depilatory cream (10/126) or to no hair removal (11/141). There was no statistically significant difference between the two groups (RR 1.02, 95% CI 0.45 to 2.31).

There were no studies comparing clipping of hair with no hair removal.

Three RCTs ( $n = 3193$  participants) compared the relative effects of shaving using razors with those of clipping on the incidence of SSI: 2.8% (46/1627) of people who were shaved developed an SSI compared with 1.3% (21/1566) who had hair clipped preoperatively. This was a statistically significant difference (RR 2.02, 95% CI 1.21 to 3.36).

Seven trials ( $n = 1213$  participants) reported in the systematic review compared the relative effects of shaving using razors with the use of depilatory cream for hair removal. Meta-analysis undertaken using a fixed effects model showed statistically significantly more SSIs in patients who were shaved (65/670) compared with those who had hair removed with depilatory cream (38/543) (RR 1.54, 95% CI 1.05 to 2.24).

There were no studies that compared clipping with depilatory cream.

#### *Clinical question*

Does the timing of preoperative hair removal affect the rate of surgical site infection?

### Introduction

The timing of hair removal may be important since deep skin organisms may be encouraged to the skin surface following skin damage and may, therefore, contaminate the operative field.

### Overview of evidence

One systematic review was identified.

The same Cochrane systematic review<sup>37</sup> (11 RCTs,  $n = 4627$  participants) examined the evidence for the timing of preoperative hair removal for the prevention of SSI. [EL = 1+]

One RCT reported in the review compared timings of hair removal. Participants were adults undergoing general clean surgery in a designated operating theatre. Observations of SSI at 15 and 30 days postoperatively were made for hair removal performed the night before and the morning of the patient's surgery. Both shaving using razors and clipping were investigated.

*Shaving the day before surgery compared with shaving on the day of surgery*

Fourteen of 271 of those shaved the day before surgery and 17/266 of those shaved on the day of surgery developed an SSI within the first 15 postoperative days ( $n = 537$  patients). The difference was not statistically significant (RR 0.81, 95% CI 0.41 to 1.61).

At 30 days postoperatively, 23/260 of those shaved the day before surgery and 26/260 of those shaved on the day of surgery developed an SSI. The finding was not statistically significant (RR 0.88, 95% CI 0.52 to 1.51).

*Clipping the day before surgery compared with clipping on the day of surgery*

Ten of 250 of people clipped the day before surgery developed an SSI 15 days postoperatively compared with 4/226 of people clipped on the day of surgery ( $n = 476$ ). The difference was not statistically significant (RR 2.26, 95% CI 0.72 to 7.11).

At 30 days postoperatively, 18/241 of patients clipped the day before surgery developed an SSI compared with 7/216 of people clipped on the day of surgery. The difference was not statistically significant (RR 2.30, 95% CI 0.98 to 5.41).

*Clinical question*

What is the cost-effective method of hair removal?

### Health economics overview of evidence

Five studies were included.<sup>39-43</sup>

The studies examined and compared different techniques of preoperative hair removal (shaving using razors, use of depilatory cream and clipping, as well as no hair removal).

It was difficult to ascertain the most cost-effective form of hair removal from these studies, most of which were more than 20 years old. Therefore, an economic model was developed to evaluate the cost-effectiveness of the various hair removal techniques in a UK context (see Appendix D). It showed that electric clippers were the most cost-effective method for preoperative hair removal.

### Health economics evidence statements

There is evidence from the literature that the use of razors to remove patients' hair prior to surgery is not cost-effective.

Evidence from a decision-analytic model showed that the use of electric clippers for preoperative hair removal was cost-effective when compared with no hair removal, shaving using razors, or depilatory cream. The use of electric clippers was not only found to generate more quality-adjusted life years (QALYs) but was also found to be less expensive than these two interventions.

### Evidence statements

There is evidence that there is no difference in SSI incidence following preoperative hair removal (using depilatory cream or by shaving using razors) or no hair removal. [EL = 1+]

There is evidence that fewer SSIs occur following hair removal with clippers or depilatory creams compared with shaving using razors. [EL = 1+]

There is insufficient evidence to determine whether the timing of the preoperative shaving using razors or clipping of hair at the operative site affects the incidence of SSI. [EL = 1+]

There is a risk of skin reactions with the use of depilatory creams.

There is evidence that shaving using razors is associated with more SSIs than any other method of hair removal. [EL = 1+]

### GDG interpretation

There is no evidence that hair removal in general influences the incidence of SSI, but it might be appropriate in some clinical circumstances. However, if hair has to be removed, there is evidence that shaving using razors increases the risk of SSI.

There is insufficient evidence on whether the timing of hair removal affects the risk of SSI but the GDG consensus was that where hair removal is required it should be undertaken as close to the time of surgery as possible but clipping on the day of surgery may be preferable. Electric clippers with single-use disposable heads are the most cost-effective method of hair removal.

#### Recommendations on hair removal

Do not use hair removal routinely to reduce the risk of surgical site infection.

If hair has to be removed, use electric clippers with a single-use head on the day of surgery. Do not use razors for hair removal, because they increase the risk of surgical site infection.

## 5.3 Patient theatre wear

### *Clinical question*

Does patient theatre attire affect the incidence of surgical site infection?

### Introduction

It has been traditional for patients to put on clean clothing (and in some units to remove underwear) on the ward before being taken to the operating theatre. Any risk of infection from airborne spread from socially clean clothing is unlikely to be large because, in comparison with the operating team, little patient movement occurs during operations thus reducing the dispersal of microorganisms from skin and clothing. The purpose of the review was to determine whether patient theatre attire can affect the incidence of SSI.

### Overview of evidence

No studies were identified that examined patient theatre attire and postoperative SSI rates.

### Evidence statement

There was no evidence identified to determine whether patient theatre attire can affect the incidence of SSI.

### GDG interpretation

There is no evidence concerning patient theatre attire but operating department clothing should maintain the dignity and comfort of the patient and allow easy access to the operative site as well as other areas for placement of intravenous cannulas, catheters and epidurals, etc. Operative wear may also be preferred when the patient's own clothes may be at risk of contamination from blood, body and washout fluids.

#### Recommendation on patient theatre wear

Give patients specific theatre wear that is appropriate for the procedure and clinical setting and that provides easy access to the operative site and areas for placing devices, such as intravenous cannulas. Consider also the patient's comfort and dignity.

## 5.4 Staff theatre wear

### *Clinical question*

What is the clinical effectiveness of theatre staff wearing non-sterile theatre wear (scrub suits, masks, hats, overshoes) for the prevention of surgical site infection?

### **Introduction**

It is traditional for the operating team to put on freshly laundered, but non-sterile, theatre wear prior to a surgical procedure in an operating theatre environment, and to change this scrub suit for a fresh set should any of it become soiled by blood or other body fluids. Scrub suits are usually re-laundered but other components are usually disposable. The purpose of the review was to determine the clinical effectiveness of theatre staff wearing non-sterile theatre wear (scrub suits, masks, hats and overshoes) for the prevention of SSI.

### **Overview of evidence**

#### *Scrub suits*

No relevant studies were identified.

#### *Surgical caps/hoods and shoe covers*

No relevant studies were identified.

#### *Masks*

One Cochrane systematic review was identified.

This well-conducted systematic review (two quasi-RCTs,  $n = 1453$  participants) was first published in 2002 and updated in May 2006.<sup>44</sup> [EL = 1+] It compared the effectiveness of using disposable face masks with the use of no mask for the prevention of postoperative SSI in clean surgery only. Pooling of results was inappropriate owing to clinical and methodological heterogeneity between the studies.

One quasi-RCT comprised 3088 patients undergoing breast, vascular and acute surgery. In the review, data were presented for the 1429 patients undergoing clean surgery. Thirteen of 706 (1.8%) wound infections occurred after clean surgery in the masked group and 10/723 (1.4%) in the non-masked group. This difference was not statistically significant (OR 1.34, 95% CI 0.58 to 3.07).

When the results for elective (clean and non-clean) surgery were combined (from the original paper,  $n = 2394$  participants), the difference in SSI incidence between the masked and non-masked group was not statistically significant (OR 1.49, 95% CI 0.97 to 2.30).

The other RCT comprising 41 gynaecological surgery patients was discontinued because 3/10 (30%) SSIs occurred in the non-masked group, although masking was not proven as causal. There were no postoperative wound infections in the masked group ( $n = 14$ ). This difference was not statistically significant (OR 0.07, 95% CI 0.00 to 1.63).

### **Evidence statements**

There is no evidence available that examines whether the wearing of scrub suits or head attire or overshoes by scrubbed or circulating theatre staff can prevent SSI.

Evidence from two quasi-RCTs show that there is no difference in the rate of SSI when face masks are worn during clean or dirty surgery. [EL = 1+]

### **GDG interpretation**

In theatre, there is a need to minimise the risk of microbial contamination of the operating site from the theatre environment. Traditionally, this has been referred to as theatre discipline. Although there is limited evidence concerning the use of specific non-sterile theatre wear (scrub suits, masks, hats and overshoes), the GDG consensus was that wearing non-sterile theatre wear is important in maintaining theatre discipline and may therefore contribute to minimising the risk of SSI.

A separate issue of the protection of operating staff from exposure to patients' body fluids was beyond the scope of the GDG and is covered by health and safety regulations.

### **Recommendation on staff theatre wear**

All staff should wear specific non-sterile theatre wear in all areas where operations are undertaken.

## 5.5 Staff leaving the operating area

### *Clinical question*

Does staff exiting and re-entering the operating room affect the incidence of surgical site infection?

### **Introduction**

It is traditional to change non-sterile theatre wear into conventional clothing when leaving the operating environment and to put on fresh theatre wear when re-entering. The purpose of the review was to determine whether staff exiting and re-entering the operating room can affect the incidence of SSI.

### **Overview of evidence**

No studies were identified that examined the effect of staff movement in and out of the operating room on SSI rates.

### **Evidence statement**

There is no evidence to determine whether staff exiting and re-entering the operating area has an effect on the incidence of SSI.

### **GDG interpretation**

It is good practice to discard all used theatre wear prior to leaving the operating area to prevent healthcare workers, patients and visitors being exposed to the risk of contamination. However, there is no evidence that this practice has any effect on the incidence of SSI.

The GDG consensus was that staff should not leave the operating theatre suite wearing non-sterile theatre wear as this is important in the maintenance of theatre discipline and may therefore contribute to minimising the risk of SSI.

### **Recommendation on staff leaving the operating area**

Staff wearing non-sterile theatre wear should keep their movements in and out of the operating area to a minimum.

## 5.6 Nasal decontamination

### *Clinical question*

Does patient nasal decontamination to eliminate *Staphylococcus aureus* affect the rate of surgical site infection?

### **Introduction**

The anterior nares (front of the nose, within the nostril) are the main reservoir for the multiplication of *Staphylococcus aureus* in the body, and *S. aureus* spreads from this site to other places on the skin surface. Up to one-third of people carry *S. aureus* persistently in their nares and about a further one-third do so intermittently. *S. aureus* is the most common cause of SSI in all types

of surgery, with the microorganism frequently being derived from the patients themselves. Measures to clear carriage of *S. aureus* from the anterior nares around the time of surgery have thus been investigated to assess whether they reduce SSI. Such measures usually involve applying topical antiseptics or antibiotics active against *S. aureus*. Theoretically, it may take several days of treatment to clear *S. aureus* from the anterior nares and also from other carriage sites and prolonged treatment may be difficult to achieve in practice for all patients.

It is important for studies in this area to determine whether the measures used have actually reduced *S. aureus* carriage and whether both *S. aureus* and total SSI rates have been influenced. This is because eliminating *S. aureus* carriage from a patient might, for example, leave them prone to acquiring carriage (and hence infection) with other bacteria.

The purpose of the review was to determine the clinical effectiveness of nasal decontamination using topical antimicrobial agents for the prevention of SSI.

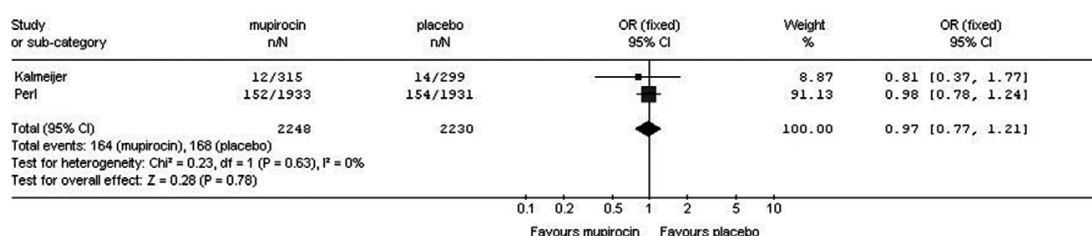
## Overview of evidence

Five RCTs were identified.

Five RCTs<sup>45–49</sup> examined the effects of nasal decontamination for prevention of SSI. Participants were undergoing orthopaedic, digestive, cardiothoracic, gynaecological, neurological, oncological and general surgery.

Three studies compared the effects of intranasal mupirocin with placebo,<sup>45–47</sup> although participants in one trial<sup>47</sup> were all *S. aureus* carriers. A further trial<sup>48</sup> compared mupirocin with no intervention and another<sup>49</sup> compared the effect of chlorhexidine mouthwash and nasal gel with that of placebo on SSI incidence.

Two RCTs<sup>45,46</sup> ( $n = 4478$  participants) examined whether there was any difference in SSI incidence following nasal decontamination with mupirocin and with placebo. [EL = 1+] Data were pooled in a meta-analysis (Figure 5.4). There was no heterogeneity and no statistically significant difference in SSI incidence between the two groups (OR 0.97, 95% CI 0.77 to 1.21).



**Figure 5.4** Meta-analysis of two trials comparing the effect of nasal decontamination with mupirocin versus placebo on SSI incidence

Two RCTs<sup>46,47</sup> examined mupirocin compared with a placebo in patients carrying *S. aureus* only. [EL = 1+] Heterogeneity between studies prevented pooling ( $I^2 = 66\%$ ) and individual findings for SSI incidence were not statistically significant for either study (respectively OR 0.84,<sup>46</sup> 95% CI 0.55 to 1.28,  $n = 891$ , and OR 1.88,<sup>47</sup> 95% CI 0.83 to 4.25,  $n = 157$ ).

These two studies<sup>46,47</sup> also presented findings for a comparison of mupirocin with placebo for *S. aureus* infections in *S. aureus* carriers ( $n = 1128$ ). [EL = 1+] There was no statistically significant difference in *S. aureus* infection incidence between the two groups of *S. aureus* carriers (OR 0.69, 95% CI 0.39 to 1.22).

One trial<sup>48</sup> ( $n = 395$  participants) compared the SSI incidence following nasal decontamination with mupirocin with that following no nasal decontamination in patients undergoing abdominal digestive surgery. [EL = 1+] There was no statistically significant difference in SSI rate between treatment arms (OR 1.39, 95% CI 0.76 to 2.52).

One trial<sup>49</sup> ( $n = 954$  participants) comparing the effect of chlorhexidine with that of placebo found no statistically significant difference in SSI rates between groups (OR 0.88, 95% CI 0.58 to 1.33). [EL = 1+]

One trial<sup>49</sup> reported one adverse event. [EL = 1+] One participant receiving chlorhexidine oral rinse and nasal gel complained of tooth staining. No other adverse events were detailed in this or any other included study.

### *Clinical question*

What is the contribution to clinical effectiveness of the timing of nasal decontamination for the prevention of surgical site infection?

### **Overview of evidence**

No single RCT compared timing of nasal decontamination for prevention of SSI.

### *Clinical question*

What is the cost-effectiveness of mupirocin nasal ointment for the prevention of surgical site infection caused by *Staphylococcus aureus*?

### **Health economics overview of evidence**

Two full economic analysis papers<sup>50,51</sup> were identified.

A cost-effectiveness analysis<sup>50</sup> compared mupirocin ointment treatment with no preventative treatment in cardiothoracic surgery patients. The outcome used was cost per SSI prevented. It was found that treating 1000 surgical patients with mupirocin would lead to a cost saving of \$747,969, which is \$16,633 saved per SSI prevented. However no staff costs were considered for the application of mupirocin, which would make using mupirocin ointment more expensive.

A cost-effectiveness analysis<sup>51</sup> compared the following strategies:

- screening patients for *S. aureus* colonisation with nasal culture and treating carriers with mupirocin
- no screening but treating all patients with mupirocin
- no screening with no preventative treatment.

The outcomes of the analysis were cost per infection avoided and cost per life year saved. The study concluded that both strategies that used mupirocin were cost-saving.

As neither published analysis was conducted in the UK, a new model was developed to assess the cost-effectiveness of mupirocin nasal ointment to prevent SSI caused by *S. aureus* (see Appendix E). Three strategies were compared:

- no treatment
- screen for *S. aureus* and treat identified carriers with mupirocin
- treat all patients with mupirocin.

The results with baseline values showed that treating all patients with mupirocin was the dominant strategy, resulting in the least number of SSIs and the lowest cost.

A deterministic threshold sensitivity analysis suggested that the cost of treating an SSI would have to be below £600 before the strategy of treating all patients with mupirocin exceeded £20,000 per QALY (the willingness-to-pay threshold used by NICE to determine cost-effectiveness). The point estimates on which baseline values were based were not statistically significant at the 5% level and a probabilistic sensitivity analysis was carried out to reflect the uncertainty in the effect size parameters. This suggested that there was approximately a 50% chance that treating all patients with mupirocin would be cost-effective.

However, this analysis did not model the potential harm of increased antibiotic resistance from treating all patients with mupirocin. Full details of the models are provided in Appendix E.

### **Health economics evidence statement**

An economic evaluation with clinical effectiveness based on a single trial suggested that there was a 50% chance that treating all patients with mupirocin nasal ointment to prevent SSI caused by *S. aureus* is a cost-effective strategy.



**Evidence statements**

There is evidence that nasal decontamination with mupirocin or chlorhexidine administered to all patients undergoing surgery does not affect the overall rate of SSI.

There is evidence that nasal decontamination with mupirocin given to *S. aureus* carriers undergoing surgery does not reduce either the incidence of *S. aureus* SSI or the incidence of all-cause SSI. [EL = 1+]

There is insufficient evidence from RCTs to determine incidence of adverse effects with nasal decontamination treatment. [EL = 1+]

There is no evidence available that examined the clinical effectiveness of the timing of nasal decontamination strategies.

**GDG interpretation**

Mupirocin or chlorhexidine nasal decontamination does not reduce the overall rate of SSI. Nevertheless, in *S. aureus* carriers, there was a non-statistically significant reduction in SSIs caused by *S. aureus* when mupirocin was used.

An economic model suggested that there was considerable uncertainty about the cost-effectiveness of treating all patients with mupirocin nasal ointment to prevent SSI caused by *S. aureus*, and the GDG consensus was that it should not be recommended, especially as the potential harm of increased antibiotic resistance had not been factored into the model.

**Recommendation on nasal decontamination**

Do not use nasal decontamination with topical antimicrobial agents aimed at eliminating *Staphylococcus aureus* routinely to reduce the risk of surgical site infection.

**Research recommendation on nasal decontamination**

Is it cost-effective to use mupirocin for nasal decontamination? In which patients is it most effective?

*Why this is important*

This is important as it is not clear how many surgical site infections would be prevented by treating all patients with nasal mupirocin, or whether only patients who are nasally colonised with methicillin-resistant *Staphylococcus aureus* should be treated. The use of mupirocin and its application is cost- and time-sensitive, apart from the concern that excessive use of mupirocin may lead to resistance. There should be further research involving large numbers of study participants undergoing different operations.

**5.7 Mechanical bowel preparation***Clinical question*

Does mechanical bowel preparation reduce the rate of surgical site infection?

**Introduction**

Most SSIs are acquired intraoperatively from the bacterial flora colonising the patient's skin, gastrointestinal tract and mucous membranes. At present, the best method to prevent SSI after colorectal surgery is a matter of debate. Traditional surgical practice has suggested that removal of faecal matter from the colon and rectum prior to elective colorectal surgery confers an advantage, and mechanical bowel preparation has become a fundamental component of intestinal surgery in many units. Mechanical bowel preparation has been considered to be advantageous for many reasons, including operative time, ease of handling of the bowel, rate of stoma formation and the ability to palpate lesions in the bowel wall. The purpose of the review was to determine the clinical effectiveness of preoperative mechanical bowel preparation for the prevention of SSI.

## Overview of evidence

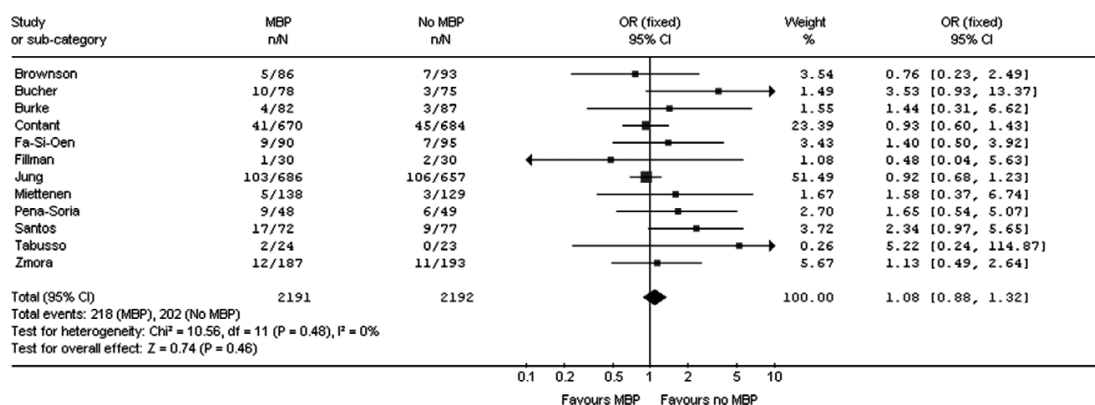
12 RCTs were identified.

A systematic review (nine RCTs,  $n = 1592$  participants) published in 2005 was identified that investigated SSI incidence (as a secondary outcome) following mechanical bowel preparation in patients undergoing colorectal surgery. All nine trials were included here, although two trial reports published after the Cochrane review was prepared were used as they contained fuller detail. A further three trials<sup>52–54</sup> published within the last 2 years were also identified. [EL = 1+]

This gives a total of 12 included trials with patients who were all undergoing colorectal surgery. Different mechanical bowel preparation solutions were administered in the studies: polyethylene glycol, mannitol, sodium picosulfate, laxative/enema/mannitol and in two studies the solution was not reported.

Data from all trials were pooled in a meta-analysis (12 RCTs,  $n = 5383$ ). All of these studies examined the clinical effectiveness of preoperative mechanical bowel preparation for the prevention of SSI.

There was no heterogeneity and no statistically significant difference in SSI incidence between the treatment and control groups ( $I^2 = 0\%$  and OR 1.08, 95% CI 0.88 to 1.32 – fixed effects model) (Figure 5.5).



**Figure 5.5** Meta-analysis of 12 trials comparing the effect of mechanical bowel preparation versus no mechanical bowel preparation on SSI incidence

## Evidence statement

There is evidence from a meta-analysis that there is no difference in the incidence rate of SSI for patients receiving bowel preparation when compared with no preparation in colorectal surgery. [EL = 1+]

## GDG interpretation

The GDG recognised that there are different types of surgery (left- or right-sided colonic resections), different bowel preparations and different diseases (cancer or diverticular disease) that may have an impact on rates of SSI. The GDG recognised that there may be other indications where bowel preparation may be used, in particular to minimise the risk of an anastomotic leak and the formation of a stoma.

However, there is no evidence that bowel preparation influences the incidence of SSI in patients undergoing colorectal surgery.

## Recommendation on mechanical bowel preparation

Do not use mechanical bowel preparation routinely to reduce the risk of surgical site infection.

## 5.8 Hand decontamination (general)

General hand decontamination is covered by the epic2 guidelines<sup>255</sup> (see Appendix H). It refers to preoperative preparation and to any contact with the patient until discharge.

## 5.9 Hand jewellery, artificial nails and nail polish

### *Clinical question*

Does the removal of hand jewellery, artificial nails and nail polish reduce the incidence of surgical site infection?

### **Introduction**

It is conventional for the operating team not to wear hand jewellery during surgical procedures, although some of the team may feel strongly about not removing wedding rings, and equally strongly that nail polish or nail extensions should be avoided. The purpose of the review was to evaluate the effects of the removal of nail polish, nail extensions and hand jewellery by the surgical scrub team on the prevention of postoperative SSI.

### **Overview of evidence**

One systematic review<sup>55</sup> was identified that examined the effect of the surgical scrub team removing finger rings and nail polish on postoperative SSI rates.

No trials were identified that compared the wearing of finger rings with their removal. No trials were identified that compared the removal or wearing of nail polish with respect to SSI.

One well-conducted systematic review<sup>55</sup> (one RCT,  $n = 102$  participants) looked at the effects of removing finger rings and nail polish on the incidence of SSI [EL = 1+]. Only one small trial was included. Participants were scrub team members. The study outcome was the bacterial load on fingernails before and after surgical scrubbing expressed as the number of colony-forming units (CFUs). The trial found no statistically significant difference in the number of CFUs between the two groups in the pre-scrubbing as in the post-scrubbing. Since there is insufficient evidence to establish a direct association between CFUs and SSI, the systematic review could not determine whether the removal or not of nail polish, hand jewellery or nail extensions has an effect on SSI rate.

### **Evidence statement**

There is insufficient evidence to determine whether the removal or not of nail polish, hand jewellery or nail extensions has an effect on SSI rate. [EL = 1+]

### **GDG interpretation**

There is no RCT evidence available to relate SSI to jewellery, nail polish or artificial nails. However, there was GDG concern that in certain circumstances artificial nails, nail polish and jewellery may conceal underlying soiling and impair hand decontamination. The GDG recognised that some rings may be difficult to remove.

### **Recommendations on hand jewellery, artificial nails and nail polish**

The operating team should remove hand jewellery before operations.

The operating team should remove artificial nails and nail polish before operations.

## 5.10 Antibiotic prophylaxis

### *Clinical question*

What is the clinical effectiveness of parenteral or oral antibiotic prophylaxis for the prevention of surgical site infection compared with placebo or no antibiotic in patients undergoing surgery involving a skin incision?

### **Introduction**

Antibiotic prophylaxis has been used effectively to prevent SSIs after appropriate operative procedures since 1969. Prophylaxis usually involves a single dose of antibiotic often given intravenously, close to the time of surgery (at induction of anaesthesia) and must be seen as different to treatment that entails a course of antibiotics over a period of time. In common with therapeutic use, the use of antibiotics for prophylaxis carries a risk of adverse drug reactions (including *Clostridium difficile*-associated diarrhoea) and increased prevalence of antibiotic-resistant bacteria. The choice of antibiotic prophylaxis should be influenced by the strength of the association between the antibiotic used and *C. difficile* diarrhoea. In this review the clinical effectiveness of antibiotic prophylaxis for various types of surgical procedures in the prevention of SSI was examined.

Searches were run for intravenous (IV) and oral antibiotic use, limited by study design (RCT and systematic reviews) but not by year.

### **Overview of evidence**

The evidence is ordered by location of surgery and by surgery type. Evidence statements are grouped by the wound classification – clean, clean-contaminated, contaminated or dirty.

### **Head and neck surgery**

#### *Craniotomy*

One systematic review was included.

One well-conducted systematic review<sup>56</sup> (eight RCTs,  $n = 2075$  participants) examined the evidence for antibiotic prophylaxis in patients who underwent a craniotomy. The antibiotics used were clindamycin, vancomycin/gentamicin, cefazolin/gentamicin, vancomycin, piperacillin, cloxacillin, oxacillin and cefotiam, and these were compared with placebo. [EL = 1+]

The meta-analysis conducted of the eight studies demonstrated that there were statistically significantly fewer infections in the patient groups given antibiotic prophylaxis (19/1014) compared with those receiving placebo (93/1061) (OR 0.20, 95% CI 0.12 to 0.33).

#### *Spinal surgery*

One systematic review was included.

A systematic review<sup>57</sup> (five RCTs, one quasi-RCT,  $n = 843$  participants) was identified that examined antibiotic prophylaxis in patients who all had spinal operations in trials of general neurosurgery and orthopaedic and spinal surgery. [EL = 1+] The antibiotics used were cefaloridine, vancomycin/gentamicin, cefazolin/gentamicin, piperacillin, oxacillin and cefazolin.

There were varying definitions of wound infection but most required the presence of purulent drainage and positive bacteriological cultures.

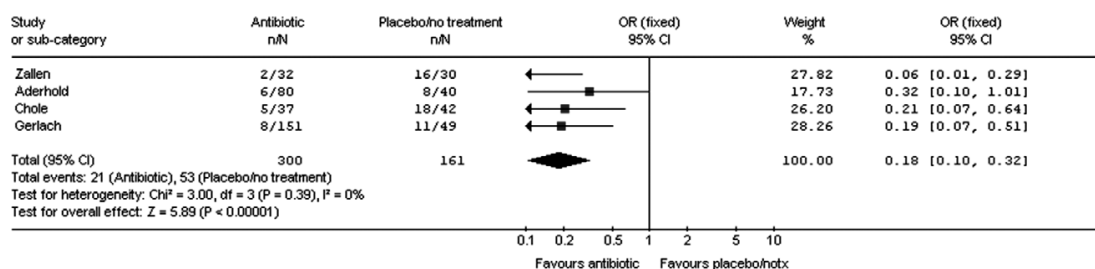
All trials reported lower rates of wound infection for the antibiotic group compared with controls although none of the differences reached statistical significance. The meta-analysis conducted of the six studies found a statistically significant protective effect of antibiotics (10/461) against wound infection compared with control (23/392) (OR 0.37, 95% CI 0.17 to 0.78).

#### *Open reduction and internal fixation of compound mandibular fractures*

One systematic review was included.

A systematic review was identified<sup>58</sup> (four RCTs,  $n = 461$  participants) that examined the use of prophylactic antibiotics in the surgical treatment of maxillofacial fractures. [EL = 1+] Patients were undergoing surgery for mandibular or facial fractures and were randomised to receive either antibiotic or placebo/no prophylaxis. The antibiotics used were not reported in three studies and in the fourth IV cefazolin was administered. All studies included wound infection as an outcome. There was a mixture of open and closed reductions in one trial.

A meta-analysis (Figure 5.6) of the four studies found statistically significantly fewer wound infections in participants given antibiotic prophylaxis compared with those given placebo or no treatment (OR 0.18, 95% CI 0.10 to 0.32). Removal of the trial that mixed open and closed reduction of fractures did not remove statistical significance (OR 0.25, 95% CI 0.08 to 0.30).



**Figure 5.6** Meta-analysis of four trials comparing the effect of antibiotic prophylaxis versus placebo or no treatment on SSI incidence in maxillofacial fracture surgery

#### *Clean, malignant, neck dissection head and neck surgery*

One RCT was identified.

An RCT<sup>59</sup> ( $n = 20$  patients) was included that examined the effect of cefamandole prophylaxis compared with placebo on wound infection in patients presenting for major head and neck cancer surgery. [EL = 1– ] The trial was stopped early before recruiting the intended 40 participants and results were presented for 20 patients. There were 3/11 wound infections in the cefamandole group and 5/9 infections in the placebo group. This difference was not statistically significant (OR 0.30, 95% CI 0.05 to 1.94).

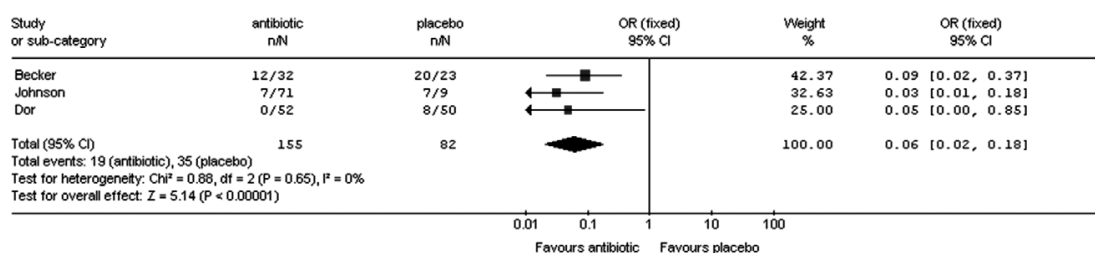
#### *Contaminated/clean-contaminated head and neck surgery*

One systematic review was included.

A systematic review<sup>60</sup> (12 RCTs) investigating antibiotic prophylaxis compared with placebo or with different antibiotic types or schedules in head and neck surgery was identified. [EL = 1+]. Three trials (237 participants) investigated the effect on wound infection of antibiotic prophylaxis compared with placebo.

All three trials included participants undergoing surgery for head and neck cancer. The antibiotics used were ampicillin/cloxacillin, cefazolin and cefoperazone/cefotaxime. One trial stopped placebo administration after examination of the results of the first 16 patients. All participants subsequently recruited instead received cefotaxime.

A meta-analysis (Figure 5.7) of these three trials found that there were statistically significantly fewer wound infections in patients who received antibiotics (19/155) than in those who received placebo (35/82) (OR 0.06, 95% CI 0.02 to 0.18).



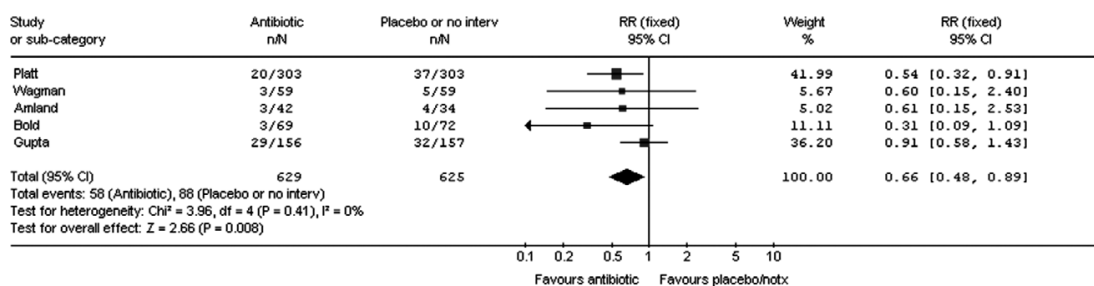
**Figure 5.7** Meta-analysis of three trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in clean-contaminated/contaminated head and neck surgery

### Breast cancer surgery

One systematic review and an RCT were identified.

One Cochrane systematic review<sup>61</sup> (six RCTs,  $n = 1302$  participants) was identified that included people with breast cancer undergoing breast surgery with or without immediate reconstruction as part of their treatment. [EL = 1+] The antibiotics used were azithromycin, cefonicid (two trials), clarithromycin, co-amoxiclav and cefazolin.

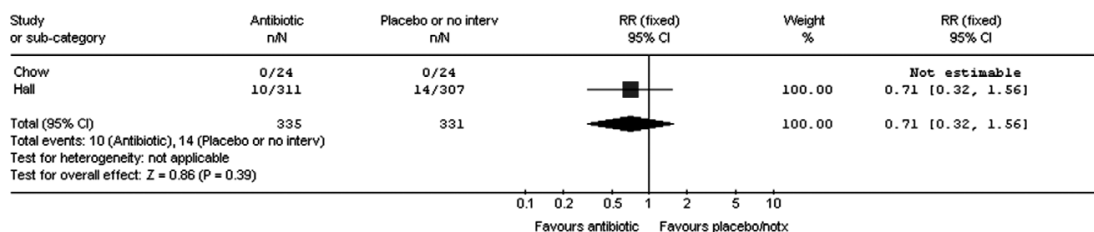
Five RCTs compared antibiotic with placebo and found statistically significantly fewer infections in the group receiving prophylaxis (RR 0.66, 95% CI 0.48 to 0.89) (Figure 5.8).



**Figure 5.8** Meta-analysis of five trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in breast cancer surgery with or without immediate reconstruction

One RCT included in the review compared clarithromycin with no intervention (RR not estimable, no events in either group).

A further, subsequently published trial ( $n = 618$  participants) was identified.<sup>62</sup> [EL = 1+] This study included patients scheduled for non-reconstructive breast surgery and compared the administration of a single dose of flucloxacillin immediately after anaesthesia induction with no treatment. The incidence of wound infection was similar in the two groups (OR 0.71, 95% CI 0.32 to 1.56) (Figure 5.9).



**Figure 5.9** Comparison of single-dose flucloxacillin prophylaxis versus placebo on SSI incidence in two trials

### Immediate breast reconstruction with or without implants

One systematic review was identified.

A systematic review<sup>61</sup> of prophylactic antibiotics to prevent surgical site infection after breast cancer surgery did not identify any eligible studies involving reconstructive surgery (with or without implants) for inclusion. [EL = 1+]

### Cardiac pacemaker insertion

One systematic review was identified.

A systematic review<sup>63</sup> (seven RCTs,  $n = 2023$  participants) of antibiotic prophylaxis for permanent pacemaker insertion was identified. [EL = 1+] All trials compared antibiotics with 'control', which was presumed to be a placebo or no treatment – this was implied although not specifically stated. The antibiotics used were flucloxacillin/benzylpenicillin, cloxacillin, cloxacillin/amoxicillin, ampicillin/flucloxacillin, cefazolin, cefazedone and flucloxacillin. The definition of infection was not given but included pocket infection and lead infection and may also have included septicaemia.

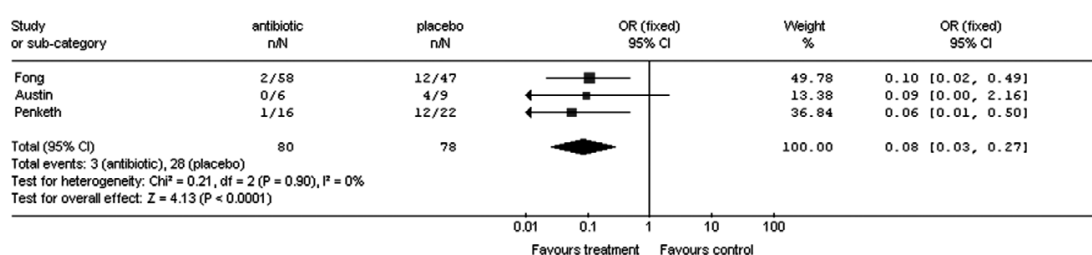
Meta-analysis of these studies demonstrated an overall statistically significant protective effect of antibiotic prophylaxis (5/1011) compared with no antibiotic treatment (37/1012) (OR 0.26, 95% CI 0.10 to 0.66) for infection.

### Open-heart surgery

Three RCTs were identified.

Two trials were identified that examined the effect of antibiotic prophylaxis compared with placebo in coronary artery bypass graft (CABG)<sup>64,65</sup> and one trial in aorto-coronary bypass operations.<sup>66</sup> [EL = 1-, EL = 1+, EL = 1+, respectively] The antibiotics used were meticillin, cefradine and cefalotin. All studies were halted to examine infection rates in both groups. One study<sup>65</sup> was re-started with placebo still given, while the other two had protocols modified.

A meta-analysis (Figure 5.10) of these three RCTs showed that antibiotic prophylaxis reduced the rate of wound infections compared with placebo (OR 0.08, 95% CI 0.03 to 0.27).



**Figure 5.10** Meta-analysis of three trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in open-heart surgery

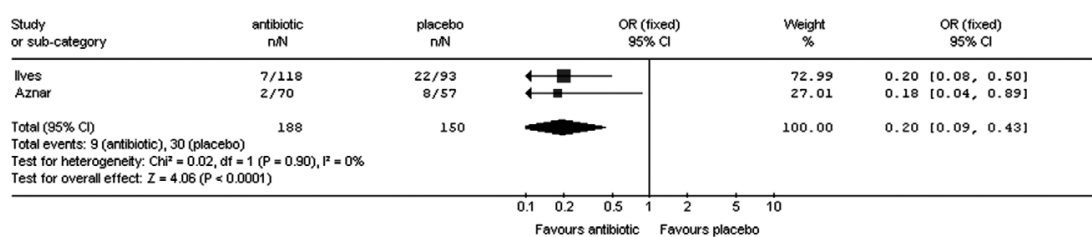
### General thoracic surgery

Two RCTs of patients undergoing operations in general thoracic surgery units were identified.

One RCT<sup>67</sup> ( $n = 211$  participants) randomised patients to receive either cefalotin or placebo at induction of anaesthesia. [EL = 1+] Patients were undergoing lung, hernia, gastroplasty and oesophageal surgery. Seven wound infections were found in the antibiotic group ( $n = 118$  participants) and 22 in the placebo group ( $n = 93$  participants) (OR 0.20, 95% CI 0.08 to 0.50).

The other RCT<sup>68</sup> ( $n = 127$  participants) randomised participants to receive either cefazolin or placebo half an hour before surgery. [EL = 1+] Patients were undergoing pulmonary resection, atypical pulmonary resection, bullectomy, chest wall resection, oesophageal surgery and surgery for mediastinal tumours. There were statistically significantly fewer wound infections in the antibiotic group (2/70) than in the placebo group (8/57) (OR 0.18, 95% CI 0.04 to 0.89).

A meta-analysis (Figure 5.11) of these two studies that included a total of 238 participants also found that there were statistically significantly fewer wound infections with antibiotic prophylaxis compared with placebo (OR 0.20, 95% CI 0.09 to 0.43).



**Figure 5.11** Meta-analysis of two trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in general thoracic surgery

## Upper gastrointestinal tract surgery

### Stomach and duodenal surgery

Four RCTs were identified.

Four trials<sup>69-72</sup> were identified that compared the use of antibiotic prophylaxis with placebo or no antibiotic in stomach and duodenal surgery. Three reported wound infection outcomes for patients and one reported wound infections as a proportion of the overall number of wounds.<sup>69</sup>

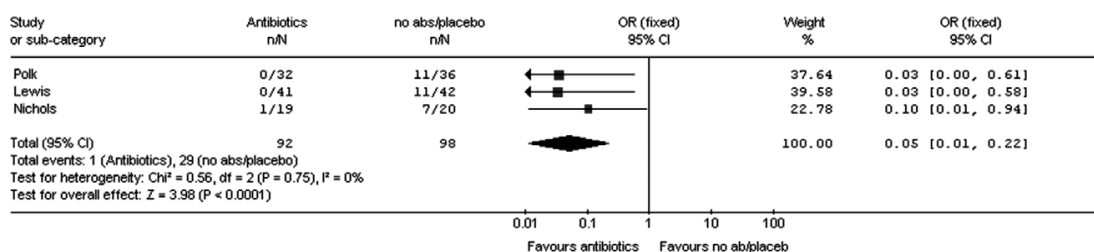
One RCT<sup>69</sup> included patients undergoing general surgery and randomised them to either cefaloridine (376 wounds) or no antibiotic (386 wounds). [EL = 1+] There was one wound infection in those undergoing gastric surgery with antibiotic prophylaxis (33 wounds) and six infections in the gastric surgery patients who did not receive antibiotics (30 wounds). This difference was not statistically significant (OR 0.13, 95% CI 0.01 to 1.11).

One RCT<sup>70</sup> included 83 patients undergoing surgery for high-risk gastroduodenal disease who were divided into two treatment arms, one of which received two doses of cefaloridine, the other no antibiotic. [EL = 1+] A further low-risk treatment arm was not considered here. No wound infections were found in the cefaloridine group ( $n = 41$  patients) compared with 11 in the no antibiotic group ( $n = 42$  patients). This difference was statistically significant (OR 0.03, 95% CI 0.00 to 0.58).

One RCT<sup>71</sup> included 39 patients undergoing gastroduodenal surgery with a high postoperative risk. [EL = 1+] One infection was found in the cefamandole group ( $n = 19$  patients) and seven were reported in the placebo group ( $n = 20$  patients). This difference was statistically significant (OR 0.10, 95% CI 0.01 to 0.94).

One RCT<sup>72</sup> included 68 consecutive patients undergoing elective surgery of the gastrointestinal tract. [EL = 1+] There were no infections in the antibiotic group ( $n = 32$  patients), but 11 in the placebo group ( $n = 36$  patients). This difference was statistically significant (OR 0.03, 95% CI 0.00 to 0.61).

A meta-analysis (Figure 5.12) of the three trials that reported wound infections in patients rather than as a proportion of all wounds found an overall statistically significant protective effect of antibiotics compared with placebo or no antibiotics (OR 0.05, 95% CI 0.01 to 0.22).



**Figure 5.12** Meta-analysis of three trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in upper gastrointestinal tract surgery

## Hepatobiliary surgery

### Bile duct surgery

One systematic review was identified.

Forty-two RCTs of biliary tract operations comparing the effects of antibiotic prophylaxis with 'control' for wound infection were pooled in a meta-analysis in a systematic review.<sup>73</sup> [EL = 1+] Biliary tract surgery was defined as all operations on the gallbladder and/or common bile duct, including cholecystectomy, exploration of the common bile duct and choledochenterostomy.

Control interventions varied (povidone-iodine, placebo, topical antibiotic, prophylaxis with/without additional antibiotic, etc.). All trials were conducted between 1965 and 1988 and reported wound infection as an outcome. Although there was a range of definitions of wound infection, the most common was 'discharge of pus' from the wound. Details of the number of participants were not given although studies of less than ten participants were excluded.

Overall, there were fewer wound infections in the antibiotic prophylaxis group compared with the 'control' group. This difference was statistically significant (OR 0.30, 95% CI 0.23 to 0.38).



*Laparoscopic gallbladder surgery*

One systematic review and two RCTs were identified.

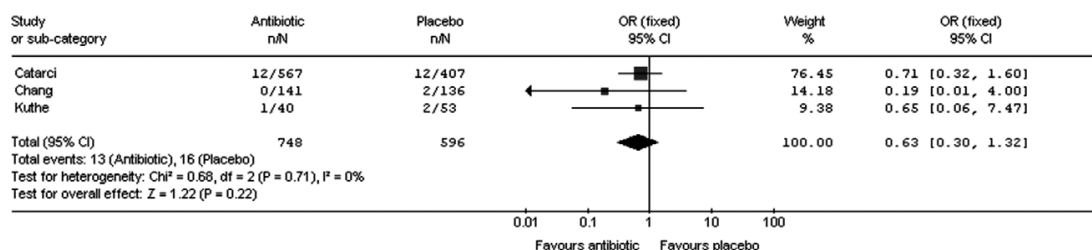
One relevant systematic review<sup>74</sup> and two more recently published RCTs from India<sup>75</sup> and Taiwan<sup>76</sup> were included.

The systematic review (six RCTs,  $n = 974$  patients) compared the effect of antibiotic prophylaxis with that of placebo on wound infection in patients undergoing low-risk laparoscopic cholecystectomy. [EL = 1+] The pooled OR was 0.71, 95% CI 0.32 to 1.60, suggesting that there was no difference in wound infection incidence following antibiotic prophylaxis (12/567) or placebo administration (12/407) in laparoscopic cholecystectomy.

One trial<sup>75</sup> included 93 patients of ASA score 1 and 2 diagnosed as having gall stone disease undergoing laparoscopic cholecystectomy. [EL = 1+] Forty patients were randomised to receive 1.5 g cefuroxime in 100 ml saline at anaesthesia induction while 53 patients received normal saline similarly administered. There were three postoperative wound infections – one in the antibiotic group and two in the placebo group. This finding was not statistically significant (OR 0.65, 95% CI 0.06 to 7.47).

One trial<sup>76</sup> included 277 patients with symptomatic gallbladder stones or polyps disease with or without acute cholestasis who were candidates for laparoscopic cholecystectomy. [EL = 1+] One hundred and forty-one patients were randomised to receive 1 g cefazolin given at anaesthetic induction and 136 received 10 ml isotonic sodium chloride solution similarly. There were two infections, both of which occurred in the placebo group. This finding was not statistically significant (OR 0.19, 95% CI 0.01 to 4.00).

A meta-analysis (Figure 5.13) of all participants' wound infection outcomes was performed that yielded a similar non-statistically significant result (OR 0.63, 95% CI 0.30 to 1.32).



**Figure 5.13** Meta-analysis of three trials comparing the effect of antibiotic prophylaxis versus placebo on SSI incidence in hepatobiliary surgery

**Lower gastrointestinal tract surgery***Appendicectomy*

One systematic review was identified.

A Cochrane systematic review<sup>77</sup> was identified that investigated the use of antibiotics compared with placebo or no prophylaxis in patients undergoing appendicectomy. [EL = 1+] Both adults and children were included.

The outcomes were described according to the nature of the appendix – simple or complicated – or ‘appendicitis’ when not specified. Seventy-one studies were included in total, all of which reported wound infection as an outcome.

Meta-analyses for both clinical and pathoanatomical descriptions of appendicitis reported statistically significantly fewer wound infections associated with the use of systemic antibiotics compared with placebo (Peto OR 0.33, 95% CI 0.29 to 0.38 and Peto OR 0.32, 95% CI 0.22 to 0.47, respectively).

Single or multiple antibiotics given as a single dose preoperatively resulted in statistically significantly fewer wound infections than preoperative placebo prophylaxis (overall Peto OR 0.34, 95% CI 0.25 to 0.45 and overall Peto OR 0.14, 95% CI 0.05 to 0.39, respectively).

Single or multiple antibiotics given as a single dose perioperatively resulted in statistically significantly fewer wound infections than perioperative placebo prophylaxis (overall Peto OR 0.43, 95% CI 0.34 to 0.55 and overall Peto OR 0.43, 95% CI 0.34 to 0.55, respectively).

A single antibiotic given at operation and subsequently given postoperatively as a single or multiple dose resulted in statistically significantly fewer wound infections than comparable placebo prophylaxis (overall Peto OR 0.16, 95% CI 0.07 to 0.36 and overall Peto OR 0.46, 95% CI 0.35 to 0.60, respectively).

Multiple antibiotics given at operation and subsequently given postoperatively in multiple doses resulted in statistically significantly fewer wound infections than comparable placebo prophylaxis (overall Peto OR 0.18, 95% CI 0.11 to 0.27).

In children, there was no statistically significant difference in SSI rates with systemic antibiotics or placebo (overall Peto OR 0.64, 95% CI 0.37 to 1.10), except in complicated (gangrenous or perforated) appendicitis (Peto OR 0.31, 95% CI 0.12 to 0.77).

### *Colorectal surgery*

A systematic review<sup>78</sup> was identified that compared antibiotic prophylaxis with no antibiotic administration in colorectal surgery. [EL = 1+]

Four trials published since 1984 were included that compared patients receiving antibiotic prophylaxis for colorectal surgery with a control group not given antibiotics. The antibiotics used prophylactically in these four trials were gentamicin plus metronidazole, metronidazole alone or metronidazole plus ampicillin, mezlocillin plus oxacillin, and cefoxitin. The results from the individual studies showed consistently that the wound infection rate was much lower in the antibiotic groups than that in the control groups (12.9% versus 40.2%; OR 0.24, 95% CI 0.13 to 0.43).

### **Hernia repair**

One systematic review and one RCT were identified.

A recently updated Cochrane systematic review<sup>79</sup> (12 RCTs,  $n = 6705$  participants) was identified that evaluated antibiotic prophylaxis compared with placebo for prevention of wound infection in hernia repair. [EL = 1+]

Six trials ( $n = 2436$  participants) used prosthetic material for hernia repair (hernioplasty) whereas the remaining studies ( $n = 4269$  participants) did not (herniorrhaphy).

For hernioplasty, there were 17 wound infections among the patients who received prophylaxis ( $n = 1196$  participants) compared with 37 in those receiving placebo ( $n = 1240$  participants). This difference in wound infection incidence was statistically significant (OR 0.48, 95% CI 0.27 to 0.85).

For herniorrhaphy, there were 103 wound infections among the patients who received prophylaxis ( $n = 2932$  participants) compared with 66 in those receiving placebo ( $n = 1337$  participants). This difference in wound infection incidence did not quite reach statistical significance.

Overall, for both hernia repair methods, there were fewer wound infections among the participants who received prophylaxis (120/4128 participants) compared with those receiving placebo (103/2577 participants). This was a statistically significant finding (OR 0.64, 95% CI 0.48 to 0.85).

A further RCT<sup>80</sup> that was not referred to in the Cochrane review was also identified that compared the effect on wound infection of a single dose of amoxicillin and clavulanic acid with that of normal saline in elective open repair of inguinal hernia using mesh. [EL = 1+] There were five reports of wound infection in the antibiotic group ( $n = 190$  participants) compared with nine in the placebo group ( $n = 189$  participants). This was not a statistically significant difference (OR 0.54, 95% CI 0.18 to 1.64).

Pooling the results of this RCT with the review of hernioplasty demonstrated a statistically significant difference between the two groups (OR 0.49, 95% CI 0.30 to 0.81).

## Pelvis surgery

### *Abdominal hysterectomy*

One systematic review was identified.

A systematic review<sup>81</sup> (17 trials,  $n = 2752$  participants) investigated wound infections in abdominal hysterectomy following randomisation to antibiotic prophylaxis or placebo. [EL = 1–] It was unclear which trials had contributed to the comparison ‘antibiotic versus placebo or no antibiotic’ and no quality assessment of methodology is provided. The group treated with cephalosporin showed a statistically significantly lower infection rate compared with the control group (9.8% versus 23.4%; OR 0.35, 95% CI 0.30 to 0.40,  $P < 0.0001$ ).

### *Caesarean section*

One systematic review was identified.

A Cochrane review<sup>82</sup> (81 trials) was identified that assessed the effects of prophylactic antibiotic treatment on infectious complications in women undergoing caesarean birth. [EL = 1+]

Seventy-five studies reported on the outcome of wound infection. The rates of wound infections in the elective, non-elective and both or undefined control groups were quite similar (8.51%, 7.61% and 10.6%, respectively). Antibiotic prophylaxis was associated with a reduction in wound infections for:

- non-elective caesarean sections ( $n = 2780$ ) – there were 41/1650 wound infections in the antibiotic group compared with 86/1130 in the control group; the RR was 0.36, 95% CI 0.26 to 0.51
- elective caesarean sections ( $n = 2015$ ) – there were 64/1134 wound infections in the antibiotic group compared with 75/881 in the control group; this difference in wound infection after an elective caesarean section was statistically significant (RR 0.73, 95% CI 0.53 to 0.99)
- all patients having a caesarean ( $n = 11\ 142$ ) – there were 234/6237 wound infections in the antibiotic group compared with 468/4905 in the control group; the RR was 0.41, 95% CI 0.29 to 0.43.

## Limb surgery

### *Open fracture*

One systematic review was identified.

A Cochrane review<sup>83</sup> (seven trials,  $n = 913$  participants) was identified that investigated the effect of antibiotics compared with placebo or no antibiotic in patients who had open fractures of the limbs. [EL = 1+] Two of the included trials were RCTs, three were quasi-RCTs and the randomisation process was unclear in the other two studies.

Statistically significantly fewer wound infections were found in the participants treated with antibiotics compared with those treated with either placebo or no antibiotic (RR 0.41, 95% CI 0.27 to 0.63).

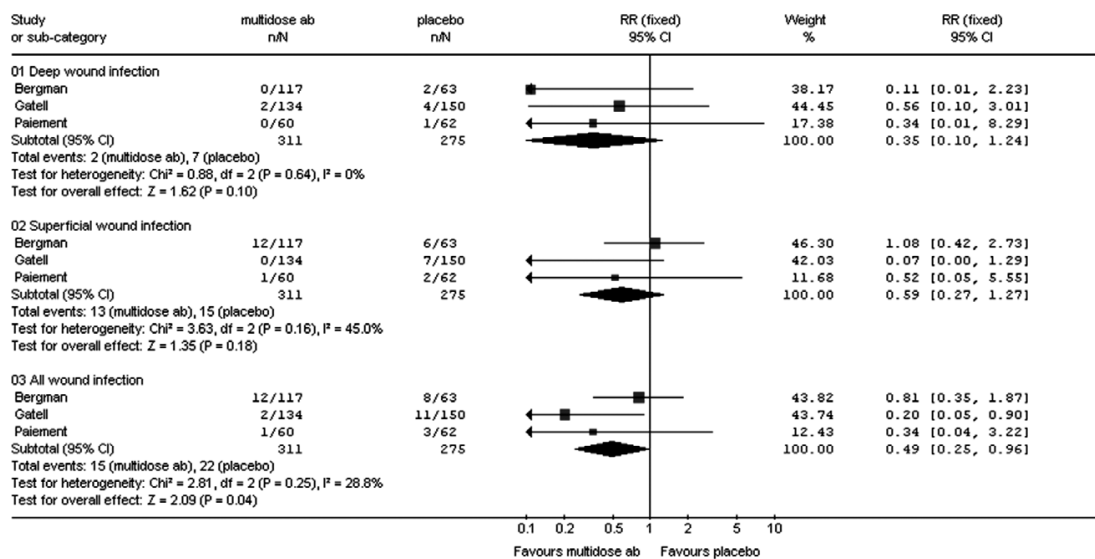
### *Open surgery for closed long bone fracture*

One systematic review was identified.

One Cochrane systematic review<sup>84</sup> was identified that investigated the effect of antibiotic prophylaxis for surgery for proximal femoral and other closed long bone fractures. [EL = 1+] This review included trials examining wound infection for hip fracture as well as trials for long bone and other unspecified closed fractures. Only long bone and other unspecified closed fracture trials that examined the effect of prophylactic antibiotics versus placebo were included.

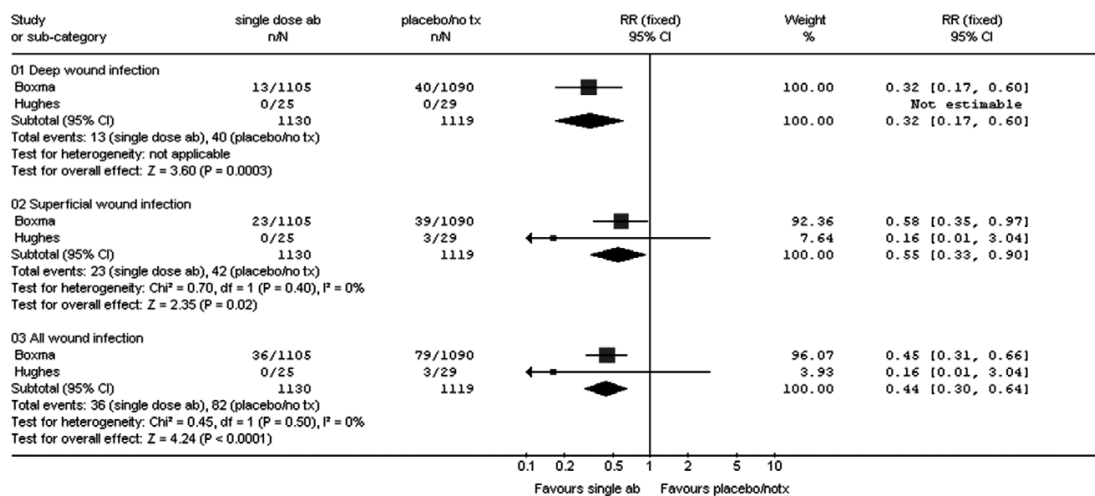
This left five trials available for inclusion in this review.

A meta-analysis (Figure 5.14) of three trials that considered the deep and superficial infection rates following multiple doses of a single antibiotic compared with placebo found that statistically significantly fewer wound infections occurred in the antibiotic group (RR 0.49, 95% CI 0.25 to 0.96,  $I^2 = 28.8\%$ ) overall. No statistically significant difference in either deep or superficial wound infection rates individually was observed.



**Figure 5.14** Meta-analyses of three trials comparing the effect of prophylaxis with multiple doses of a single antibiotic versus placebo for deep, superficial and all SSI prevention in open surgery for closed long bone fractures

A meta-analysis (Figure 5.15) of two trials that considered the deep and superficial infection rates following a single dose of one antibiotic as prophylaxis compared with placebo found that statistically significantly fewer wound infections occurred in the antibiotic group (RR 0.44, 95% CI 0.30 to 0.64) overall. Statistically significant differences in both deep and superficial wound infection rates individually were also observed.



**Figure 5.15** Meta-analyses of two trials comparing the effect of single dose antibiotic prophylaxis versus placebo for deep, superficial and all SSI prevention in open surgery for closed long bone fractures

### Hip fracture

One systematic review was identified.

The systematic review<sup>85</sup> investigated the effect of antibiotic prophylaxis administered pre-, peri- and/or postoperatively compared with placebo for hip fracture surgery. [EL = 1+] The main outcome was wound infection rate and further analysis of deep and superficial infection was provided.

Ten trials (n = 2417 participants) investigated wound infection and found that statistically significantly fewer wound infections occurred in those patients given antibiotics compared with those given placebo (OR 0.55, 95% CI 0.35 to 0.85).

Seven studies ( $n = 1782$  participants) investigated superficial infection (OR 0.67, 95% CI 0.44 to 1.01) and six studies investigated deep infection (OR 0.53, 95% CI 0.20 to 1.38), although neither reached statistical significance. Addition of a further two studies ( $n = 419$  participants) describing infections as 'major' rather than deep found statistically significantly fewer infections in the antibiotic prophylaxis group (OR 0.52, 95% CI 0.28 to 0.99).

#### *Lower limb amputation*

One systematic review was identified.

One RCT<sup>86</sup> ( $n = 152$  participants) was identified that examined the use of cefoxitin (five doses of 2 g during the first 24 hours, starting 30 minutes before amputation and then every 6 hours) compared with placebo (no further details) in patients admitted for amputation due to arteriosclerosis. [EL = 1+] There were statistically significantly more wound infections in the placebo group compared with the antibiotic group (RR 3.3, 95% CI 1.5 to 7.5,  $P < 0.004$ ).

#### *Vascular surgery*

One systematic review was identified.

One Cochrane systematic review<sup>87</sup> (35 RCTs) was identified that sought to determine the effectiveness of perioperative strategies to prevent infection in patients undergoing peripheral arterial reconstruction. [EL = 1+] Ten studies compared antibiotic prophylaxis with placebo. A meta-analysis of these ten studies demonstrated that prophylactic systemic antibiotics reduced the risk of wound infection (RR 0.25, 95% CI 0.17 to 0.38) compared with placebo or no prophylaxis.

### **Evidence statements – clean surgery**

There is evidence that administration of antibiotics in craniotomy results in fewer wound infections compared with placebo. [EL = 1+]

There is evidence that administration of antibiotics in spinal surgery results in fewer wound infections compared with placebo. [EL = 1+]

There is evidence that pre- or perioperative antibiotics used as prophylaxis for breast cancer surgery results in fewer wound infections compared with placebo, although there is insufficient evidence to determine whether this effect is also true when antibiotics are compared with no prophylaxis. [EL = 1+]

There is insufficient evidence to determine the effect of antibiotic prophylaxis on wound infection in immediate breast reconstruction surgery with or without implants. [EL = 1+]

There is evidence that antibiotic prophylaxis during cardiac pacemaker surgery results in fewer infections compared with no antibiotic prophylaxis. [EL = 1+]

There is evidence that antibiotic prophylaxis reduces wound infection incidence in open-heart surgery compared with placebo. [EL = 1+]

There is evidence that antibiotic prophylaxis reduces wound infection incidence in thoracic surgery compared with placebo. [EL = 1+]

There is evidence that antibiotic prophylaxis reduces the incidence of wound infection compared with placebo in hernia repair in general and when hernioplasty is used. [EL = 1+]

However, currently there is evidence of no difference in wound infection rates when antibiotic prophylaxis or placebo is used in herniorrhaphy. [EL = 1+]

There is insufficient evidence available (owing to poor reporting) to determine the effect on wound infection in abdominal hysterectomy of antibiotic prophylaxis compared with placebo or no prophylaxis. [EL = 1- ]

There is evidence that prophylactic antibiotics result in fewer wound infections in non-elective caesarean sections and for all patients undergoing a caesarean delivery. [EL = 1+]

There is currently evidence of fewer wound infections when antibiotic prophylaxis is given in elective caesarean delivery compared with placebo or no prophylaxis. [EL = 1+]

There is evidence from two meta-analyses that single and multidose antibiotic prophylaxis results in fewer wound infections than use of placebo or no prophylaxis in surgery for long bone and other unspecified closed fractures. [EL = 1+]

There is evidence that antibiotic prophylaxis results in fewer wound infections than placebo in surgery for hip fracture. [EL = 1+]

There is currently evidence of no difference in superficial wound infection rates when antibiotic prophylaxis or placebo is given in hip fracture surgery. However, there is some evidence that deep infection rate is reduced with antibiotic prophylaxis compared with placebo. [EL = 1+]

There is evidence from one trial that the use of antibiotics results in fewer wound infections than placebo in patients undergoing leg amputation for arteriosclerosis. [EL = 1+]

There is evidence that the use of systemic antibiotics results in fewer wound infections in patients undergoing peripheral arterial reconstruction. [EL = 1+]

### **Evidence statements – clean-contaminated surgery**

There is evidence that there are fewer infections when patients are given antibiotic prophylaxis for contaminated/clean-contaminated head and neck cancer surgery compared with placebo. [EL = 1+]

There is evidence that antibiotic prophylaxis reduces wound infection incidence in gastroduodenal surgery compared with placebo or no antibiotic. [EL = 1+]

There is evidence that antibiotic prophylaxis reduces wound infection incidence in biliary tract surgery compared with placebo or no antibiotic. [EL = 1+]

There is evidence of no difference of effect of antibiotic prophylaxis compared with placebo for the prevention of wound infection in laparoscopic cholecystectomy. [EL = 1+]

There is evidence that systemic antibiotics result in fewer wound infections in surgery for appendicitis when compared with placebo. [EL = 1+]

There is evidence that there are fewer wound infections in surgery for appendicitis when single or multiple antibiotics given as a single dose preoperatively or perioperatively compared with placebo. [EL = 1+]

There is evidence that there are fewer wound infections in surgery for appendicitis when a single antibiotic is given at operation and subsequently given postoperatively as a single or multiple dose compared with placebo. [EL = 1+]

There is evidence that there are fewer wound infections in surgery for appendicitis when multiple antibiotics are given at operation and subsequently given postoperatively in multiple doses compared with placebo. [EL = 1+]

There is evidence that in children there is no difference of effect of antibiotic prophylaxis for non-complicated appendicitis. [EL = 1+] In children presenting with complicated appendicitis, there is evidence that antibiotics confer a protective effect against SSI. [EL = 1+]

There is evidence that antibiotic prophylaxis results in fewer wound infections than no antibiotic in colorectal surgery. [EL = 1+]

### **Evidence statement – contaminated surgery**

There is evidence that antibiotic prophylaxis reduces the incidence of SSI in open reduction of mandibular fracture. [EL = 1+]

### **Evidence statement – dirty surgery**

There is evidence that antibiotic prophylaxis results in fewer wound infections than placebo or no antibiotic in open limb fractures [EL = 1+]

### Summary of evidence

There is evidence that prophylactic administration of antibiotics results in fewer SSIs compared with no other antibiotic treatment or with placebo in:

- craniotomy [EL = 1+]
- spinal surgery [EL = 1+]
- breast cancer surgery [EL = 1+]
- pacemaker insertion [EL = 1+]
- open-heart surgery [EL = 1+]
- thoracic surgery [EL = 1+]
- hernioplasty [EL = 1+]
- emergency and elective caesarean section [EL = 1+]
- long bone and other unspecified closed fractures [EL = 1+]
- hip fractures [EL = 1+]
- open limb fractures [EL = 1+]
- amputation [EL = 1+]
- peripheral arterial reconstruction [EL = 1+]
- head and neck surgery [EL = 1+]
- open reduction of mandibular fracture [EL = 1+]
- gastroduodenal surgery [EL = 1+]
- open biliary surgery [EL = 1+]
- appendicectomy [EL = 1+]
- colorectal surgery. [EL = 1+]

There is evidence to show that prophylactic antibiotics are not effective in:

- herniorrhaphy [EL = 1+]
- laparoscopic cholecystectomy. [EL = 1+]

There is insufficient evidence that prophylactic administration of antibiotics results in fewer SSIs compared with no other antibiotic treatment or with placebo in:

- breast reconstruction with or without implants [EL = 1+]
- abdominal hysterectomy (clean-contaminated) [EL = 1+]
- uncomplicated appendicectomy in children. [EL = 1+]

#### *Clinical question*

For which types of surgery would prophylaxis be clinically and cost-effective? When should antibiotic prophylaxis be given – pre/peri/postoperatively?

### Health economics overview of evidence

Nineteen papers were identified for further review. Only three compared antibiotic prophylaxis with no antibiotic prophylaxis. One study was identified that compared a 24 hour prophylactic antibiotic regimen with a one-dose regimen.

One study<sup>88</sup> compared no antibiotic prophylaxis with antibiotic therapy. One study found no statistically significant difference in SSI rate in patients undergoing neck dissections<sup>89</sup> although this was based on retrospective data from 1977 to 1989. One study found a statistically significant difference in SSI rate in patients undergoing appendicectomies and colorectal operations.<sup>88</sup> One study was underpowered.<sup>90</sup> As none of these studies were carried out in the UK the costs are not generalisable to this setting.

The most recent study<sup>91</sup> was a Brazilian study that used historical controls. A 24 hour prophylactic antibiotic regimen was compared with one-dose antibiotic prophylaxis given at anaesthesia induction. No statistically significant difference was found between SSI rate (2% and 2.1%, respectively,  $P = 0.67$ ). A cost-minimisation analysis was thus carried out and using one dose of antibiotics was the lowest cost intervention. If similar SSI rates can be applied to a UK setting with reduced antibiotic prophylaxis, then a one-dose antibiotic prophylaxis protocol will be cost-saving compared with a 24 hour antibiotic regimen.

### Timing of antibiotic prophylaxis

A prospective observational study using logistic regression to analyse data collected from patients undergoing elective clean or clean-contaminated surgery at a teaching hospital examined the timing of antibiotic prophylaxis administration as a risk factor for SSI.<sup>92</sup> [EL = 2+] Patients were assigned to groups according to the time between their first dose of antibiotic prophylaxis and the initial surgical incision. The early group received prophylaxis 2–24 hours pre-incision, the preoperative group 0–2 hours pre-incision, the perioperative group up to 3 hours post-incision and the postoperative group received antibiotic prophylaxis 3–24 hours post-incision.

Forty-four of 2847 included patients (1.5%) developed SSI. Logistic regression demonstrated that there were statistically significantly more infections in the early and postoperative groups compared with the perioperative group (OR 4.3, 95% CI 1.8 to 10.4 and OR 5.8, 95% CI 2.4 to 13.8, respectively).

Results were further stratified according to the hour that prophylaxis was administered in relation to the time of surgery – the early group were excluded from this analysis. The lowest SSI rate occurred in patients receiving antibiotic prophylaxis 0–2 hours prior to surgery. A statistically significant trend was observed toward higher rates of infection with each successive hour that antibiotic administration was delayed after the surgical incision ( $z$  score = 2.00,  $P < 0.05$  Wilcoxon test).

### Evidence statement – timing of antibiotic prophylaxis

There is evidence that administration of antibiotic prophylaxis up to 2 hours preoperatively is associated with the lowest rates of infection in clean and clean-contaminated surgery. [EL = 2+]

### GDG interpretation

Many of these studies used antibiotics that are not in current use and some were used for prolonged periods but comparable studies using modern antibiotics could not now be conducted ethically with the use of a placebo. In certain types of surgery (for example, orthopaedic prosthetic surgery) the GDG felt that even in the absence of adequate studies antibiotic prophylaxis would be appropriate.

Antibiotics are inexpensive and are likely to be cost-effective compared with no antibiotic prophylaxis if they prevent SSI as the cost of treating an SSI is approximately £3,500.

There is evidence that a single dose at the time of operation is effective.

Where antibiotic prophylaxis is administered, a repeat dose is only indicated when there is excessive blood loss or if surgery is unexpectedly prolonged.

If there is significant unexpected contamination encountered during an operation or existing infection then prophylaxis should be converted into a treatment regime.

The risk of adverse events, *C. difficile* diarrhoea, resistance and drug hypersensitivity must be considered. The GDG felt that the lack of evidence on the effectiveness of prophylaxis in the following procedures is insufficient reason to withhold antibiotic prophylaxis:

- breast reconstruction with/without implants
- abdominal hysterectomy (clean-contaminated)
- elective caesarean section
- uncomplicated appendicectomy in children.

In some of these groups (abdominal hysterectomy, elective caesarean section and appendicitis in children), unforeseen infection or contamination may be encountered that would make antibiotic prophylaxis appropriate. In breast reconstruction the presence of an implant may increase the risk of infection.



**Recommendations on antibiotic prophylaxis**

Give antibiotic prophylaxis to patients before:

- clean surgery involving the placement of a prosthesis or implant
- clean-contaminated surgery
- contaminated surgery.

Do not use antibiotic prophylaxis routinely for clean non-prosthetic uncomplicated surgery.

Use the local antibiotic formulary and always consider potential adverse effects when choosing specific antibiotics for prophylaxis.

Consider giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia. However, give prophylaxis earlier for operations in which a tourniquet is used.

Before giving antibiotic prophylaxis, consider the timing and pharmacokinetics (for example, the serum half-life) and necessary infusion time of the antibiotic. Give a repeat dose of antibiotic prophylaxis when the operation is longer than the half-life of the antibiotic given.

Give antibiotic treatment (in addition to prophylaxis) to patients having surgery on a dirty or infected wound.

Inform patients before the operation, whenever possible, if they will need antibiotic prophylaxis, and afterwards if they have been given antibiotics during their operation.

# 6 Intraoperative phase

## 6.1 Hand decontamination

*Clinical question*

What is the clinical hand decontamination strategy to use between subsequent surgeries?

### Introduction

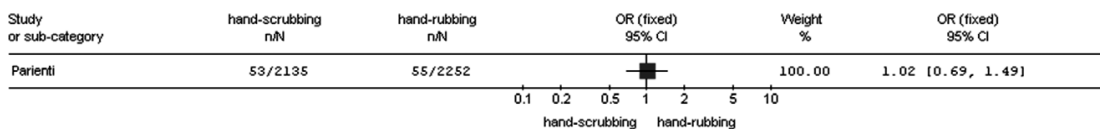
Hand decontamination prior to surgery is required to minimise the risk that either the resident flora of microorganisms that normally colonise the skin or transient organisms acquired by touch contaminate the surgical wound. While transient microorganisms are readily removed by soap and water, antiseptics such as alcohol or detergent solutions containing chlorhexidine and povidone-iodine are required to eliminate resident microorganisms that reside in deep crevices and hair follicles. Chlorhexidine has been shown to have a persistent suppressive effect against bacterial regrowth on the skin, potentially lasting throughout several operations. Although alcohol rapidly kills microorganisms, it does not physically remove organic material and it should, therefore, not be used when the hands are visibly soiled.

The operating team must decontaminate their hands many times a day. The regimen chosen should thus not damage the skin: it is often recommended that the first decontamination of the day should involve an antiseptic detergent at the sink with attention given to cleaning under the nails with a clean brush or pick. Scrubbing brush use on the skin is not recommended except for removal of 'ground-in' dirt. The purpose of the review was to evaluate the clinical effectiveness of hand decontamination for surgical interventions to prevent SSI.

### Overview of evidence

A cluster RCT<sup>93</sup> was identified.

The trial ( $n = 4823$  participants) looked at incidence of SSI when comparing surgical hand rubbing (SHR) with 75% aqueous alcohol solution (AAS) against surgical hand scrubbing (SHS) with 4% povidone-iodine or 4% chlorhexidine before surgery [EL = 1+]. Six surgical services took part in the study. Services were randomly assigned to the two intervention group clusters. Participants were patients undergoing clean or clean-contaminated surgery. The outcome of interest was the incidence of SSI. No statistically significant difference was found between the two hand decontamination techniques in the prevention of SSI (OR 1.02, 95% CI 0.69 to 1.49) (Figure 6.1).



**Figure 6.1** Comparison of hand scrubbing versus hand rubbing on SSI incidence in a cluster randomised trial

*Clinical question*

What is the cost-effective hand decontamination strategy to use between subsequent surgeries?

### Health economics overview of evidence

One study was included.<sup>94</sup>

A study<sup>94</sup> compared techniques established according to the recommendations for surgical hand disinfection of the French Society of Hospital Hygiene and the European recommendations. It

found that SHR was equivalent to SHS in preventing SSI after clean and clean-contaminated surgery. SHR reduced the cost of hand disinfection by 67%.

### Health economics evidence statement

In the French costing analysis,<sup>94</sup> SHR was found to be cost-saving, which was mainly due to the additional cost of water filters and sterile towels used in the SHS technique. The GDG thought sterile towels and water filters would not be used in the UK. The UK costing analysis therefore showed very little difference in the total costs of SHR or SHS techniques once these costs were removed.

### Evidence statement

There is evidence to suggest that there is no difference in the incidence of SSI between using alcohol hand rubbing with 75% AAS when compared with hand scrubbing with aqueous 4% povidone-iodine or 4% chlorhexidine. [EL = 1+]

### GDG interpretation

There is a concern that the evidence is derived from only one RCT in clean and clean-contaminated surgery. It is difficult to extrapolate these results to all types of surgical procedures.

Hand cleaning with alcohol rub or gel is less effective against the spores of *C. difficile* and therefore initial washing should be with an antiseptic surgical scrub solution using an alcoholic hand rub in between cases. In addition, gel can leave residual material on the hands. However, if the hands are contaminated, a full surgical scrub should be employed.

No evidence was identified concerning the use of brushes or picks. However the GDG felt that if either was to be used during the surgical scrub procedure, they should be single-use.

The economic analysis from this RCT may not have direct relevance to UK practice but suggests that the rubbing technique may be cheaper.

### Recommendations on hand decontamination

The operating team should wash their hands prior to the first operation on the list using an aqueous antiseptic surgical solution, with a single-use brush or pick for the nails, and ensure that hands and nails are visibly clean.

Before subsequent operations, hands should be washed using either an alcoholic hand rub or an antiseptic surgical solution. If hands are soiled then they should be washed again with an antiseptic surgical solution.

## 6.2 Incise drapes

### *Clinical questions*

Is the use of incise drapes clinically and cost-effective in reducing the incidence of surgical site infection?

Which incise drapes are clinically and cost-effective in reducing the incidence of surgical site infection?

### Introduction

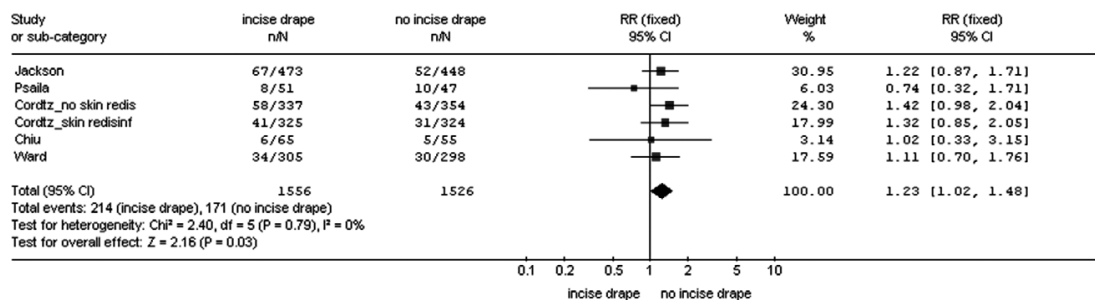
Incise drapes are adhesive films used to cover the skin at the site of the incision with the intention of minimising the contamination of the operative wound by microorganisms colonising the skin of the patient around the operative site. The purpose of the review was to address the clinical effectiveness of using incise drapes during surgery in the prevention of SSI.

### Overview of evidence

A systematic review<sup>95</sup> and an RCT<sup>96</sup> were identified.

*Incise drapes (without added antimicrobial properties) compared with no incise drapes*

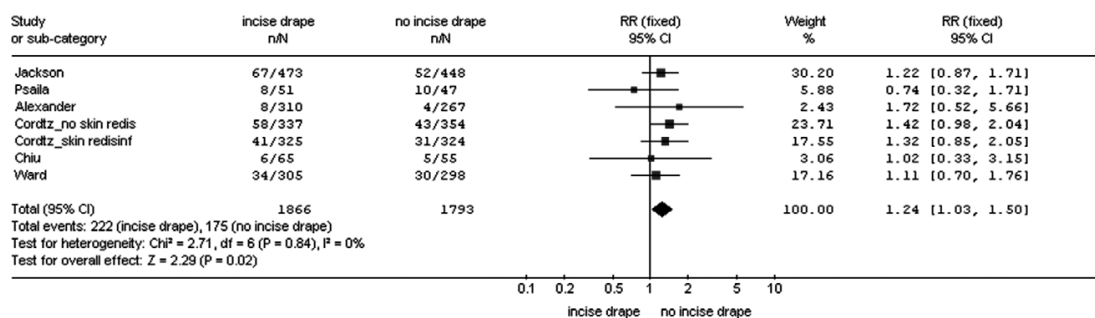
Five trials ( $n = 3082$ ) from a well-conducted systematic review<sup>95</sup> examined the effect of the use of surgical incise drapes without added antimicrobials on the incidence of SSI. [EL = 1+] Surgery performed included general or abdominal surgery, caesarean sections and hip surgery. The main outcome considered was SSI even if the definition criteria varied among the studies. A meta-analysis (Figure 6.2) was performed pooling all the trials together ( $I^2 = 0\%$ ). It showed a statistically significant difference between the two groups, with more SSI events in the incise drape group than in the no incise drape group (RR 1.23, 95% CI 1.02 to 1.48).



**Figure 6.2** Meta-analysis of five trials comparing the effect of the use of incise drapes (without added antimicrobial properties) versus no use of incise drapes on SSI incidence

One RCT<sup>96</sup> ( $n = 577$ ) examined the role of adhesive incise drapes in surgical patients for the prevention of SSI. [EL = 1+] It found no statistically significant results (RR 1.72, 95% CI 0.52 to 5.66).

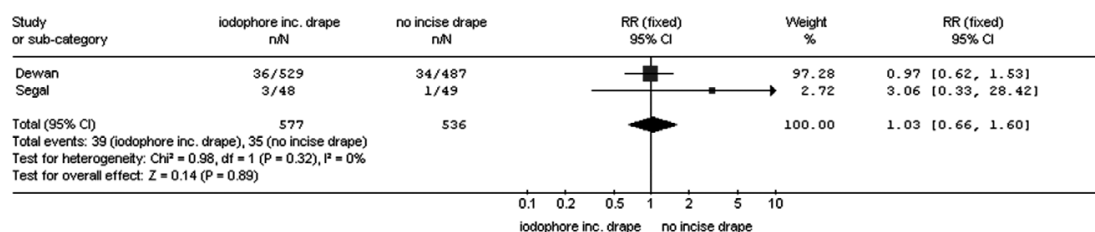
The trial did not bring substantial changes to the overall results (RR 1.24, 95% CI 1.03 to 1.50,  $I^2 = 0\%$ ) when added to the previous meta-analysis (Figure 6.3).



**Figure 6.3** Meta-analysis of six trials comparing the effect of the use of incise drapes (without added antimicrobial properties) versus no use of incise drapes on SSI incidence

*Iodophor-impregnated incise drapes compared with no incise drapes*

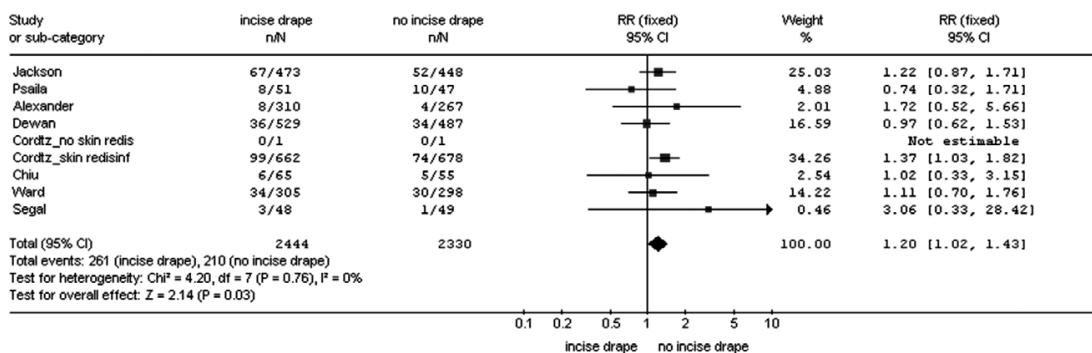
Two RCTs from the above systematic review<sup>95</sup> were included under this comparison. The studies ( $n = 1113$  participants) investigated whether the use of incise drapes impregnated with iodophor had an effect in the incidence of SSI when compared with no incise drapes. [EL = 1+] Participants were patients undergoing abdominal and cardiac surgical procedures. In both studies SSI was reported. The data from the two trials were combined in a meta-analysis ( $I^2 = 0\%$ ) (Figure 6.4). The analysis showed no statistically significant difference (RR 1.03, 95% CI 0.66 to 1.60).



**Figure 6.4** Meta-analysis of two trials comparing the effect of the use of iodophor impregnated incise drapes versus no use of incise drapes on SSI incidence

*Incise drapes without added antimicrobial properties and iodophor-impregnated incise drapes compared with no incise drapes*

When all the trials were pooled together in a meta-analysis (Figure 6.5), a statistically significant difference was found that favoured the non-use of incise drapes in the prevention of SSI when compared with the use of an incise drape (whether impregnated with an antimicrobial or not) (RR 1.20, 95% CI 1.02 to 1.43).



**Figure 6.5** Meta-analysis of eight trials comparing the effect of the use of incise drapes versus no use of incise drapes on SSI incidence

**Evidence statements**

There is evidence to suggest that the use of non-iodophor-impregnated incise drapes increase the risk of SSI. [EL = 1+]

There is evidence to suggest that there is no difference in risk of SSI between iodophor-impregnated incise drapes and no incise drape. [EL 1+]

**GDG interpretation**

Although the use of non-iodophor-impregnated incise drapes is routine in some operations (such as prosthetic joint or graft surgery), they may marginally increase the risk of SSI. The GDG recognised that adhesive drapes may have a role in maintaining the integrity of the operative site/field.

**Recommendations on incise drapes**

Do not use non-iodophor-impregnated incise drapes routinely for surgery as they may increase the risk of surgical site infection.

If an incise drape is required, use an iodophor-impregnated drape unless the patient has an iodine allergy.

**6.3 Use of sterile gowns**

*Clinical question*  
 Is the use of gowns clinically effective in reducing the incidence of surgical site infection?

**Overview of evidence**

No studies were identified that examined the use of sterile gowns in the prevention of SSI.

**Evidence statement**

There is insufficient evidence to determine whether the use of sterile gowns is clinically effective in the prevention of SSI.

### GDG interpretation

It is good practice to use sterile gowns in the operating area to prevent healthcare workers and patients from being exposed to the risk of contamination. However, there is no evidence that this practice has any effect on the incidence of SSI.

The GDG consensus was that the operating team should wear sterile gowns in the operating theatre as this is important in the maintenance of theatre discipline, and may therefore contribute to minimising the risk of SSI.

#### Recommendation on use of sterile gowns

The operating team should wear sterile gowns in the operating theatre during the operation.

## 6.4 Disposable or reusable drapes and gowns

### Clinical question

Is the use of reusable or disposable surgical drapes and gowns related to surgical site infection?

### Introduction

Surgical attire is intended to function as a barrier between the surgical field and the potential sources of microorganisms in the environment, skin of the patient or the staff involved in the operation. It also performs an additional function of protecting the operator from exposure to blood or body fluids. The extent to which the materials used for gowns and drapes acts as a barrier depends on the closeness of the weave and water-resistant properties. The purpose of the review was to assess whether the use of drapes and gowns influences the rate of SSI.

### Overview of evidence

Two RCTs were identified.<sup>97,98</sup>

The two RCTs ( $n = 496$  participants<sup>98</sup> and  $n = 505$  participants<sup>97</sup>) looked at the effects of using disposable drapes and gowns compared with reusable drapes and gowns in the incidence of SSI. [EL = 1+] Participants in one trial<sup>98</sup> were booked for isolated coronary artery surgery and in the other trial<sup>97</sup> participants underwent elective surgery (the most common procedures were hernia repair and uncomplicated cholecystectomy). Surgical site infection was the main outcome measured although the definition criteria for SSI were different in the two studies. Neither RCT found a statistically significant difference between the use of disposable or reusable drapes and gowns (SSI RR 0.99,<sup>97</sup> 95% CI 0.30 to 3.28,  $P = 0.98$ ) (Figure 6.6), (Sternal SSI RR 1.02,<sup>98</sup> 95% CI 0.46 to 2.29) (Figure 6.7) and (Leg SSI RR 0.78,<sup>98</sup> 95% CI 0.45 to 1.35,  $P = 0.37$ ) (Figure 6.8).

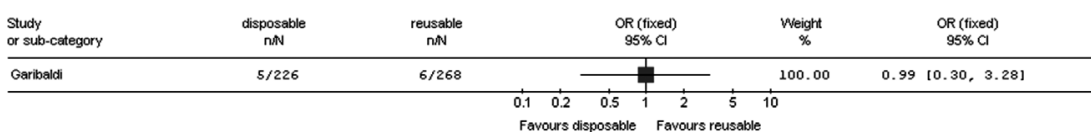


Figure 6.6 Comparison of the effect of using disposable versus reusable gowns on SSI rates

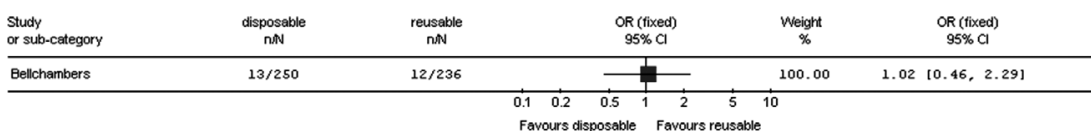


Figure 6.7 Comparison of the effect of using disposable versus reusable gowns on sternal SSI rates in CABG surgery

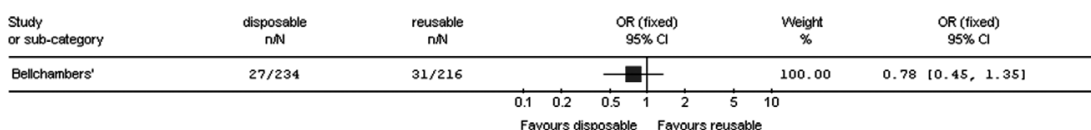


Figure 6.8 Comparison of the effect of using disposable versus reusable gowns on leg harvest site SSI rates in CABG surgery

**Evidence statement**

There is evidence of no difference in the incidence of SSI between the use of reusable drapes and gowns when compared with the use of disposable drapes and gowns. [EL = 1+]

**GDG interpretation**

There is evidence to show that there is no difference between reusable and disposable drapes and gowns in terms of SSI incidence. However, the GDG recognised that since these studies were undertaken there have been technological developments in the materials used to make both reusable and disposable surgical drapes and gowns that may invalidate this interpretation. In addition, industry standards have subsequently been introduced, for example, BS EN 13795.

Although the use of reusable or disposable drapes and gowns is not apparently an issue with regard to risk of SSI, disposable drapes and gowns would be appropriate when the patient was considered to be at risk of infections such as HIV.

**Research recommendation on disposable or reusable drapes and gowns**

What is the cost-effectiveness of new materials used in reusable and disposable operative drapes and gowns in reducing the incidence of surgical site infection?

**6.5 Gloves***Clinical questions*

Is there a difference between double- versus single-gloving affecting the incidence of surgical site infection?

Does the puncture rate of gloves correlate to the incidence of surgical site infection?

**Introduction**

Modern gloves are made of latex and are single-use, sterile and disposable. Other varieties are available for those allergic to latex. Use of gloves is part of the aseptic surgical ritual to reduce the risk of introducing infection. They protect the operating team's hands and also protect the team from viral transmission from patients' body fluids (hepatitis and HIV) during surgery. The use of two pairs of gloves has also been suggested as a means of reducing glove puncture and hence potential contamination of the surgical wound by microorganisms from the operator's skin. The purpose of the review was to assess whether wearing two pairs of gloves affects the rate of SSI.

**Overview of evidence***Double-gloving compared with single-gloving*

No studies were identified that investigated the use of double-gloving compared with single-gloving in the prevention of SSI.

*Glove puncture rate*

From a well-conducted systematic review two RCTs were identified.<sup>99,100</sup>

Two RCTs ( $n = 50$  participants<sup>99</sup> and  $n = 71$  participants<sup>100</sup>) examined the correlation between the use of different double-gloving techniques and glove puncture rates and the incidence of SSI. [EL = 1–] Patients were undergoing elective orthopaedic procedures. The two studies had glove perforation as their main outcome and SSI rate as the secondary outcome. There were no SSI cases in either trial.

**Evidence statements**

There is insufficient evidence to determine whether there is a difference between double- or single-gloving in terms of affecting SSI rates.

There is not enough evidence to establish a correlation between the incidence of SSI and glove puncture rate.

### GDG interpretation

There is no available evidence that double-gloving reduces the risk of SSI or that glove perforation increases the risk of SSI. However, the GDG recognised current practice for double-gloving in certain circumstances when the risk of glove perforation and its consequences for contamination of the operative field (in prosthetic surgery for example) is high.

#### Recommendation on gloves

Consider wearing two pairs of sterile gloves when there is a high risk of glove perforation and the consequences of contamination may be serious.

## 6.6 Antiseptic skin preparation

### *Clinical question*

Is the use of preoperative skin antiseptics clinically effective in the prevention of surgical site infection?

### Introduction

When the skin is incised, microorganisms colonising the surface may contaminate the exposed tissues and subsequently cause SSI. Skin antiseptics are therefore used to reduce the number of microorganisms on the skin around the incision. The resident flora that normally reside in crevices and skin appendages are not readily removed by soap and water but their numbers can be reduced by antiseptics such as chlorhexidine and povidone-iodine. Chlorhexidine has been demonstrated to have a persistent suppressive action against bacterial regrowth on the skin potentially lasting throughout the operation. Alcohol-based solutions have the advantage of being both microbicidal and drying rapidly. The purpose of the review was to determine the clinical effectiveness of preoperative skin antiseptics for the prevention of SSI.

### Overview of evidence

One systematic review and four further RCTs were identified.

One well-conducted systematic review (six trials,  $n = 2850$  participants) was identified that examined the effects of preoperative skin antiseptics for prevention of SSI in clean surgery only. [EL = 1+] Three trial reports from this review were included, with one report describing two trials – preliminary and definitive.

A range of operations were undertaken in the eight included trials: CABG, elective laparotomy and non-laparoscopic abdominal operations. Two trials did not specify the operations. The antiseptics investigated were iodine/iodophors (including povidone-iodine), alcohol at various concentrations, and chlorhexidine.

### Antiseptic compared with no antiseptic

One quasi-RCT<sup>101</sup> conducted in an outpatient setting examined the effects of showering with soap then saline irrigation of the operative site compared with showering with soap and povidone-iodine scrub and paint of operative site. [EL = 1–] Although this study was adequately powered, no SSIs were found in either treatment arm.

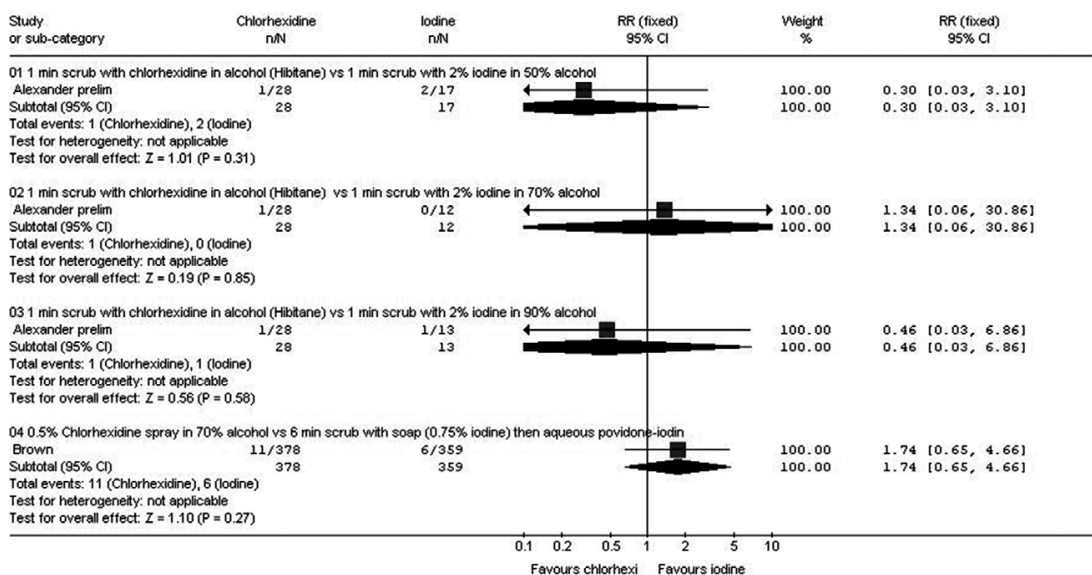
### Antiseptic 1 compared with antiseptic 2

#### *Chlorhexidine compared with iodine*

Two trials that examined chlorhexidine compared with iodine were identified in the systematic review. One preliminary trial<sup>96</sup> compared chlorhexidine in alcohol with 2% iodine in three different concentrations (50%, 70% and 90%) of alcohol, although an iodophor incise drape was used in all operations. [EL = 1+] The number of participants in each treatment arm was small (total  $n = 70$ ) and no statistically significant findings were reported (RR 0.30, 95% CI 0.03 to 3.10, RR 1.34, 95% CI 0.06 to 30.86 and RR 0.46, 95% CI 0.03 to 6.86, respectively) (Figure 6.9).



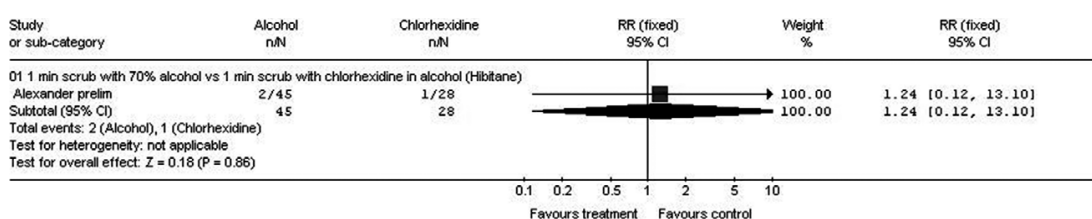
The other trial<sup>102</sup> ( $n = 737$  participants) compared the use of chlorhexidine spray 70% in alcohol with scrubbing and painting with iodine soap and aqueous povidone-iodine paint. [EL = 1+] No statistically significant difference in SSI rate between the two groups was found (RR 1.74, 95% CI 0.65 to 4.66) (Figure 6.9).



**Figure 6.9** Comparison of the effect of using chlorhexidine versus iodine in alcohol for skin preparation on SSI rates in two trials

*Alcohol compared with chlorhexidine*

One preliminary trial<sup>96</sup> compared a 1 minute scrub with 70% alcohol with a 1 minute scrub with chlorhexidine in alcohol (Hibitane®). [EL = 1+] Both arms used iodophor polyester incise drape. This comparison was underpowered and there were no statistically significant differences in SSI rate (RR 1.24, 95% CI 0.12 to 13.10) (Figure 6.10).



**Figure 6.10** Comparison of the effect of using alcohol versus chlorhexidine for skin preparation on SSI incidence

*Iodine 1 compared with iodine 2*

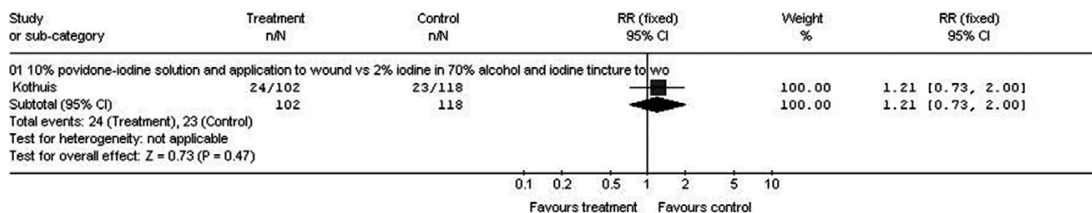
Iodine in alcohol compared with iodine in different concentrations of alcohol:

One preliminary trial<sup>96</sup> ( $n = 42$  participants) that compared 2% iodine in three different concentrations (50%, 70% and 90%) of alcohol was identified. [EL = 1+] It was underpowered to detect any differences among the three iodine in alcohol solutions tested and used an iodophor incise drape throughout. Comparisons were made of 2% iodine in 50% versus 70% alcohol, 50% versus 90% alcohol and 70% versus 90% alcohol and no statistically significant differences in SSI incidence were reported (RR not estimable – no events in either group, RR 0.26, 95% CI 0.01 to 5.89 and RR 0.36, 95% CI 0.02 to 8.05, respectively).

Aqueous iodine compared with iodine in alcohol:

One quasi-RCT<sup>103</sup> ( $n = 220$  participants) found little difference between aqueous iodine and iodine in alcohol. [EL = 1–] Patients’ skin disinfected with 10% povidone-iodine solution which was then applied to wound edges was compared with disinfection with 2% iodine in 70% alcohol

and then application of iodine tincture to wound edges. No statistically significant difference in SSI incidence between the two groups was found (RR 1.21, 95% CI 0.73 to 2.00) (Figure 6.11).



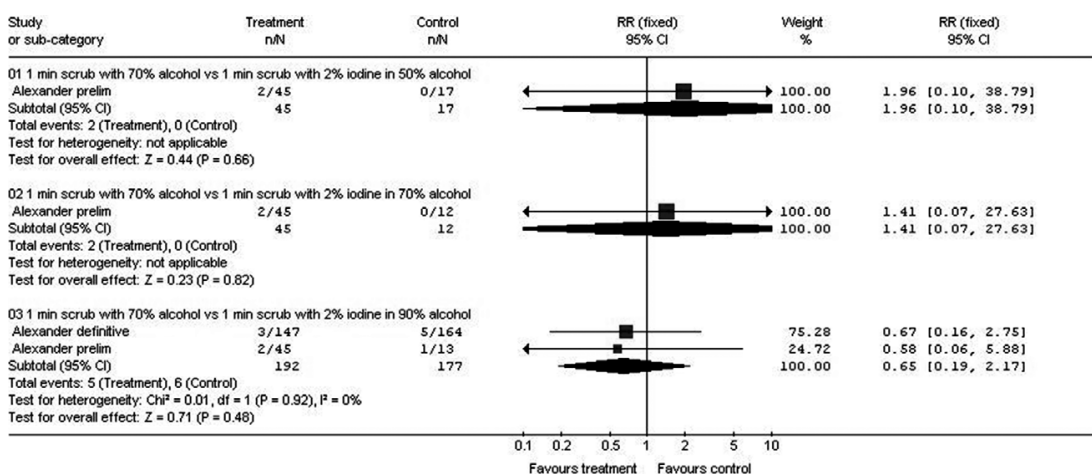
**Figure 6.11** Comparison of the effect of using aqueous iodine versus iodine in alcohol for skin preparation on SSI incidence in a quasi-randomised trial

#### *Alcohol compared with iodine in alcohol*

Two studies<sup>96</sup> (preliminary and definitive) made four comparisons of alcohol versus iodine in alcohol, although antimicrobial/iodophor drapes were used throughout. [EL = 1+]

In the preliminary trial ( $n = 87$  participants), comparisons were made of 70% alcohol versus 2% iodine in 50% alcohol, 70% alcohol versus 2% iodine in 70% alcohol and 70% alcohol versus 2% iodine in 90% alcohol and no statistically significant differences in SSI incidence were found (RR 1.96, 95% CI 0.10 to 38.71, RR 1.41, 95% CI 0.07 to 27.63 and RR 0.58, 95% CI 0.06 to 5.88, respectively) (Figure 6.12).

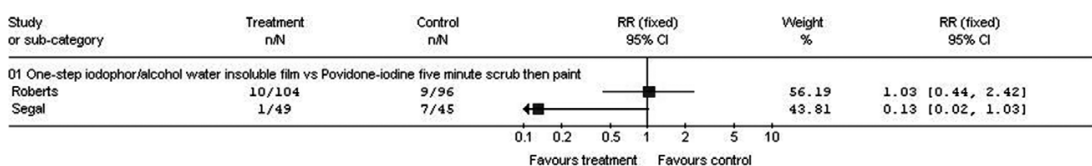
In the definitive trial ( $n = 311$  participants), the incidence of SSI was reported after preoperative antisepsis using 70% alcohol compared with 2% iodine in 90% alcohol. No statistically significant difference in SSI incidence between the two groups was found (RR 0.67, 95% CI 0.16 to 2.75) (Figure 6.12).



**Figure 6.12** Comparisons of the effect on SSI incidence of scrubbing with 70% alcohol versus 2% iodine in 50% alcohol and 70% alcohol versus 2% iodine in 70% alcohol in two trials and a meta-analysis of two trials comparing the effect on SSI incidence of scrubbing with 70% alcohol versus 2% iodine in 90% alcohol

#### *Iodophor film compared with iodine/iodophor scrub and paint*

Two RCTs identified from the Cochrane review<sup>104</sup> examined the effects of an iodophor-in-alcohol, film-forming, water-insoluble antiseptic compared with an aqueous iodophor scrub and paint. [EL = 1+] Heterogeneity prevented pooling of results ( $I^2 = 71.2\%$ ) and no statistically significant differences in SSI incidence between groups were found in either study of clean surgery (RR 1.03, 95% CI 0.44 to 2.42 and RR 0.13, 95% CI 0.02 to 1.03, respectively) (Figure 6.13).



**Figure 6.13** Comparison of the effect of using iodophor film versus iodine/iodophor scrub and paint for skin preparation on SSI incidence in two trials

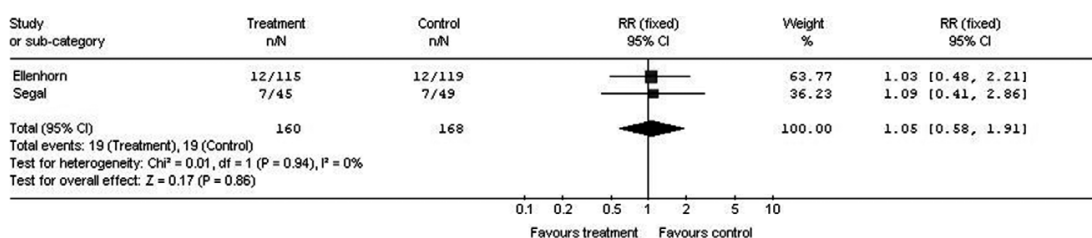
### One antiseptic application compared with more than one application

Two studies compared single and multiple applications of povidone-iodine.

One trial<sup>105</sup> compared a single application of povidone-iodine paint versus a 5 minute scrub with povidone-iodine followed by povidone-iodine paint; both solutions were aqueous. [EL = 1+]

One trial<sup>106</sup> compared a single application of povidone-iodine paint versus a 5 minute scrub with povidone-iodine soap followed by aqueous povidone-iodine paint, and was designed as an equivalence study. [EL = 1+]

The meta-analysis (Figure 6.14) showed there was little difference between single and multiple applications, although the confidence interval was fairly wide (RR 1.05, 95% CI 0.58 to 1.91).



**Figure 6.14** Meta-analysis of two trials comparing the effect on SSI incidence of skin preparation by application of povidone-iodine paint versus by a 5 minute povidone-iodine scrub followed by povidone-iodine paint application

### Health economics overview of evidence

No evidence was identified that met the inclusion criteria for the health economics analysis. The unit costs of various skin antiseptics, for skin preparation before surgery, are presented in the Table 6.1.

**Table 6.1** Costs of chlorhexidine and povidone-iodine skin antiseptics<sup>107</sup>

Solution	Quantity	Cost
Chlorhexidine 0.05%	1000 ml	£0.77
Povidone-iodine:		
Antiseptic paint 10%	8 ml	£0.93
Alcoholic solution 10%	500 ml	£1.83
Antiseptic solution 10%	500 ml	£1.68
Skin cleanser solution 4%	250 ml	£1.97
Surgical scrub 7.5%	500 ml	£1.70

### Evidence statements

There is evidence from a single quasi-RCT that there is no difference in SSI rate with or without an antiseptic for clean surgery in an outpatient setting. [EL = 1-]

There is evidence from one RCT that shows no difference in SSI rate between preoperative skin preparation with alcohol-based chlorhexidine spray or iodine soap/aqueous povidone-iodine paint. [EL = 1+]

There is insufficient evidence from one underpowered RCT to establish whether there is any difference in SSI rate following preoperative skin preparation with chlorhexidine or alcohol. [EL = 1+]

There is insufficient evidence from one underpowered RCT to establish whether there are any differences in SSI rate following preoperative skin preparation with 2% iodine in 50%, 70% or 90% alcohol. [EL = 1+]

There is insufficient evidence from a single quasi-RCT to determine whether preoperative skin preparation with aqueous iodine or iodine in alcohol affects the rate of SSI. [EL = 1-]

There is insufficient evidence to demonstrate any difference on SSI rate of adding free iodine to an alcohol-based scrub solution or using alcohol as a preoperative skin preparation. [EL = 1+]

There is insufficient evidence to demonstrate any difference on SSI rate of using an iodophor-in-alcohol, film-forming, water-insoluble antiseptic compared with an aqueous iodophor scrub and paint for preoperative skin preparation. [EL = 1+]

There is evidence from meta-analysis of two RCTs that there is no difference in SSI rate following preoperative skin preparation by scrubbing and painting or painting alone with an aqueous solution of povidone-iodine. [EL = 1+]

### Health economics evidence statements

There is no evidence of a difference of effect between the use of chlorhexidine and the use of povidone-iodine in the skin preparation prior to surgery on the prevention of SSI. Both antiseptics have similar costs.

### GDG interpretation

Only one study of poor quality addressed whether *any* skin preparation should be used prior to the skin incision and this was in an outpatient setting and showed no difference in the incidence of SSI. Most of the other comparisons involved small sample sizes from which interpretations cannot be made. However, the GDG considered skin preparation to have a clear theoretical basis and to be an important part of surgical discipline.

The GDG highlighted the need for safe theatre practice when using alcoholic antiseptic skin preparations prior to incision with diathermy.

There is no evidence of difference between chlorhexidine and povidone-iodine (either aqueous or alcohol-based preparation) and the costs are similar.

### Recommendations on antiseptic skin preparation

Prepare the skin at the surgical site immediately before incision using an antiseptic (aqueous or alcohol-based) preparation: povidone-iodine or chlorhexidine are most suitable.

If diathermy is to be used, ensure that antiseptic skin preparations are dried by evaporation and pooling of alcohol-based preparations is avoided.

## 6.7 Diathermy

### *Clinical question*

Does use of diathermy for surgical incisions affect the rate of surgical site infection?

### Introduction

Diathermy is a technique used for coagulating bleeding vessels and cutting tissues. Alternating current with a high frequency creates a localised heating effect that can be accurately applied to tissues. The use of diathermy to gain access through an incision, instead of the use of scalpel or scissors, is controversial as it may cause more tissue damage although it might reduce the incidence of postoperative haematoma. The purpose of this review was to determine whether the use of diathermy to make an incision causes more SSIs.

### Overview of evidence

Eight RCTs were identified.

In total, eight trials<sup>108-115</sup> ( $n = 1122$  patients) were included, with patients undergoing surgery for abdominal or thoracic operations, radial artery harvesting, cholecystectomy, mastectomy for breast cancer and gastrectomy for gastric cancer. No study specified that children were included.

Incisions were made with various types of cutting instrument and were grouped as scalpel, scissors, diathermy (cautery unit, electrocautery, electrosurgery, diathermy scissors, electrocautery scalpel and monopolar electrosurgery), laser (carbon dioxide and Nd:YAG) and ultrasonic scalpel (Ultracision® harmonic shears).

*Diathermy compared with scalpel or scissors*

Six RCTs<sup>108-113</sup> ( $n = 1002$  participants) compared the effect on SSI rate of incision made with diathermy or scalpel/scissors. [EL = 1+] Meta-analysis (Figure 6.15) showed that there was no statistically significant difference between the use of diathermy compared with scalpel or scissors for incisions (OR 0.78, 95% CI 0.51 to 1.20).

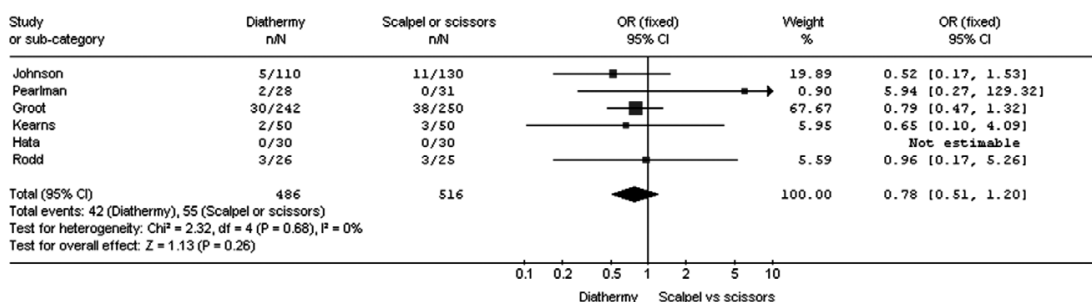


Figure 6.15 Meta-analysis of six trials comparing the effect on SSI incidence of using diathermy versus scalpel or scissors for incision

*Diathermy compared with laser*

Two trials<sup>112,114</sup> ( $n = 78$  participants) examined the comparative effect on SSI incidence following incision made with diathermy or laser. Both trials involved patients undergoing cholecystectomy, but both had included few patients in treatment arms.

One trial of 21 patients in total reported a protective effect of diathermy use that nearly reached statistical significance (OR 0.10, 95% CI 0.01 to 1.10).<sup>114</sup> [EL = 1+] The other trial showed no statistical difference in SSIs with the use of diathermy compared with laser (OR 2.15, 95% CI 0.10 to 25.19).<sup>112</sup> [EL = 1+] Heterogeneity prevented pooling of results ( $I^2 = 67.4\%$ ) (Figure 6.16).

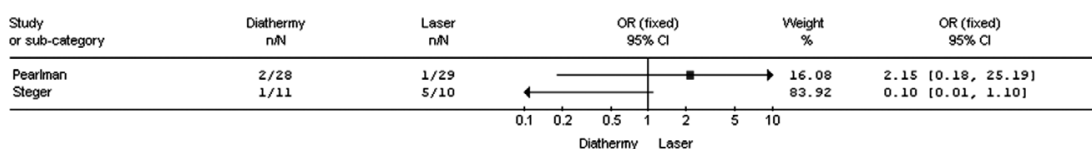


Figure 6.16 Comparison of the effect of using diathermy versus laser for incision on SSI rates

*Diathermy compared with ultrasonic scalpel*

Two trials compared the relative effects of using diathermy with those of ultrasonic scalpel for incision on the incidence rate of SSI, although both studies were underpowered.

One study reported no SSIs in either treatment group<sup>109</sup> [EL = 1+] and the other showed no statistically significant difference in SSI incidence between groups (OR 3.35, 95% CI 0.32 to 35.36)<sup>115</sup> (Figure 6.17). [EL = 1+]

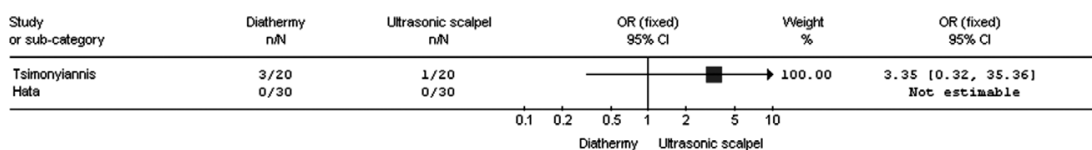


Figure 6.17 Comparison of the effect of using diathermy versus ultrasonic scalpel for incision on SSI rates

### Evidence statements

There is evidence of no difference in SSI incidence following incisions made by scalpel or diathermy. [EL = 1+]

There is insufficient evidence on whether the use of diathermy compared with laser or ultrasonic scalpel for incisions has an effect on SSI incidence. [EL = 1+]

### GDG interpretation

The evidence suggests that there is no difference between rates of SSI where diathermy is used to make an incision compared with conventional techniques.

There is no difference between diathermy and laser or harmonic scalpel to make an incision on the incidence of SSI.

#### Recommendation on diathermy

Do not use diathermy for surgical incision to reduce the risk of surgical site infection.

## 6.8 Maintaining patient homeostasis

During surgery, particularly with a general anaesthetic, patient homeostasis has to be maintained by the operating team. All tissues heal most effectively in optimal conditions of oxygenation, perfusion and body temperature. This review examines the maintenance of oxygenation, perfusion and blood glucose for the reduction of SSIs.

### 6.8.1 Warming

The effects of maintenance of normothermia for the prevention of SSI are addressed in the 'Inadvertent perioperative hypothermia' guideline (NICE clinical guideline 65), available from [www.nice.org.uk/CG65](http://www.nice.org.uk/CG65).

#### Recommendation on maintaining patient homeostasis (warming)

Maintain patient temperature in line with 'Inadvertent perioperative hypothermia' (NICE clinical guideline 65).

### 6.8.2 Oxygenation

#### *Clinical question*

Is patient perioperative oxygenation clinically effective for the prevention of surgical site infection?

#### Introduction

All tissues require an adequate level of oxygenation to heal effectively without the risk of SSI. Tissue oxygenation is determined by oxygen delivery, which in turn is dependent on tissue blood flow, the degree of oxygen saturation of the circulating haemoglobin, the level of oxygen dissolved in plasma and local tissue conditions that may influence oxygen uptake. The purpose of the review was to determine the clinical effectiveness of perioperative administration of higher oxygen concentrations/supplemental oxygen for the prevention of postoperative SSI.

#### Overview of the evidence

Five RCTs were identified.

*Perioperative high oxygen concentration compared with perioperative low oxygen concentration*  
Four RCTs<sup>116–119</sup> ( $n = 989$  adults) examined the effect of the administration of high concentrations of oxygen during surgery and following surgery on the incidence of SSI. [EL = 1+] The participants

were adults booked for elective surgery. Incidence of SSI was the primary outcome measured in all studies, although definitions varied among studies.

Two of the studies ( $n = 500$  adults<sup>116</sup> and  $n = 291$  adults<sup>117</sup>) found a statistically significant difference favouring the administration of high concentrations of oxygen in the prevention of SSI (OR 0.43, 95% CI 0.22 to 0.86 and OR 0.54, 95% CI 0.30 to 0.97, respectively) (Figure 6.18). Another of the studies<sup>118</sup> ( $n = 160$  adults) found a statistically significant difference favouring the low oxygen concentrations group (OR 2.63, 95% CI 1.11 to 6.20) (Figure 6.19). The smaller study<sup>119</sup> ( $n = 38$  adults) found no statistically significant difference between the two groups (OR 0.63, 95% CI 0.09 to 4.26) (Figure 6.18).

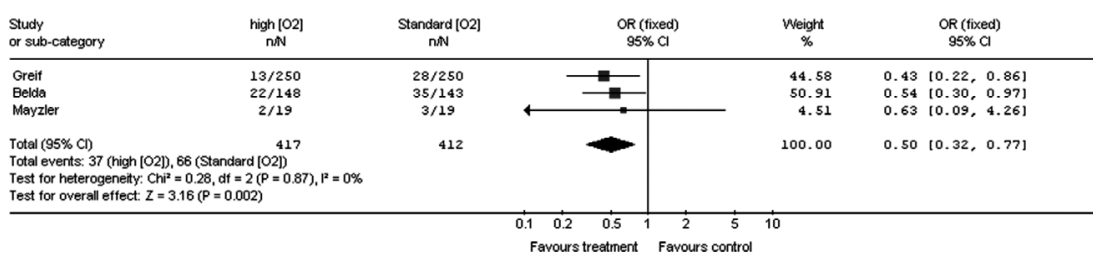


Figure 6.18 Meta-analysis of three trials comparing the effect on SSI incidence of high versus low perioperative oxygen concentrations

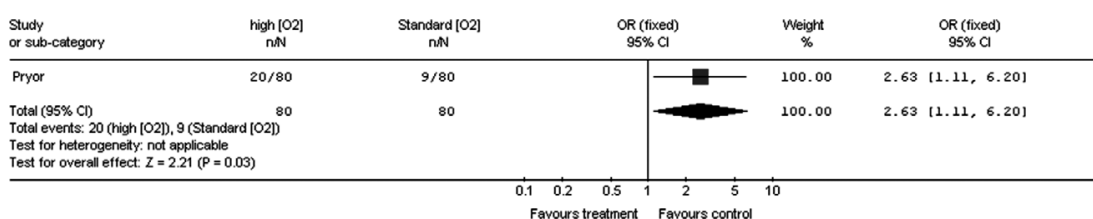


Figure 6.19 Comparison of the effect on SSI incidence of high versus low perioperative oxygen concentrations

Analysis of these four RCTs presented significant heterogeneity ( $I^2 = 74.5\%$ ) attributable to one of the studies.<sup>118</sup> Removal of the heterogeneous study showed a statistically significant difference favouring the administration of high concentrations of oxygen (OR 0.50, 95% CI 0.32 to 0.77) (Figure 6.18).

#### Postoperative supplemental oxygenation compared with standard treatment

A single RCT<sup>120</sup> ( $n = 24$  participants) compared the effects of postoperative oxygenation administered in the recovery room with the standard postoperative treatment, where no oxygenation was provided, on the healing process of the wounds. [EL = 1–] The participants were patients undergoing cervical spine surgical procedures. No SSI case (ASEPSIS score > 20) was reported and therefore no statistically significant difference was found between the two groups.

#### Evidence statements

There is evidence to suggest that higher inspired oxygen concentrations in the perioperative period reduce SSI rates when compared with lower oxygen concentrations. [EL = 1+]

There is insufficient evidence to suggest that there is a difference in SSI rates when supplemented oxygen is used in the recovery room. [EL = 1–]

#### GDG interpretation

There is concern over trial methodology and whether a fraction of inspired oxygen ( $\text{FiO}_2$ ) of 80% can be achieved in the recovery room. It is normal practice to ensure that oxygenation in the recovery room is optimal (sufficient to provide more than 95% haemoglobin saturation). Giving an  $\text{FiO}_2$  of more than 40% may not offer any further benefit. Patients with chronic obstructive pulmonary disease (COPD) might well be put at a disadvantage by an  $\text{FiO}_2$  above 40%.

The physiological mechanisms underlying the use of an FiO<sub>2</sub> of 80% to reduce the incidence of SSI are unclear. However, optimisation of perioperative oxygen delivery by careful regard to fluid balance, inotropes, blood glucose control and warming has been shown as a benefit in secondary outcome measures such as reduction of length of stay and this may form the basis of future research, in particularly in relation to the incidence of SSI.

**Recommendation on maintaining patient homeostasis (oxygenation)**

Maintain optimal oxygenation during surgery. In particular, give patients sufficient oxygen during major surgery and in the recovery period to ensure that a haemoglobin saturation of more than 95% is maintained.

**Research recommendation on maintaining patient homeostasis (oxygenation)**

What is the value of supplemented oxygenation in the recovery room in the prevention of surgical site infection? What are the likely mechanisms of action?

*Why this is important*

There have been several randomised control trials (RCTs) that show a contradictory effect of supplemental oxygenation in the recovery room period, some showing benefit, some not. Two separate trials indicate that surgical site infection rates can be halved simply by increasing the amount of inspired oxygen. However, a fraction of inspired oxygen (FiO<sub>2</sub>) of 0.8 cannot be achieved using a face mask, and all patients already receive an increased FiO<sub>2</sub> to give a haemoglobin saturation of at least 95% by their anaesthetist during the operation and in the immediate postoperative period. The mechanism for improved blood oxygen carriage due to increased FiO<sub>2</sub> is physiologically not clear. However, this simple, cheap intervention deserves further investigation.

**6.8.3 Perfusion**

*Clinical question*

What is the clinical effectiveness of perioperative perfusion and hydration for the prevention of surgical site infection?

**Introduction**

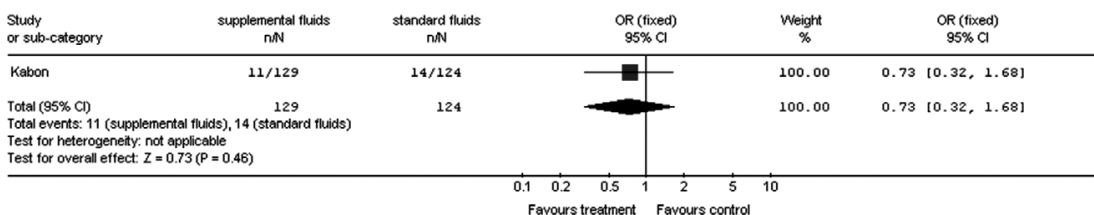
Patients should be optimally hydrated, in particular, prior to general anaesthetic. The purpose of the review was to determine the clinical effectiveness of perioperative perfusion and hydration for the prevention of SSI.

**Overview of the evidence**

A single RCT was identified.

*Supplemental perioperative fluid management compared with standard perioperative fluid management*

The RCT<sup>121</sup> (n = 256 participants) looked at the effects of perioperative administration of supplemental IV fluids on SSI rates and wound healing. [EL = 1+] The study included adults undergoing open elective colon resection. Incidence of SSI was the primary outcome measure (other outcomes were the ASEPIS score for wound healing assessment, intensive care unit (ICU) admissions and length of hospitalisation). No statistically significant difference was found between the two groups (OR 0.73, 95% CI 0.32 to 1.68) (Figure 6.20).



**Figure 6.20** Comparison of the effect on SSI incidence of supplemental vs standard perioperative fluid management



**Evidence statement**

There is insufficient evidence to suggest that supplemental perioperative IV fluids reduce SSI rates compared with standard perioperative fluid management. [EL = 1+]

**GDG interpretation**

The GDG recognised the importance of good hydration of the patient during the perioperative period. However, the administration of supplemental fluids once a good haemodynamic balance is maintained has not been proven to reduce the incidence of SSI.

**Recommendation on maintaining patient homeostasis (perfusion)**

Maintain adequate perfusion during surgery.

**6.8.4 Perioperative blood glucose control**

*Clinical question*

What is the clinical effectiveness of strict blood glucose control to reduce surgical site infection?

**Introduction**

Insulin-resistant hyperglycaemia is part of the metabolic response to surgery. Elevated blood glucose levels cause the release of pro-inflammatory cytokines that depress the immune system, thus increasing susceptibility to SSI. In critical illness, rigorous control of blood glucose levels has been shown to reduce infective complications. Strict blood glucose control has not been universally adopted in routine surgical practice outside of the intensive care setting, although some investigators have suggested this as a method to reduce SSI. The purpose of the review was to determine the clinical effectiveness of maintaining blood glucose in the normal range in the prevention of SSI.

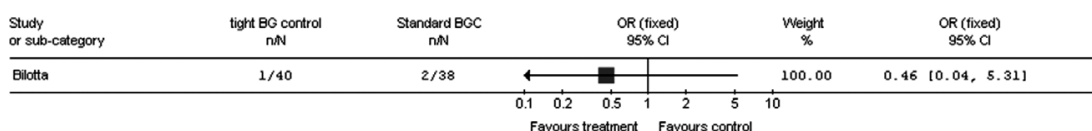
**Overview of the evidence**

*Postoperative intensive blood glucose control compared with postoperative standard blood glucose control*

Two RCTs were identified.

An RCT<sup>122</sup> ( $n = 61$  participants) included adult patients of a general surgical ICU requiring treatment for hyperglycaemia. [EL = 1–] The trial examined the effects of postoperative tight glycaemic control (blood glucose maintained below 20 mg/dl) on SSI rates. Incidence of SSI was reported as one of the outcomes (other outcomes were serum glucose values and other types of nosocomial infection). The study reported a statistically significant reduction of SSI in the group that received the more rigorous blood glucose control (approximate values from histogram provided by the authors: OR 0.15, 95% CI 0.03 to 0.77).

Another RCT<sup>123</sup> ( $n = 78$  participants) compared the effect of intensive glycaemic control (blood glucose maintained between 80 and 120 mg/dl) and insulin therapy against conventional intensive glycaemic control (blood glucose maintained below 220 mg/dl) and insulin therapy. [EL = 1–] Participants were patients with acute subarachnoid haemorrhage admitted to a postoperative neurosurgical ICU. The primary outcome of the study was the overall infection rate (42% in the control group and 27% in the intervention group,  $P < 0.001$ ). The number of wound infections was 1 SSI out of 40 in the intensive blood glucose control group and 2 SSIs out of 38 in the standard blood glucose control group (OR 0.46, 95% CI 0.04, 5.31) (Figure 6.21).



**Figure 6.21** Comparison of the effect on SSI incidence of intensive versus standard postoperative blood glucose control

### Evidence statement

There is insufficient evidence that strict blood glucose control in the postoperative period affects the incidence of SSI. [EL 1–]

### GDG interpretation

Raised blood glucose can often occur after major surgery. However, there is limited evidence to recommend the routine use of insulin infusion in patients who do not have diabetes to control blood sugar in an accepted normal postoperative range.

There are two underpowered RCTs, only one of which shows a statistically significant risk for SSI after raised postoperative blood glucose.

### Recommendations on maintaining patient homeostasis (perioperative blood glucose control)

Do not give insulin routinely to patients who do not have diabetes to optimise blood glucose postoperatively as a means of reducing the risk of surgical site infection.

### Research recommendation on maintaining patient homeostasis (perioperative blood glucose control)

What are the possible benefits of improved postoperative blood glucose control on the incidence of surgical site infection?

*Why this is important*

There have been several large cohort studies in cardiac surgery which indicate that tight postoperative blood glucose control can reduce the risk of surgical site infections, and the serious complication of sternal incision infection in particular. A blood glucose level above the normal range is typical after major trauma and has been considered part of the 'normal' metabolic response. Further studies should be adequately powered RCTs covering a wide range of surgical procedures to show unequivocally that tight blood glucose control is acceptable (even if it lowers the risk of surgical site infections in general) as the lowering of glucose in the immediate postoperative period may have unwanted complications and will require added careful surveillance. Again, the physiological mechanisms that reduce the risk of surgical site infection are not entirely clear.

## 6.9 Wound irrigation and intracavity lavage

### *Clinical question*

Is intracavity lavage or wound irrigation clinically effective for the prevention of surgical site infection?

### Introduction

Wound irrigation has been widely practised as a theoretical means of reducing SSI. Hypothetically, organisms that have emerged from the incised skin edges during surgery, or that have contaminated the wound from the environment, can be washed away. It is usually undertaken at the end of an operative procedure, just prior to closure of the wound.

Intracavity lavage is undertaken based on the same principles. However, the host defence, mounted through the arrival of white cells and particularly macrophages into the cavity or space in the early inflammatory phase, could be unnecessarily 'diluted'. Intracavity lavage and wound irrigation with antiseptics might also have the effect of further reducing numbers of microorganisms.

## Overview of evidence

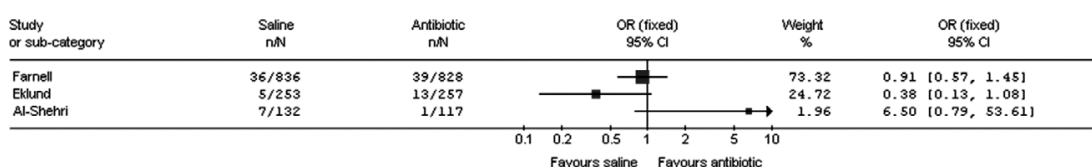
Twenty RCTs were identified.

### Wound irrigation

Five studies<sup>124–128</sup> ( $n = 4021$  participants) were included in the review of wound irrigation. Patients were undergoing surgery for acute appendicitis, general abdominal surgery and general surgery. Two studies<sup>125,126</sup> specified including both children and adults.

Saline compared with antibiotic wound irrigation:

Three RCTs<sup>124,126,127</sup> ( $n = 2423$  participants) were included in this comparison. [all EL = 1+] Heterogeneity prevented meta-analysis ( $I^2 = 66.6\%$ ). None of the studies found a statistically significant difference in wound infection rates following irrigation with saline or with antibiotic (Figure 6.22).



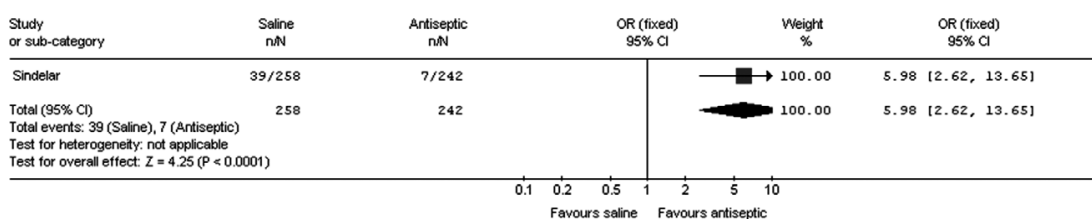
**Figure 6.22** Comparison of the effect on SSI incidence of saline versus antibiotic wound irrigation in three trials

One trial<sup>124</sup> ( $n = 249$  participants) reported no statistically significant differences in SSI incidence between the group receiving ampicillin and the saline group (OR 6.50, 95% CI 0.79 to 53.61).

The other two studies<sup>126,127</sup> also reported no statistically significant differences in SSI incidence between the saline groups and groups receiving tinidazole (OR 0.38, 95% CI 0.13 to 1.08) and DAB solution (OR 0.91, 95% CI 0.57 to 1.45).

Saline compared with antiseptic:

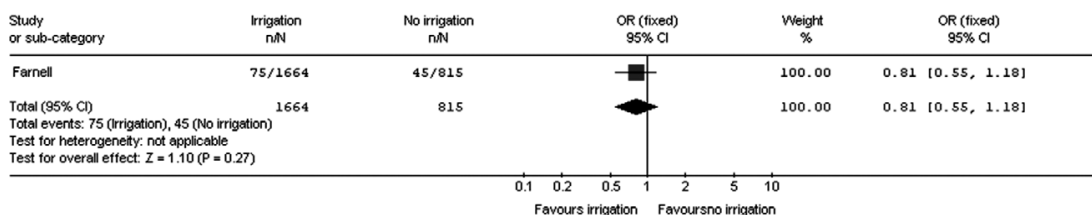
One study<sup>128</sup> ( $n = 500$  participants) examined the effect of saline compared with povidone-iodine irrigation on the incidence of wound infection. [EL = 1+] Participants were undergoing general surgery. There were statistically significantly more wound infections in the saline group than in the group that had wounds irrigated with antiseptic (OR 5.98, 95% CI 2.62 to 13.65) (Figure 6.23).



**Figure 6.23** Comparison of the effect on SSI incidence of saline versus povidone-iodine wound irrigation

Irrigation (with antibiotic or saline) compared with no irrigation:

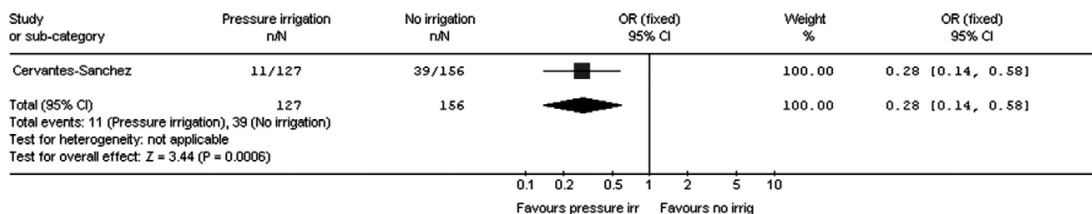
One study<sup>126</sup> ( $n = 1979$  participants) with three relevant treatment arms examined the relative effect of irrigation (with antibiotic or saline via subcutaneous catheter, in two of the three study arms) compared with no irrigation (subcutaneous catheter only). [EL = 1+] No statistically significant difference in wound infection rate was found (OR 0.81, 95% CI 0.55 to 1.18) (Figure 6.24).



**Figure 6.24** Comparison of the effect on SSI incidence of wound irrigation using either antibiotic or saline versus no irrigation

Wound syringe pressure irrigation with saline compared with no irrigation:

One study<sup>125</sup> ( $n = 283$  participants) of people undergoing surgery for an acute abdomen indicative of acute appendicitis compared the effect on wound infection of saline wound syringe pressure irrigation of the muscles and subcutaneous fat tissue with no irrigation. [EL = 1+] A statistically significant difference in wound infection rate favouring saline wound pressure irrigation in appendicectomy was demonstrated (OR 0.28, 95% CI 0.14 to 0.58) (Figure 6.25).



**Figure 6.25** Comparison of the effect on SSI incidence of wound syringe pressure irrigation versus no irrigation

### Intracavity lavage

Fifteen studies<sup>129-143</sup> ( $n = 2421$  participants) were included in this review of intracavity lavage. Patients were undergoing surgery for perforated appendicitis and/or peritonitis, general surgery, hemiarthroplasty, colorectal surgery, biliary operation, rectal resection, proctectomy, caesarean section, abdominal surgery, intestinal surgery and surgery with a likelihood of bacterial contamination of the peritoneum. Two studies<sup>130,136</sup> specified including both children and adults and three studies<sup>134,138,142</sup> only included children.

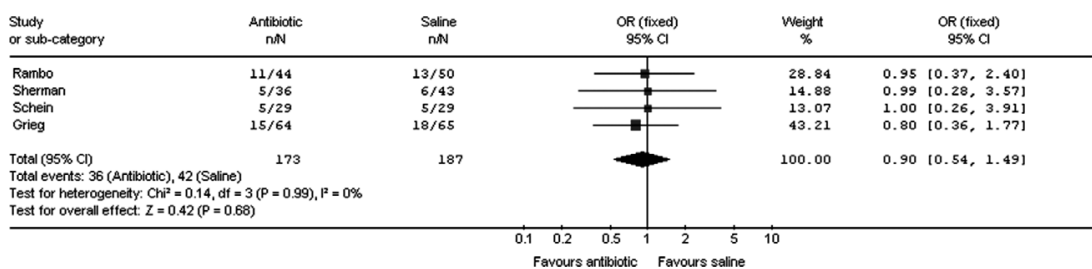
Intraoperative<sup>129,132,134,137-143</sup> and postoperative<sup>130,133</sup> lavage was performed in 12 studies. One study<sup>136</sup> did not specify the timing of lavage.

One study<sup>143</sup> compared intraoperative saline pulsed lavage with saline washout using a jug or syringe in the operative site of patients undergoing hemiarthroplasty.

Two studies were of both wound irrigation and intracavity lavage (antibiotic versus saline<sup>135</sup> and compared with IV antibiotics alone with antibiotics given IV plus via lavage<sup>131</sup>).

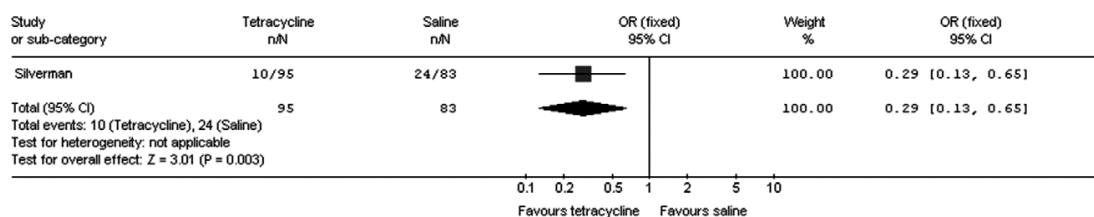
Antibiotic lavage compared with saline lavage:

Four studies<sup>132,136,138,139</sup> ( $n = 360$  participants) were included in a meta-analysis of the comparison antibiotic lavage against saline lavage. [all EL = 1+] The antibiotics used were cefotetan, cefalotin, chloramphenicol and kanamycin. Individual study results and the pooled estimate (OR 0.90, 95% CI 0.54 to 1.49) showed no statistically significant differences in SSI incidence between antibiotic lavage and saline lavage usage (Figure 6.26).



**Figure 6.26** Meta-analysis of four trials comparing the effect on SSI incidence of antibiotic versus saline lavage

One study<sup>140</sup> reported results in 'wounds' rather than in individuals. [EL = 1+] This study compared the use of peritoneal lavage with tetracycline saline solution with saline alone in patients undergoing intestinal surgery. A statistically significant difference in wound infection incidence was found that favoured tetracycline lavage (OR 0.29, 95% CI 0.13 to 0.65) (Figure 6.27). [EL = 1+]

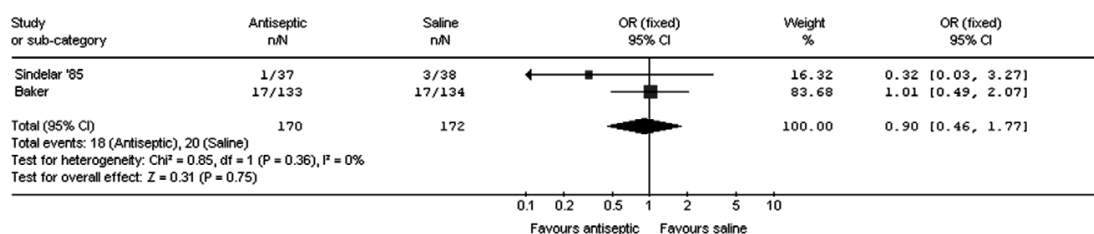


**Figure 6.27** Comparison of the effect on SSI incidence (wounds denominator) of peritoneal lavage using tetracycline saline versus saline solution

Antiseptic lavage compared with saline lavage:

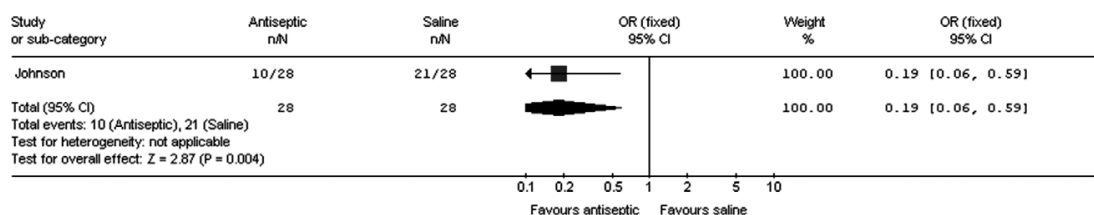
Two RCTs of intraoperative lavage<sup>129,141</sup> and one of postoperative lavage<sup>133</sup> were included. [all EL = 1+] The antiseptics used in the intraoperative studies were taurolidine<sup>129</sup> and 10% povidone-iodine solution.<sup>141</sup> The postoperative lavage study also used povidone-iodine solution.

A meta-analysis (Figure 6.28) of the intraoperative lavage studies showed no statistically significant difference in SSI incidence between antiseptic and saline intracavity lavage (OR 0.90, 95% CI 0.46 to 1.77).



**Figure 6.28** Comparison of the effect on SSI incidence of intraoperative lavage using antiseptics versus saline in two trials

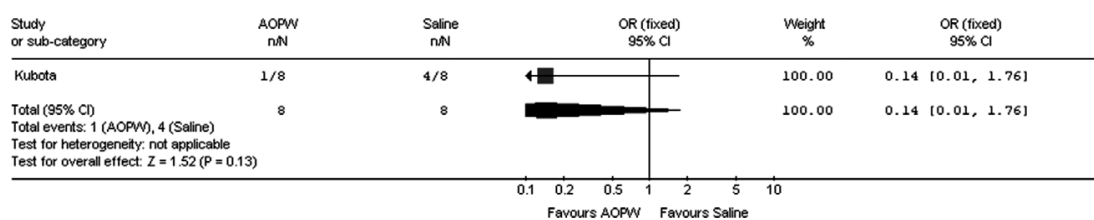
One trial,<sup>133</sup> which included 56 patients undergoing rectal excision for cancer, showed that postoperative lavage of the perineal space with povidone-iodine resulted in statistically significantly fewer wound infections than when saline was used (OR 0.19, 95% CI 0.06 to 0.59) (Figure 6.29). [EL = 1+]



**Figure 6.29** Comparison of the effect on SSI incidence of postoperative lavage using povidone iodine versus saline

AOPW lavage compared with saline lavage:

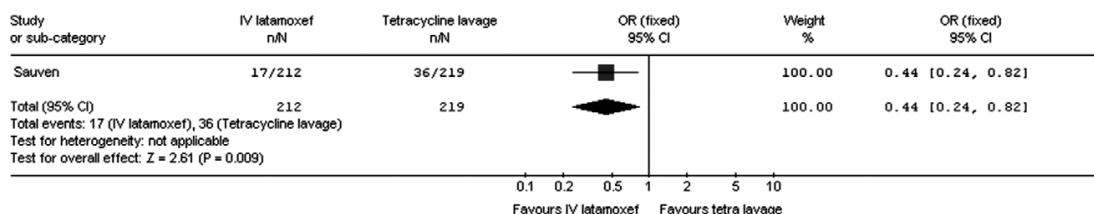
One underpowered study of children with appendicitis and peritonitis compared the effects of acidic oxidative potential water (AOPW) lavage with saline lavage.<sup>134</sup> [EL = 1-] No statistically significant difference in wound infection rate was identified (OR 0.14, 95% CI 0.01 to 1.76). (Figure 6.30)



**Figure 6.30** Comparison of the effect on SSI incidence of wound irrigation using APOW versus saline lavage

IV antibiotic 1 compared with lavage antibiotic 2:

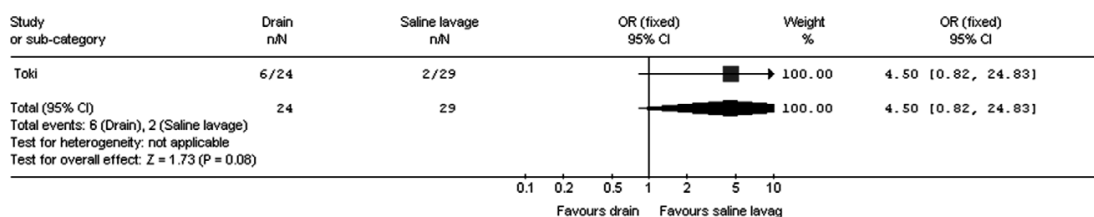
One study<sup>137</sup> ( $n = 431$ ) of participants undergoing abdominal surgery compared the effects of 1 g IV latamoxef to tetracycline lavage on SSI incidence. [EL = 1+] A statistically significant difference in wound infection incidence was found that favoured IV latamoxef (OR 0.44, 95% CI 0.24 to 0.82) over tetracycline lavage, although the dose of tetracycline given could vary between 1 and 7 g (Figure 6.31).



**Figure 6.31** Comparison of the effect on SSI incidence of IV latamoxef administration versus tetracycline

Drain compared with lavage:

One study<sup>142</sup> of 53 children with perforated appendix found no statistically significant difference in SSI incidence between the insertion of peritoneal drains alone and lavage with saline (OR 4.50, 95% CI 0.82 to 24.83) (Figure 6.32). [EL = 1+]



**Figure 6.32** Comparison of the effect on SSI incidence of peritoneal drains versus saline lavage

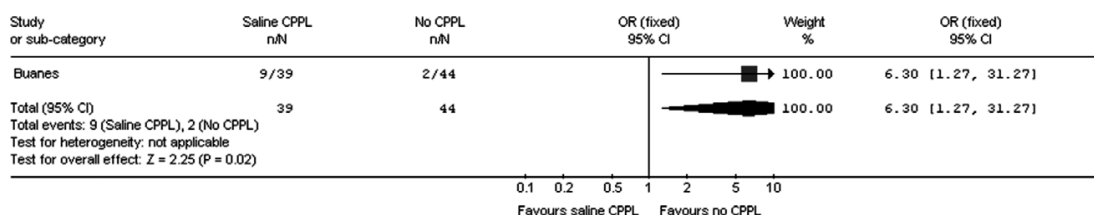
Pulsed saline lavage compared with saline lavage with a jug or syringe:

One RCT<sup>143</sup> ( $n = 356$  participants) compared the effect of intraoperative 2 litres pulsed saline lavage with that of saline lavage given using a jug or syringe in patients undergoing hemiarthroplasty for displaced intracapsular fractured neck of the femur. [EL = 1-] Poor reporting failed to preclude the possibility of bias arising from treatment groups being dissimilar from outset and from patients not receiving pulsed lavage as assigned.

Statistically significant differences in the overall and deep SSI infection rates following pulsed lavage were described (15.6% control versus 5.6% pulsed lavage,  $P = 0.002$ , for SSI overall and 5.2% control versus 1.8% pulsed lavage,  $P = 0.009$ , for deep SSI incidence).

Saline CPPL compared with no saline CPPL:

Another small study<sup>130</sup> of 83 patients with perforated appendicitis and peritonitis found statistically significantly fewer SSIs in the group randomised to no treatment with closed saline postoperative peritoneal lavage (CPPL) compared with the group treated with saline CPPL (OR 6.30, 95% CI 1.27 to 31.27) (Figure 6.33). [EL = 1-]



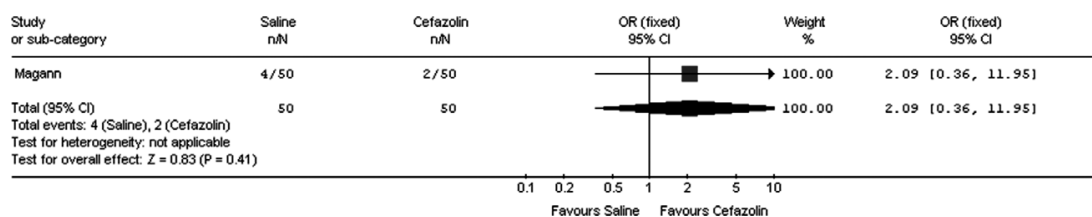
**Figure 6.33** Comparison of the effect on SSI incidence of closed saline postoperative peritoneal lavage (CPPL) versus no saline CPPL

IV antibiotic compared with lavage and irrigation antibiotic compared with lavage and irrigation and IV antibiotic:

One study<sup>131</sup> ( $n = 88$  participants) with three treatment arms found no statistically significant differences in wound infection incidence among any comparisons of IV antibiotic versus lavage and irrigation antibiotic versus lavage and irrigation and IV antibiotic. [EL = 1+] The antibiotic used was cefamandole. The reported results were as follows: IV cefamandole versus lavage and irrigation cefamandole (OR 0.23, 95% CI 0.01 to 5.95); IV cefamandole versus lavage and irrigation and IV cefamandole (OR 0.23, 95% CI 0.01 to 5.95); lavage and irrigation and IV cefamandole versus lavage and irrigation cefamandole (OR 1.00, 95% CI 0.06 to 11.95).

Lavage and irrigation saline compared with lavage and irrigation antibiotic:

One RCT<sup>135</sup> ( $n = 100$  participants) of women undergoing caesarean section found no difference in wound infection rate following lavage and wound irrigation with either saline or cefazolin (OR 2.09, 95% CI 0.36 to 11.95) (Figure 6.34). [EL = 1+]



**Figure 6.34** Comparison of the effect on SSI incidence of saline lavage and irrigation saline versus cefazolin lavage and irrigation

## Evidence statements

### *Wound irrigation*

There is evidence of no difference in SSI incidence after intraoperative subcutaneous wound irrigation using antibiotics or saline. [EL = 1+]

There is evidence from one study of decreased SSI incidence following intraoperative subcutaneous wound irrigation using povidone-iodine compared with saline. [EL = 1+]

There is evidence from one study of no difference in SSI incidence following use of subcutaneous wound irrigation compared with the use of a drain but with no irrigation. [EL = 1+]

There is evidence from one study that wound irrigation of the muscles and subcutaneous fat tissue (using saline under pressure with a syringe) compared with no irrigation decreases the incidence of SSI. [EL = 1+]

### *Intracavity lavage*

There is evidence of no difference in SSI incidence after antibiotic compared with saline lavage. [EL = 1+]

There is evidence from one study that the incidence of SSI is decreased when tetracycline lavage is compared with saline lavage. [EL = 1+]

There is evidence of no difference in SSIs incidence between antiseptic and saline intraoperative intracavity lavage. [EL = 1+]

There is evidence from one small study of fewer wound infections when povidone-iodine is used for postoperative lavage of the perineal space compared with saline. [EL = 1+]

There is evidence from one small study that there is no difference in wound infection rates between use of AOPW compared with saline for lavage. [EL = 1-]

There is evidence from one trial that the incidence of SSI is lower following treatment with intravenous latamoxef compared with lavage with tetracycline. [EL = 1+]

There is evidence of no difference in SSI incidence following the use of drains alone compared with saline lavage. [EL = 1+]

There is evidence from one study of fewer SSIs occurring following pulsed saline lavage compared with saline lavage with a jug or syringe during hemiarthroplasty for displaced intracapsular fractured neck of femur. [EL = 1– ]

There is evidence from one small study that there is a significant increase in wound infection rates using saline CPPL compared with no CPPL. [EL = 1–]

Evidence from one small trial suggests that there is no difference in SSI rates between use of IV cefamandole or lavage and irrigation with cefamandole or lavage and irrigation and IV cefamandole. [EL = 1+]

Evidence from one small trial suggests that there is no difference in wound infection rate following lavage and wound irrigation with either saline or cefazolin. [EL = 1+]

### **GDG interpretation**

#### *Wound irrigation*

Evidence from small surgery-specific studies up to 20–30 years old suggest that intraoperative subcutaneous wound irrigation with povidone-iodine or with saline under pressure reduces the incidence of SSI. Although this was considered to be an adjunct to antibiotic prophylaxis in contaminated surgery, current practice has improved to make this approach unnecessary for the prevention of SSI.

The single study that suggests that wound irrigation with saline under pressure reduces the incidence of SSI shows promise and should be researched further.

Although wound irrigation with povidone-iodine may reduce SSI, povidone-iodine is only licensed for use on intact skin.

#### *Intracavity lavage*

There is no evidence that intracavity lavage with antibiotics, other than a single small study of tetracycline lavage after contaminated surgery, reduces the incidence of SSI.

There is some evidence that postoperative lavage of the perineal space with povidone-iodine reduces SSI.

Routine tetracycline intracavity lavage to reduce the risk of SSI should not be used with the advent of rational effective antibiotic prophylaxis.

A single poorly reported RCT suggests that use of pulsed saline lavage may reduce SSI incidence following orthopaedic surgery compared with washout with saline in a jug or syringe. However, this finding is specific to hemiarthroplasty surgery and is not generalisable to other types of surgery.

Improvements in current practice might have made wound and intracavity lavage unnecessary for the prevention of SSI.

### **Recommendations on wound irrigation and intracavity lavage**

Do not use wound irrigation to reduce the risk of surgical site infection.

Do not use intracavity lavage to reduce the risk of surgical site infection.

### **Research recommendation on wound irrigation**

Does irrigation with modern antiseptics and saline under pressure with or without added antiseptics in a broader range of surgery allow the development of a strategy less dependent on antibiotic prophylaxis to reduce the incidence of surgical site infection?



## 6.10 Antiseptic and antimicrobial agents before wound closure

### *Clinical question*

Is the application of intraoperative topical antiseptics/antimicrobials before wound closure clinically effective in reducing surgical site infection rates?

### Introduction

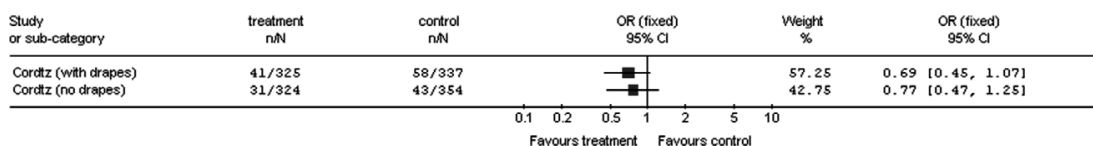
It is thought that the application of topical antiseptics and antimicrobials to surgical incisions prior to their closure reduces the risk of SSIs. This is therefore often practised as a method of intraoperative decontamination after contaminated and dirty surgical procedures, or operations that involve the insertion of an orthopaedic or vascular prosthesis. The purpose of the review was to evaluate the effects of using intraoperative antiseptics or antibiotics topically and just before wound closure for the prevention of SSI.

### Overview of evidence

#### *Intraoperative topical antiseptics before wound closure*

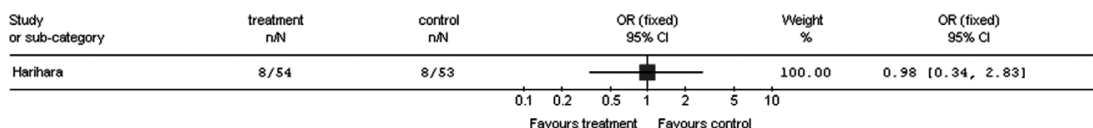
Five RCTs were identified.

Skin iodine re-disinfection before wound closure compared with no skin iodine re-disinfection: One multicentre RCT<sup>144</sup> ( $n = 1340$  participants) looked at the effect of skin iodine re-disinfection, with and without the use of incise drapes, just before wound closure in the prevention of SSI. [EL = 1+] Participants were women undergoing caesarean section. The trial found a lower rate of SSI in the groups receiving the iodine application but the difference was not statistically significant (OR 0.69, 95% CI 0.45 to 1.07 and OR 0.77, 95% CI 0.47 to 1.25, respectively) (Figure 6.35).



**Figure 6.35** Comparison of the effect on SSI incidence of iodine skin re-disinfection versus no iodine skin re-disinfection, with and without the use of incisional drapes

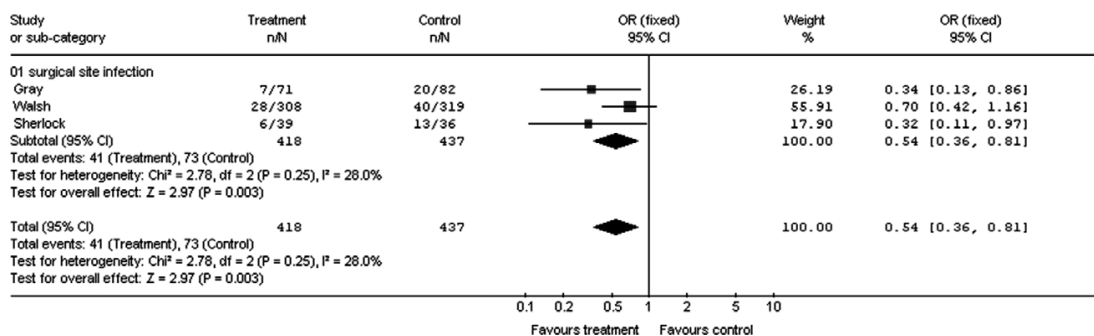
One RCT<sup>145</sup> ( $n = 107$  participants) investigated the effect of povidone-iodine applied to the surgical site before closure on the incidence of SSI. [EL = 1–] Patients were undergoing gastric and colorectal surgery. The main outcome reported was SSI. The study found no statistically significant difference between the groups (OR 0.98, 95% CI 0.34 to 2.83) (Figure 6.36).



**Figure 6.36** Comparison of the effect on SSI incidence of intraoperative skin re-disinfection with iodine versus no re-disinfection

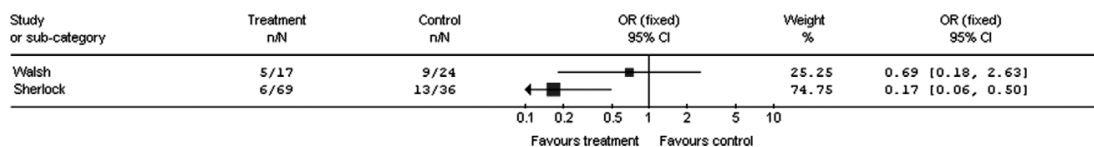
Povidone-iodine spray application before wound closure compared with no iodine spray application:

Three RCTs ( $n = 855$  participants) examined the effect of povidone-iodine spray (a povidone-iodine dry powder<sup>146,147</sup> and a povidone-iodine solution<sup>148</sup>) applied to the wound before its closure. [EL = 1+] Participants were patients undergoing abdominal surgery. The outcome reported in all the studies was infection of the surgical site. The data from the three RCTs were pooled together in a meta-analysis ( $I^2 = 28\%$ ) that showed a statistically significant difference favouring the use of the povidone-iodine spray (OR 0.54, 95% CI 0.36 to 0.81) (Figure 6.37).



**Figure 6.37** Meta-analysis of three trials comparing the effect on SSI incidence of povidone-iodine spray application before wound closure versus no iodine spray application

Topical iodine application in dirty surgery compared with no topical iodine application: Under this comparison, two of the above RCTs reported data for dirty surgery on the effect of iodine application before wound closure on the incidence of SSI. [EL = 1+] Participants underwent surgical procedures for perforated appendicitis<sup>147</sup> and dirty abdominal surgery.<sup>148</sup> Pooling the data together was inappropriate owing to high heterogeneity ( $I^2 = 65\%$ ). Both trials found that the application of iodine to the wound favoured the prevention of SSI. This finding was statistically significant for the larger RCT<sup>147</sup> (OR 0.17, 95% CI 0.06 to 0.50) (Figure 6.38).



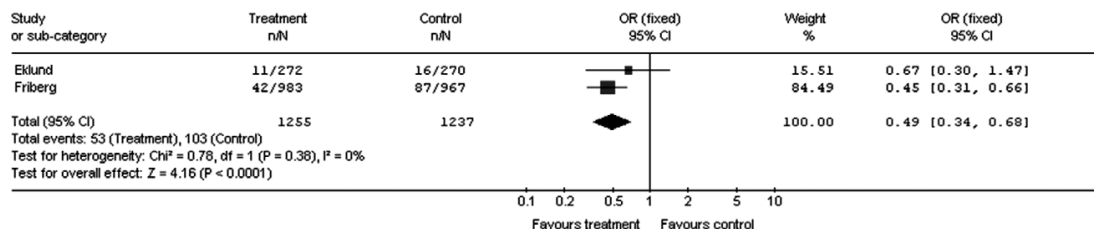
**Figure 6.38** Comparison of the effect on SSI incidence of topical iodine application versus no topical iodine application in dirty surgery in two trials

#### *Intraoperative topical antibiotics before wound closure*

Three RCTs were identified.

Intraoperative gentamicin implant before wound closure compared with no topical gentamicin implant:

Two RCTs<sup>149,150</sup> ( $n = 2492$  participants) investigated whether an implant of gentamicin-collagen applied underneath the sternum before wound closure, in addition to systemic antibiotic prophylaxis, had an effect in the prevention of post-surgical wound infections. [EL = 1+] The participants were patients undergoing cardiac surgery. The incidence of post-surgery sternal infection was the outcome reported and the criteria defining an SSI were the same in both trials. When the two studies were combined in a meta-analysis, a statistically significant difference was found favouring the gentamicin implant (OR 0.49, 95% CI 0.34 to 0.68,  $I^2 = 0\%$ ) (Figure 6.39).

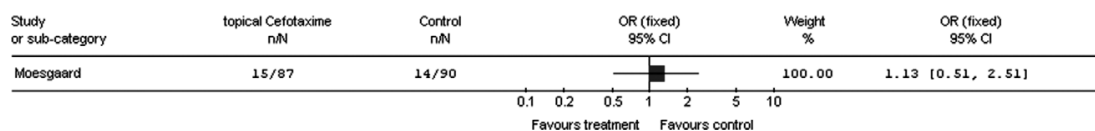


**Figure 6.39** Meta-analysis of two trials comparing the effect in cardiac surgery on SSI incidence of inserting a gentamicin implant before wound closure versus no insertion of a gentamicin implant

Intraoperative topical cefotaxime before wound closure in contaminated surgery compared with no topical cefotaxime before wound closure:

A single RCT<sup>151</sup> ( $n = 177$  participants) examined the effects of cefotaxime applied to the subcutaneous layer at the time of wound closure in contaminated surgery. [EL = 1+] Participants

had abdominal surgery for peritonitis. The outcome reported was SSI defined as accumulation of pus. The study found no statistically significant difference between the two groups (OR 1.13, 95% CI 0.51 to 2.51) (Figure 6.40).



**Figure 6.40** Comparison of the effect in contaminated surgery on SSI incidence of application versus no application of topical cefotaxime before wound closure

### Evidence statements

There is evidence from several small studies that topical povidone-iodine spray onto the superficial wound layers prior to incision closure can reduce the incidence of SSI. [EL = 1+]

There is evidence that re-disinfection of the skin adjacent to the wound with iodine in alcoholic solution prior to incisional closure has no effect on the incidence of SSI. [EL = 1+]

There is evidence that insertion of sub-sternal gentamicin-collagen implants prior to sternal closure after cardiac surgery, and in addition to systemic antibiotic prophylaxis, reduces the rate of sternal SSIs. [EL = 1+]

There is evidence that the addition of topical cefotaxime to systemic antibiotic prophylaxis has no effect on the incidence of SSI in patients undergoing abdominal surgery. [EL = 1+]

### GDG interpretation

There is some evidence that spraying povidone-iodine into wounds, after colorectal surgery or surgery for perforated or gangrenous appendix in adults (both classified as contaminated surgery), prior to incisional closure, reduces the incidence of SSI. Although this interpretation is based on three studies that are underpowered, show some heterogeneity and do not reflect current clinical practice, the GDG considered this to be of clinical relevance based on the meta-analysis. However, re-disinfection of the skin adjacent to the wound using alcoholic iodine solution has no effect.

As povidone-iodine is rapidly inactivated by exposure to blood, the GDG felt that there was a need for further research on the use of other antiseptics. In addition, povidone-iodine is only licensed for use on intact skin.

The insertion of a gentamicin-collagen implant into sternal wounds prior to closure after cardiac surgery appears to reduce the incidence of SSI, based on a meta-analysis of two studies from a single centre. However, there were concerns about the potential adverse effects of topical antibiotics on microbial resistance. The GDG would prefer to see these results replicated in other centres and the long-term effects on microbial resistance should be evaluated.

The instillation of cefotaxime into wounds prior to closure appears to have no effect on SSI incidence after surgery for peritonitis.

### Recommendations on antiseptic and antimicrobial agents before wound closure

Do not use intraoperative skin re-disinfection or topical cefotaxime in abdominal surgery to reduce the risk of surgical site infection.

### Research recommendations on antiseptic and antimicrobial agents before wound closure

Does the use of antiseptic products applied to the wound prior to closure in elective clean non-prosthetic surgery reduce the reliance on antibiotic prophylaxis to reduce the incidence of surgical site infection?

What is the cost-effectiveness of collagen implants with antibiotics or antiseptics in the reduction in the incidence of surgical site infection?

## 6.11 Closure methods

### *Clinical question*

Which type of suture is clinically effective as a closure method?

### **Introduction**

The role that suture materials and methods play in SSIs is still not well understood. It is thought that silk and catgut, which are currently abandoned in medical practice, might elicit a foreign body or excessive tissue reaction known to be related to an increased risk of SSIs. This review aimed at identifying wound closing materials and methods that might influence the incidence of SSIs.

### **Overview of evidence**

One systematic review and 46 RCTs were identified.

#### *Characteristics of clinical studies included in the review*

All studies included adults except for four<sup>152–155</sup> that were exclusively in children. In three studies,<sup>156–158</sup> wounds rather than patients were randomised.

There was a range of type of surgery from minor operations (for example, to remove benign skin lesions from the back) to major operations (for example, for extensive cancer). Some operations were classified as 'clean' and others as 'clean/contaminated', 'contaminated' or 'dirty' (for example, where abdominal trauma such as a gunshot wound had perforated the bowel). Despite the recent withdrawal of catgut from the UK market, three studies were included that used catgut to close deeper tissue layers and comparisons of suture materials were restricted to superficial layers. This was to ensure that the GDG could give consider the widest available evidence base. All studies were of parallel-group design except two that were of split-body design<sup>159,160</sup> and one<sup>161</sup> that randomised the upper and lower parts of the wound. The tissue adhesive studies excluded surgical procedures on high-tension sites such as the elbow and knee.

Seven studies<sup>156,158,162–166</sup> included in the review had three or more relevant comparison arms.

#### *Methodological quality of included clinical studies*

Overall, the quality of reporting was low, despite over half of the studies being published in the last decade.

In three studies, wounds rather than people were randomised and it was unclear whether this had been accounted for in two of the analyses.<sup>157,158</sup>

The method of randomisation was reported in 19 studies and was classified as adequate.<sup>153,156,159,160,163,164,166–178</sup> The rest did not state the method of randomisation or were unclear.

Allocation concealment was reported in 14 studies and was assessed as being adequate or partially adequate.<sup>153–156,164,166,168–170,176,178–180,182</sup>

There was an attempt at blinding the outcome assessor in 11 studies.<sup>153,154,159,163,166,171,175,182–185</sup> In ten studies<sup>152,155,158,160,161,164,167,179,186,187</sup> the outcome assessors were not blinded, and in the rest blinding was not stated.

There were no withdrawals in nine studies.<sup>152,162,167,170,172,173,188–190</sup> One study<sup>164</sup> had more than 20% loss to follow-up (22–32% across groups). Only two studies<sup>167,178</sup> stated that they had carried out intention-to-treat analyses. Comparability of the groups at study entry was usually demonstrated.

Nine studies<sup>153,155,156,161,163,164,169,172,176</sup> reported an *a priori* sample size power calculation.

The following comparisons were examined:

- closure of the skin
  - suture material 1 compared with suture material 2
  - suture technique 1 compared with suture technique 2
  - non-suture closure material compared with suture closure material
  - non-suture closure material 1 compared with non-suture closure material 2
  - primary skin closure compared with delayed skin closure

- closure of internal layers
  - suture material 1 compared with suture material 2
  - suture technique 1 compared with suture technique 2
  - health economics assessment of suture types (adhesive tape, tissue adhesives, standard sutures and clips).

### 6.11.1 Closure of the skin

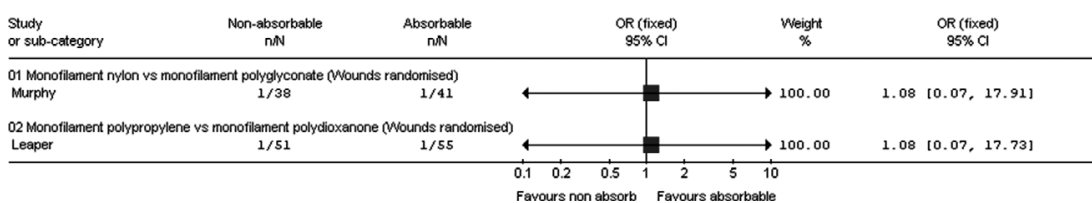
#### *Suture material 1 compared with suture material 2*

Non-absorbable monofilament sutures compared with absorbable monofilament sutures: Two studies involving 185 participants reported the incidence of wound infection. Patients were undergoing vascular and open-heart surgery and wounds rather than patients were randomised in both studies.

In one RCT,<sup>191</sup> ( $n = 79$ ) there was one infection identified in each treatment group (non-absorbable polyamide (nylon) suture group  $n = 38$  and absorbable polyglyconate sutures  $n = 41$ ). [EL = 1–] Assessment of infection was made at up to 2 weeks postoperatively and bacteriological confirmation of infection was required.

In the other RCT,<sup>157</sup> ( $n = 106$ ) infection was defined as the presence of discharge and wound infection was measured at up to 6 weeks. [EL = 1–] There was one infection identified in each treatment group (non-absorbable polypropylene  $n = 51$  and absorbable polydioxanone  $n = 55$ ).

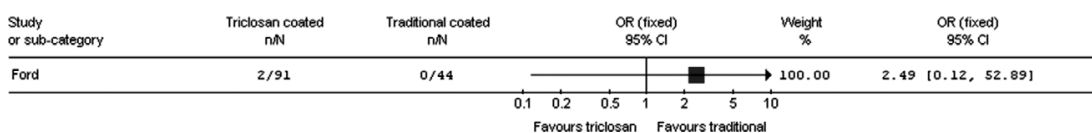
The incidence of SSI in these two studies was low, confidence intervals were wide and neither result was statistically significant (Figure 6.41).



**Figure 6.41** Comparison of the effect on SSI incidence of non-absorbable monofilament sutures versus absorbable monofilament sutures for skin closure in two trials (wounds randomised)

#### Triclosan-coated compared with traditional-coated polyglactin 910 sutures:

One study<sup>152</sup> ( $n = 135$ ) included paediatric patients undergoing general surgery in a trial comparing the effects of triclosan-coated versus traditional-coated polyglactin 910 sutures on SSI incidence. [EL = 1–] There were two infections in the triclosan-coated suture group ( $n = 91$ ) and none in the traditional-coated suture group ( $n = 44$ ). This difference was not statistically significant (OR 2.49, 95% CI 0.12 to 52.89) (Figure 6.42).



**Figure 6.42** Comparison of the effect on SSI incidence of triclosan-coated versus traditional-coated polyglactin 910 sutures for skin closure

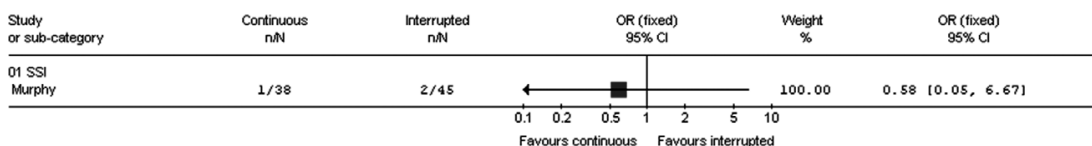
#### *Suture technique 1 compared with suture technique 2*

It should be noted that the transcutaneous suture technique is more commonly described as an ‘interrupted mattress’, ‘percutaneous’ or ‘transdermal’ suture technique. The intracutaneous technique is more commonly called a ‘subcuticular’ suture technique.

#### Polyamide continuous compared with polyamide interrupted for skin closure:

One study<sup>158</sup> ( $n = 60$ ) of patients undergoing clean orthopaedic procedures randomised wounds to continuous polyamide ( $n = 38$  wounds) or interrupted polyamide ( $n = 45$  wounds) suture techniques for closure of the skin. [EL = 1–] There was one infection found in the continuous

suture technique group and two in the interrupted suture technique group. The confidence interval was too wide to draw conclusions from this study (OR 0.58, 95% CI 0.05 to 6.67) (Figure 6.43).



**Figure 6.43** Comparison of the effect on SSI incidence of use of continuous suturing technique using polyamide sutures versus interrupted suturing technique using polyamide sutures for skin closure

Bilayer technique compared with buried vertical mattress sutures:

One study<sup>185</sup> ( $n = 100$ ) reported 3/50 SSIs in patients having excision of benign pigmented lesions on the back whose wounds were closed with the bilayer method, compared with 2/50 for the vertical mattress sutures group. [EL = 1–] Both arms appeared to use the same suture material. This difference was not statistically significant (OR 1.53, 95% CI 0.24 to 9.59).

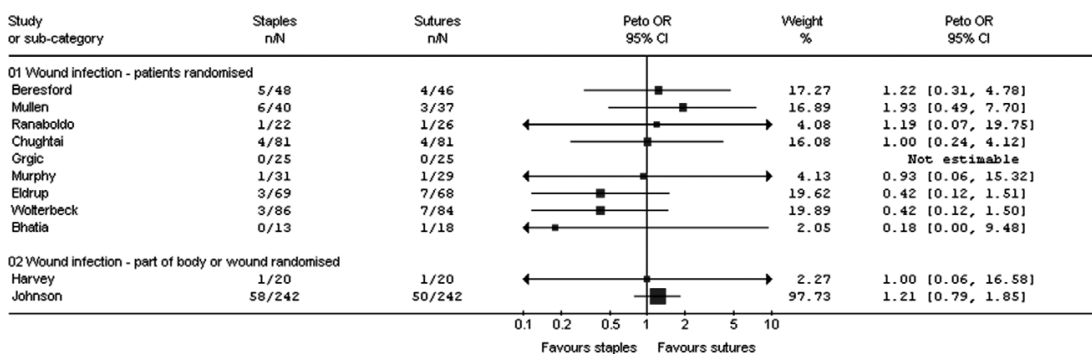
*Non-suture closure material compared with suture closure material*

Staples compared with skin sutures:

Eleven RCTs<sup>160,161,165,167,178,179,184,186,187,191,192</sup> (total  $n = 1353$ ) were identified. Only one study<sup>178</sup> was believed to be at low risk of bias. [EL = 1+] Bias was possible or likely in the other ten RCTs [all EL = 1–] owing to poor reporting or uncertain methodology.

Patients were undergoing abdominal hysterectomy,<sup>179</sup> CABG,<sup>161,165,186</sup> surgery for Dupuytren's contracture,<sup>167</sup> head and neck tumour surgery,<sup>192</sup> elective abdominal and breast surgery,<sup>187</sup> clean orthopaedic procedures,<sup>191</sup> abdominal surgery with a midline wound<sup>184</sup> and vascular procedures.<sup>160,178</sup>

All trials assessed wound infection. One study<sup>160</sup> had within-patient randomisation and another<sup>161</sup> had within-wound (upper/lower) randomisation. No study found a statistically significant difference in SSI incidence following closure with staples or sutures (Figure 6.44).



**Figure 6.44** Comparison of the effect on SSI incidence of use of staples versus sutures for skin closure in 11 trials (in two trials treatments were randomised by wound, not patient)

Two studies<sup>191,192</sup> also compared wound dehiscence following closure using staples or sutures although neither was adequately powered to detect a difference between the groups for this outcome.

One trial<sup>191</sup> ( $n = 60$ ) found one episode of dehiscence in each arm ( $n = 31$  with staples and 29 with sutures). [EL = 1–]

One trial<sup>192</sup> ( $n = 50$ ) reported no dehiscence in either group. [EL = 1–]

Tissue adhesive compared with suture:

Thirteen studies were identified.

Five studies<sup>155,169,175,182,193</sup> compared closure with butylcyanoacrylate adhesive with suture closure. Eight studies<sup>153,154,159,163,166,170,183,194</sup> compared octylcyanoacrylate adhesive with suture closure.

The studies were examined as two subgroups according to the particular cyanoacrylate adhesive used (butyl or octyl) and the results were pooled overall where appropriate. This pooling was performed despite differences in comparator suture materials and techniques.

Outcome 1 – SSI incidence

Nine studies<sup>153,155,163,169,170,175,183,193,194</sup> ( $n = 637$  patients) reported wound infection as an outcome, but this was measured at varying times, there were different definitions of infection and some reports did not describe how it was measured (Figure 6.45).

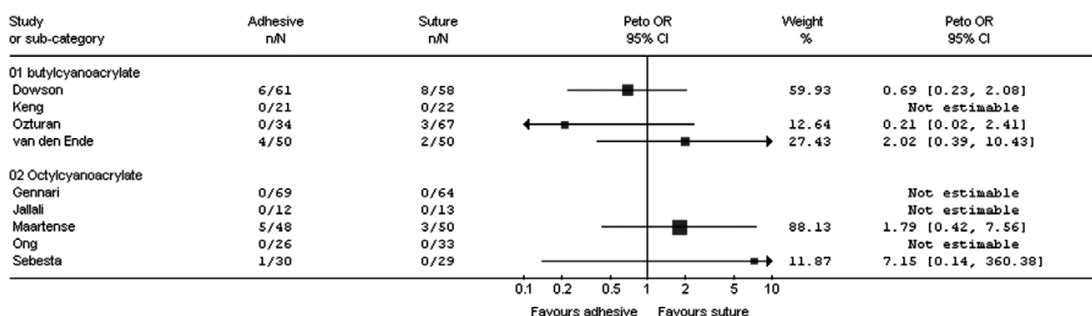


Figure 6.45 Comparison of the effect on SSI incidence of use of butylcyanoacrylate adhesive or octylcyanoacrylate adhesive versus sutures for skin closure in nine trials

Four RCTs<sup>155,169,175,193</sup> ( $n = 363$ ) that compared butylcyanoacrylate adhesive closure with suture closure reported the incidence of SSI. Participants were undergoing herniotomy or orchidopexy, laparoscopic general surgery, rhinoplasty or septorhinoplasty, and groin incisions, respectively. One study included only children.<sup>155</sup>

Overall, more SSIs were found in the suture group (13/197) than in the adhesive group (10/166), although one underpowered study<sup>193</sup> found no SSIs in either group. [EL = 1–] No individual study reported a statistically significant outcome. Pooling was inappropriate given the likelihood of bias in two studies<sup>169,193</sup> [both EL = 1–] and conflicting results in the remaining two studies<sup>155,175</sup> [both EL = 1+]

Five RCTs<sup>153,163,170,183,194</sup> ( $n = 374$ ) compared octylcyanoacrylate adhesive closure with suture closure and reported the incidence of SSI. In two studies, participants were undergoing laparoscopic surgery<sup>163,194</sup> and in the remaining studies participants were undergoing breast surgery,<sup>183</sup> herniotomy<sup>153</sup> and laparoscopic cholecystectomy.<sup>170</sup> One study included only children.<sup>153</sup>

There were very few infections overall: 6/185 in the adhesive group and 3/189 in the suture group. Three studies<sup>153,183,194</sup> found no infection in either treatment group. One RCT<sup>163</sup> ( $n = 98$ ) reported 5/48 SSIs in the adhesive group compared with 3/50 in the suture group. [EL = 1+] A further RCT<sup>194</sup> ( $n = 59$ ) of laparoscopic wounds found one infection in the adhesive group ( $n = 30$ ) only. [EL = 1–] Neither result was statistically significant.

Outcome 2 – wound dehiscence

Nine trials<sup>153–155,159,166,169,175,182,183</sup> reported the rate of incisional dehiscence following closure with tissue adhesives or suture (Figure 6.46).

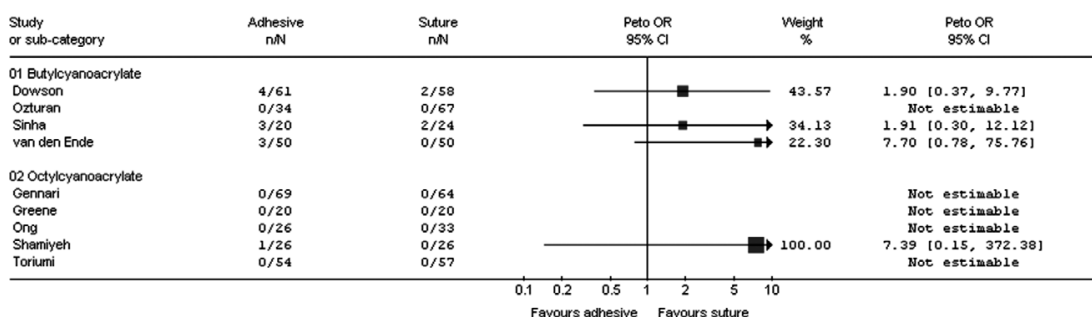


Figure 6.46 Comparison of the effect on wound dehiscence incidence of use of butylcyanoacrylate adhesive or octylcyanoacrylate adhesive versus sutures for skin closure in nine trials

Four RCTs<sup>155,169,175,182</sup> ( $n = 364$ ) that compared butylcyanoacrylate adhesive closure with suture closure reported the incidence of wound dehiscence. Participants were undergoing herniotomy or orchidopexy, laparoscopic general surgery, rhinoplasty or septorhinoplasty, and hand or wrist surgery, respectively. One study included only children.<sup>155</sup>

Overall, more wound dehiscence was found in the adhesive group (20/165) than in the suture group (40/199), although one study reported no episodes of wound dehiscence in either group.<sup>175</sup> [EL = 1+]

Three trials<sup>155,169,182</sup> found greater incidence of wound dehiscence in the adhesive group, but these findings were not statistically significant. In one trial,<sup>169</sup> 4/61 occurrences of wound dehiscence were reported in the adhesive group compared with 2/58 in the suture group. [EL = 1–] Another study<sup>182</sup> found 3/20 occurrences of minor wound dehiscence (gaping of 1–2 mm) in the adhesive group compared with 2/24 in the suture group. [EL = 1+]

One study<sup>155</sup> ( $n = 100$ ) in which children who were undergoing herniotomy or orchidopexy were randomised to butylcyanoacrylate adhesive or suture closure found no wound dehiscence in the suture group (0/50) and 3/50 wounds dehiscence for more than half their length (average wound length 2.5 cm) in the tissue adhesive group. [EL = 1+]

Pooling of the three higher quality studies<sup>155,175,182</sup> suggested that there was no difference in wound dehiscence rate following closure of the skin with either butylcyanoacrylate adhesive (6/104) or sutures (2/141) (Peto OR 3.31, 95% CI 0.79 to 13.95,  $I^2 = 0\%$ ).

Five RCTs<sup>153,154,159,166,183</sup> ( $n = 395$ ) that compared octylcyanoacrylate adhesive closure with suture closure reported the incidence of wound dehiscence. Patients were undergoing breast surgery,<sup>183</sup> blepharoplasty,<sup>159</sup> herniotomy,<sup>153</sup> varicose vein surgery<sup>166</sup> and surgery for face and neck skin lesions.<sup>154</sup> One study included both adults and children.<sup>154</sup>

There was one report of wound dehiscence ( $n = 195$ ) in the octylcyanoacrylate tissue adhesive group and none in the suture group ( $n = 200$ ). This finding from one study<sup>166</sup> was not statistically significant (Peto OR 7.39, 95% CI 0.15 to 372.38). [EL = 1+]

Results from both comparisons were pooled to investigate the incidence of SSI following skin closure with butyl- or octylcyanoacrylate tissue adhesive. Studies thought to be potentially biased and given a quality assessment of EL = 1– were removed.<sup>154,159,169</sup>

Pooling the remaining higher quality trials<sup>153,155,166,175,182,183</sup> demonstrated that, overall, there were 7/225 occurrences of wound dehiscence in the butyl- and octylcyanoacrylate tissue adhesive groups and 2/264 wounds that underwent dehiscence in the suture group. [EL = 1+] There was thus no statistically significant difference in the incidence of wound dehiscence for the use of tissue adhesives compared with sutures (Peto OR 3.64, 95% CI 0.95 to 14.05).

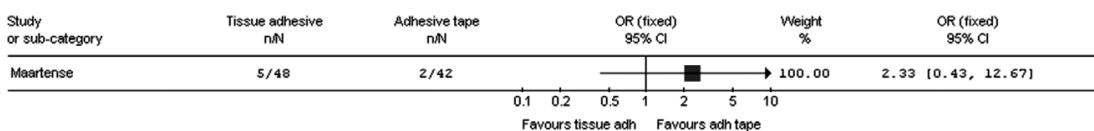
#### *Non-suture closure material 1 compared with non-suture closure material 2*

Tissue adhesive compared with adhesive tape:

Two studies compared the use of octylcyanoacrylate tissue adhesive with adhesive tape for skin closure.<sup>163,166</sup>

#### Outcome 1 – SSI

One study<sup>163</sup> ( $n = 90$ ) that included participants undergoing elective laparoscopic surgery compared the effect on SSI of using tissue adhesive with that of adhesive tape. [EL = 1+] No statistically significant difference in SSI incidence was identified (OR 2.33, 95% CI 0.43 to 12.67) (Figure 6.47).



**Figure 6.47** Comparison of the effect on SSI incidence of use of octylcyanoacrylate tissue adhesive versus adhesive tape for skin closure

#### Outcome 2 – wound dehiscence

One trial<sup>166</sup> ( $n = 79$ ) that included patients undergoing varicose vein surgery found no statistically significant difference in wound dehiscence rate following skin closure with octylcyanoacrylate tissue adhesive compared with adhesive tape (OR 0.96, 95% CI 0.06 to 16.23). [EL = 1+]



*Primary skin closure compared with delayed skin closure*

One RCT was identified.

One trial<sup>177</sup> ( $n = 48$ ) randomised patients undergoing surgery for colon injuries to either having their wounds left open and packed with saline-soaked dressings or having primary closure with staples. [EL = 1+] Statistically significantly more SSIs were found in the group having their wounds primarily closed with staples (17/26) than in the group whose wounds were randomised to delayed wound closure (8/22) (OR 0.30, 95% CI 0.09 to 0.99). This trial also reported wound dehiscence in 8/26 patients with primary wound closure compared with 3/22 patients in the delayed wound closure group (OR 0.36, 95% CI 0.08 to 1.55).

**6.11.2 Closure of internal layers**

*Suture material 1 compared with suture material 2*

Non-absorbable suture material compared with absorbable suture material:

Five RCTs were identified.

Five studies<sup>168,171,180,195,196</sup> compared a non-absorbable synthetic suture with an absorbable synthetic suture. There were a total of 1567 participants in these studies undergoing abdominal laparotomy. All studies reported the incidence of SSI and all-layer wound dehiscence (burst abdomen).

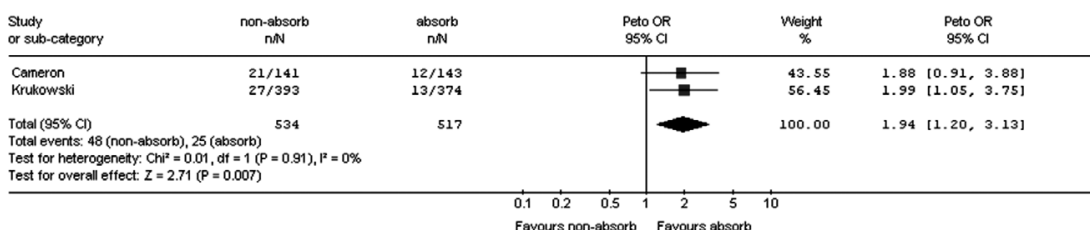
Outcome 1 – SSI

Two trials compared polyamide monofilament with polyglyconate monofilament.<sup>168,195</sup> One trial<sup>168</sup> ( $n = 181$ ) identified four infections in the group receiving polyamide sutures ( $n = 91$ ) and two in the polyglyconate suture group ( $n = 90$ ). [EL = 1+] One trial<sup>195</sup> ( $n = 132$ ) found 14 infections in the polyamide suture group ( $n = 67$ ) and ten in the polyglyconate suture group ( $n = 65$ ). [EL = 1+] Neither of these individual findings was statistically significant nor the finding of the pooled results (Peto OR 1.55, 95% CI 0.71 to 3.36).

Two trials<sup>171,180</sup> compared polypropylene monofilament with polydioxanone monofilament. One trial<sup>180</sup> ( $n = 284$ ) identified 21 infections in the non-absorbable (polypropylene) group ( $n = 141$ ) and 12 in the group that received polydioxanone sutures ( $n = 143$ ). [EL = 1+] This finding was not statistically significant.

The largest trial<sup>171</sup> ( $n = 767$ ) found a statistically significant difference favouring the use of absorbable polydioxanone sutures over polypropylene sutures for closure of all layers (Peto OR 1.99, 95% CI 1.05 to 3.75). [EL = 1+]

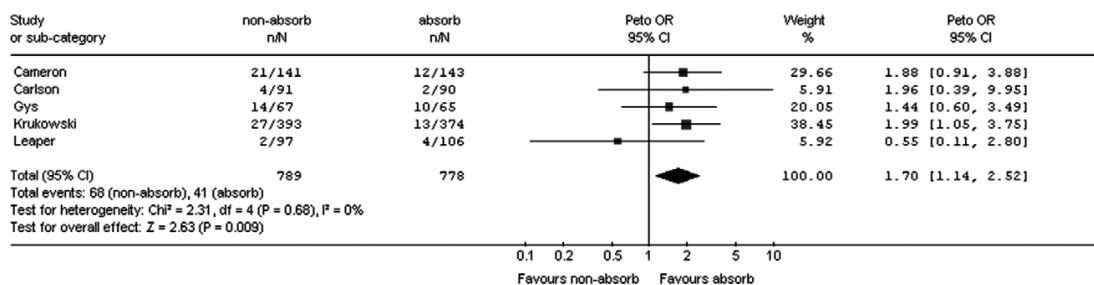
The pooled findings of these two trials demonstrated an overall statistically significant effect favouring the use of absorbable polydioxanone sutures over polypropylene sutures for closure of all layers (Peto OR 1.94, 95% CI 1.20 to 3.13) (Figure 6.48).



**Figure 6.48** Meta-analysis of two trials comparing the effect on SSI incidence of using non-absorbable (polypropylene monofilament) sutures versus absorbable (polydioxanone monofilament) sutures for closure of all tissue layers

One trial<sup>196</sup> ( $n = 203$ ) compared polyamide sutures with polydioxanone sutures. [EL = 1+] Two major SSIs were identified in the polyamide suture group ( $n = 97$ ) while four were identified in the absorbable polydioxanone suture group ( $n = 106$ ). This finding was not statistically significant.

Overall, in a meta-analysis of these five studies ( $n = 1557$ ) a statistically significant protective effect of using absorbable sutures was found compared with non-absorbable sutures in closure of all tissue layers (Peto OR 1.70, 95% CI 1.14 to 2.52) (Figure 6.49).



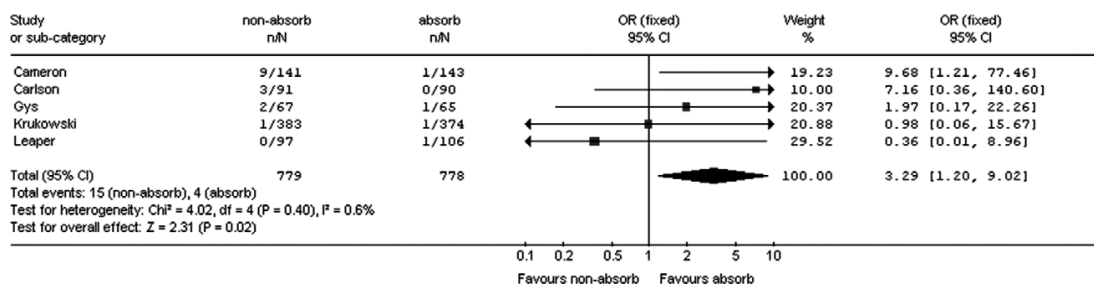
**Figure 6.49** Meta-analysis of five trials comparing the effect on SSI incidence of using non-absorbable sutures versus absorbable sutures for closure of all tissue layers

#### Outcome 2 – wound dehiscence

Five trials<sup>168,171,180,195,196</sup> reported the incidence of wound dehiscence (burst abdomen) in the postoperative period.

One study<sup>180</sup> found a statistically significant difference in wound dehiscence incidence that favoured the use of absorbable polydioxanone sutures over polypropylene sutures. However, the confidence interval for this finding (OR 9.68, 95% CI 1.21 to 77.46), and for the non-statistically significant findings of the other trials, was very wide.

A meta-analysis (Figure 6.50) of these five studies (non-absorbable sutures compared with polydioxanone sutures) showed little heterogeneity ( $I^2 = 0.6\%$ ) and statistically significantly more wound dehiscence occurring in the non-absorbable suture group (15/779) compared with the absorbable suture group (4/778) (Peto OR 3.29, 95% CI 1.20 to 9.02). The confidence interval for this finding was also wide with the lower estimate close to the null value.



**Figure 6.50** Meta-analysis of five trials comparing the effect on wound dehiscence incidence of using non-absorbable sutures versus absorbable sutures for closure of all tissue layers

#### Suture technique 1 compared with suture technique 2

Continuous compared with interrupted:  
 Two relevant trials were identified.

One trial<sup>183</sup> ( $n = 599$ ) assessed the method of closing the internal tissue layers by mass closure with either continuous or interrupted polyglactin 910 sutures.<sup>183</sup> [EL = 1+] Participants were undergoing major abdominal surgery. There were 17 SSIs in both the continuous ( $n = 163$ ) and the interrupted ( $n = 164$ ) groups. More patients were available for assessment of wound dehiscence (continuous  $n = 194$  and interrupted  $n = 192$ ) and three cases were reported in each group. Neither outcome finding was statistically significant (OR 1.01, 95% CI 0.49 to 2.05 and (OR 0.99, 95% CI 0.20 to 4.96, respectively).

One trial<sup>173</sup> ( $n = 402$ ) examined the comparative effects on SSI and wound dehiscence rates of continuous or interrupted fascial closure techniques with monofilament polyglyconate. [EL = 1+] Participants were undergoing gynaecological surgery. There were nine wound infections reported in the continuous group ( $n = 201$ ) and four infections in the interrupted group ( $n = 201$ ). This difference was not statistically significant (OR 1.27, 95% CI 0.70 to 7.62). No wound dehiscence was identified in either group.

Continuous loop compared with continuous mass closure:

One study<sup>188</sup> ( $n = 100$ ) compared continuous loop with continuous mass closure with polypropylene sutures in patients undergoing laparotomy. [EL = 1+] There were six infections in the continuous loop group ( $n = 50$ ) compared with nine in the continuous mass closure group ( $n = 50$ ). This difference was not statistically significant (OR 0.62, 95% CI 0.20 to 1.90).

Continuous loop compared with continuous running suture:

One study<sup>172</sup> ( $n = 390$ ) compared closure using continuous loop with a continuous running polydioxanone suture. [EL = 1+] There were 17 wound infections and seven dehiscenced wounds in the continuous loop group ( $n = 186$ ) compared with 13 wound infections and four wounds that underwent dehiscence in the continuous running group ( $n = 204$ ). Neither of these differences was statistically significant (OR 0.68, 95% CI 0.32 to 1.43 and OR 0.51, 95% CI 0.15 to 1.78, respectively).

Non-closure compared with closure of subcutaneous tissue:

One systematic review<sup>197</sup> that included five trials and four more recent trials<sup>162,176,189,190</sup> were identified to include in this comparison of closure versus non-closure of the subcutaneous tissue. [all EL = 1+]

The 2189 participants were undergoing caesarean section and procedures for CABG saphenectomy,<sup>189</sup> elective pelvic surgery,<sup>162</sup> elective abdominal surgery<sup>176</sup> and pilonidal sinus<sup>190</sup> and were included in a meta-analysis of these nine studies. All studies reported outcomes for SSI.

There was no heterogeneity and the pooled results demonstrated no statistically significant difference in SSI incidence for the comparison (OR 0.92, 95% CI 0.65 to 1.30) (Figure 6.51).

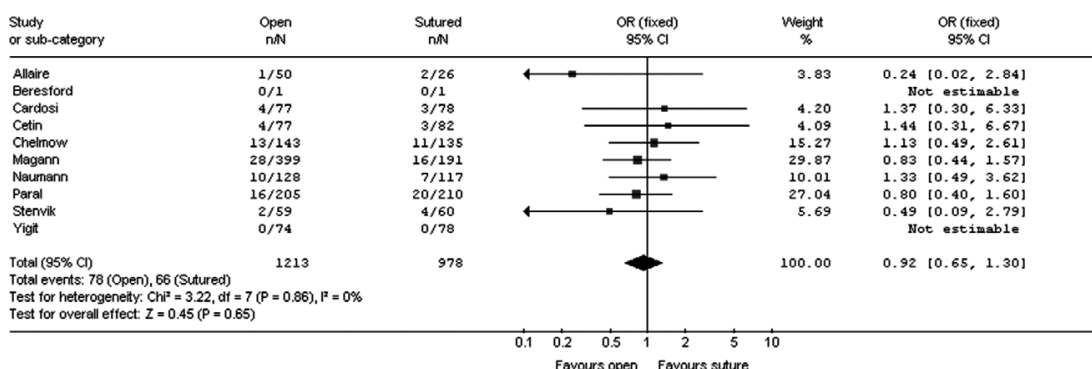


Figure 6.51 Meta-analysis of nine trials comparing the effect on SSI incidence of non-closure versus closure of subcutaneous tissue

Non closure of subcutaneous fat compared with drain insertion:

Two trials<sup>162,164</sup> with three treatment arms were identified. [EL = 1+]

This allowed comparison of no suturing of subcutaneous fat with insertion of a drain in two groups of patients undergoing caesarean section and elective pelvic surgery (total  $n = 495$ ). Results were conflicting and pooling created heterogeneity ( $I^2 = 48%$ ): no statistically significant difference in SSI rate was observed in either study (OR 0.69,<sup>162</sup> 95% CI 0.32 to 1.50 and OR 3.62,<sup>164</sup> 95% CI 0.39 to 33.18) (Figure 6.52). [EL = 1+]

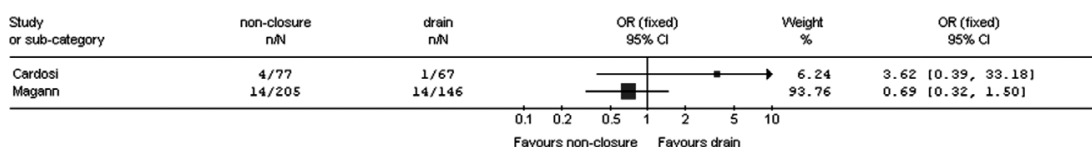
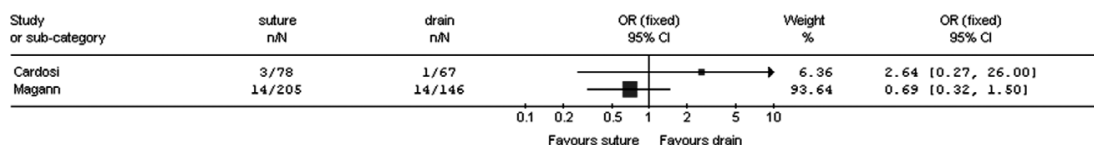


Figure 6.52 Meta-analysis of two trials comparing the effect on SSI incidence of not suturing subcutaneous fat versus insertion of a drain

Suture of subcutaneous fat compared with drain insertion:

Data on SSI rates for suturing subcutaneous fat and drain groups can also be compared from these two studies<sup>162,164</sup> ( $n = 495$  participants). [EL = 1+] Again, results were conflicting and no statistically significant difference in SSI rate was observed in either study (Figure 6.53).



**Figure 6.53** Comparison of the effect on SSI incidence of suturing subcutaneous fat versus insertion of a drain in two trials

#### Clinical question

Which type of suture is clinically and cost-effective as a closure method?

### Health economics overview of evidence

Six studies<sup>163,166,194,198–200</sup> were included in the health economics assessment of the cost-effectiveness of closure methods (Appendix F).

The studies included material costs, costs for use of operating rooms and medical personnel time. No costs for treating wound infection were included.

Two studies<sup>163,166</sup> reported that adhesive tape was a faster and less costly closure method than tissue adhesive and sutures. Tissue adhesives were also found to be faster and less expensive than standard sutures in three of the other studies.<sup>194,198,199</sup> One study<sup>200</sup> that compared sutures with clips found the latter to be more costly when considering application, removal and dressings.

### Health economics evidence statements

Tissue adhesive is consistently the most expensive for material costs. Adhesive tape is consistently the cheapest for material costs and closure also takes the least time. Sutures require the greatest time for wound closure and also require a postoperative outpatient visit for removal.

There is evidence that wound closure using tissue adhesives generates cost savings when compared with sutures for skin closure owing to shorter time for wound closure and no need for a postoperative outpatient visit.

There is evidence that wound closure with adhesive tape generates cost savings when compared with tissue adhesives or sutures; adhesive tape was found to be faster to apply and less costly.

There is evidence that sutures are less expensive than clips.

### Evidence statements – closure of skin

For skin closure, there is insufficient evidence to determine whether there is a difference in the incidence of SSI between absorbable and non-absorbable monofilament sutures. [EL = 1–]

For skin closure, there is insufficient evidence to determine whether there is a difference in the incidence of SSI between using triclosan-coated or traditional non-coated polyglactin 910 sutures. [EL = 1–]

For skin closure, there is insufficient evidence to determine whether there is a difference in the incidence of SSI between continuous and interrupted, non-absorbable sutures. [EL = 1–]

For skin closure, there is insufficient evidence to determine whether there is a difference in the incidence of SSIs between bilayer and vertical mattress sutures. [EL = 1–]

For skin closure, there is evidence of no difference in SSI incidence following use of staples or sutures. [EL = 1+]

For skin closure, there was insufficient evidence to determine whether there is a difference in the incidence of SSI following use of tissue adhesives or sutures. [EL = 1–]

For skin closure, there is evidence of no difference in the rate of wound dehiscence between individual tissue adhesives and sutures, or for the comparison between both adhesives and sutures. [EL = 1–]

For skin closure, there is insufficient evidence to determine whether there is a difference in the incidence of SSI or wound dehiscence between tissue adhesive and adhesive tape. [EL = 1+]

There is evidence from one trial that delayed closure of the skin using saline-soaked dressings to pack wounds results in fewer wound infections than primary closure with staples. [EL = 1–]

### **Evidence statements – closure of internal layers**

For closure of the abdominal wall, there is good evidence that there are fewer SSIs following the use of absorbable polydioxanone monofilament interrupted sutures compared with non-absorbable polypropylene monofilament interrupted sutures. [EL = 1+]

However, there is insufficient information available from five trials to indicate whether the incidence of wound dehiscence is affected by the use of non-absorbable or absorbable sutures. [EL = 1+]

A meta-analysis of two studies suggested no difference in the incidence of SSI between continuous and interrupted sutures. However, one of the studies was probably confounded by the significant differential use of antibiotics. [EL = 1+]

There is evidence from a meta-analysis of five trials that use of polydioxanone sutures causes fewer episodes of wound dehiscence than use of polypropylene sutures for closure of internal layers, although the confidence interval for this finding was wide. [EL = 1+]

There was insufficient evidence in a single study to determine whether there is a difference in the incidence of SSI between continuous loop and continuous mass closure for closure of internal soft tissue layers. [EL = 1+]

There is insufficient evidence to determine whether there is a difference in the incidence of SSI between continuous loop and continuous running sutures for closure of internal soft tissue layers. [EL = 1+]

There is evidence of no difference in on the incidence of SSI after suturing the subcutaneous fat layer compared with its non-closure. [EL = 1+]

There is insufficient evidence to determine whether there is a difference in the incidence of SSI between inserting a drain or not in the subcutaneous fat layer after abdominal/pelvic surgery. [EL = 1+]

There is insufficient evidence to determine whether there is a difference in the incidence of SSI between suturing or inserting a drain in the subcutaneous fat layer. [EL = 1+]

### **GDG interpretation**

There is insufficient evidence to determine whether suturing or not suturing, or placing a drain, in the subcutaneous fat tissues reduces the risk of SSI.

There is insufficient evidence that technique or material used to close the abdominal wall influences the incidence of SSI or dehiscence.

The continuous loop technique of abdominal wall closure is not currently used.

Considering the inconsistencies in the evidence stated above, no recommendation can be made.

### **Research recommendation on closure methods**

What types of closure method will reduce the risk of surgical site infection?

*Why this is important*

Although there are many studies in the field of wound closure, there are still several areas in which questions remain unanswered. Natural suture materials such as catgut and silk have been replaced by tailor-made absorbable and non-absorbable polymers. However, more

research is needed to convince surgeons to stop using mass closure of the abdominal wall or subcuticular sutures for skin closure, as these methods have become standard practice. The use of monofilaments or braids also depends on personal preference and further trials are unlikely to show differences in surgical site infection. There are data to show some techniques can allow more rapid closure, such as the use of staples or adhesive acrylate glues. Again, these have other disadvantages that could only be proven in what would be large, single-intervention RCTs. Further research is required on use of different suture materials and skin adhesives and their effect on the rate of surgical site infection. Research should be multi-centred, adequately powered, single-intervention RCTs. Studies should also include the cost-effectiveness of different closure methods.

## 6.12 Wound dressings

### *Clinical question*

Which type of dressing is advocated for immediate postoperative wound/incision coverage? Is it clinically and cost-effective to use interactive dressings in the immediate postoperative management of a surgical wound to prevent surgical site infection?

### Introduction

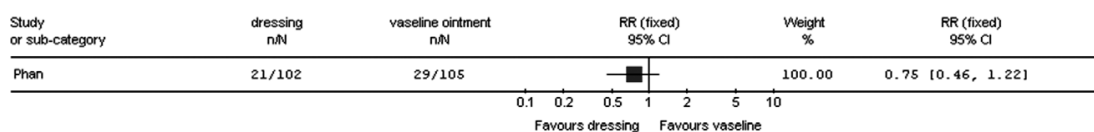
The main purposes of surgical dressings are to allow appropriate assessment of the wound postoperatively, to absorb exudates, to ease pain and to provide protection for newly formed tissue. They maintain an optimal moist wound environment<sup>201</sup> without causing maceration of the surrounding skin as the dressing material is permeable to moisture and gas (see Appendix C). Some dressings allow early bathing or showering of the rest of the patient in the first few postoperative days, which is part of early mobilisation. This review sets out to evaluate the clinical and cost-effectiveness of immediate postoperative dressings for the prevention of SSIs.

### Overview of evidence

Eight RCTs<sup>202–209</sup> were identified for inclusion.

#### *Initial dressing compared with no dressing*

An RCT<sup>202</sup> ( $n = 207$  participants) compared the use of a dry gauze dressing for 5 days with a Vaseline® ointment application without dressing. [EL = 1+] Participants were patients undergoing head and neck surgery for cancer. The outcome reported was the rate of SSI. The study found no statistically significant difference between the two groups (RR 0.75, 95% CI 0.46 to 1.22) (Figure 6.54).

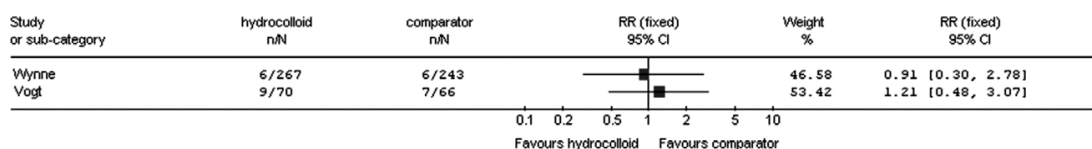


**Figure 6.54** Comparison of the effect on SSI incidence of initially dressing the surgical site (dry gauze dressing for 5 days) versus not dressing the surgical site (Vaseline® ointment only)

#### *Dressing 1 compared with dressing 2*

Hydrocolloid dressing compared with absorbent dressing:

Two RCTs<sup>203,204</sup> ( $n = 670$  participants) compared the use of hydrocolloid dressings with the use of dry absorbent dressings for the prevention of SSI. [EL = 1+] Participants were patients that had undergone cardiac surgery with a median sternotomy incision<sup>203</sup> and elective vascular surgery.<sup>204</sup> Infection of the post-surgical wound was registered in the two studies but definition criteria used were different between them. None of the trials found a statistically significant difference between the two dressing groups regarding the incidence of wound infection (RR 0.91,<sup>203</sup> 95% CI 0.30 to 2.78 and RR 1.21,<sup>204</sup> 95% CI 0.48 to 3.07) (Figure 6.55).

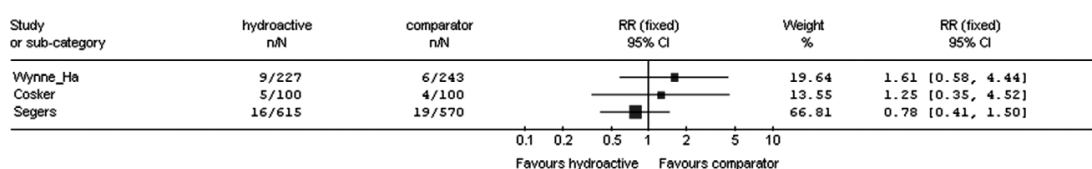


**Figure 6.55** Comparison of the effect on SSI incidence of using hydrocolloid dressings versus dry absorbent dressings in two trials

Hydroactive dressing compared with absorbent dressing:

Two RCTs<sup>203,205</sup> and a quasi-RCT<sup>206</sup> ( $n = 1879$  participants) compared the use of hydroactive dressings with the use of dry absorbent dressings for the prevention of SSI. Participants were patients that had undergone sternotomy for cardiothoracic surgery<sup>203,206</sup> and orthopaedic surgery.<sup>205</sup> Surgical site infection was a primary outcome in all studies even if definition criteria varied among the studies.

The two RCTs<sup>203,205</sup> found no statistically significant difference in SSI incidence between the hydroactive and absorbent dressing groups (RR 1.61,<sup>203</sup> 95% CI 0.58 to 4.44 and RR 1.25,<sup>205</sup> 95% CI 0.35 to 4.52) (Figure 6.56). [EL = 1+]

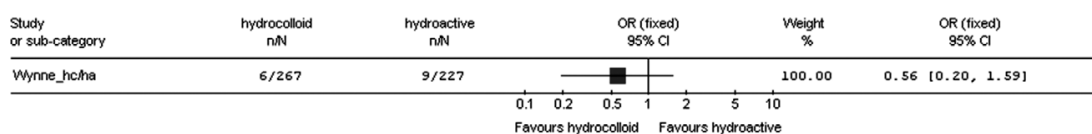


**Figure 6.56** Comparison of the effect on SSI incidence of using hydroactive dressings versus dry absorbent dressings in three trials

The quasi-RCT<sup>206</sup> also found no statistically significant difference between the groups (RR 0.78, 95% CI 0.41 to 1.50) (Figure 6.56). [EL = 1-]

Hydroactive dressing compared with hydrocolloid dressing:

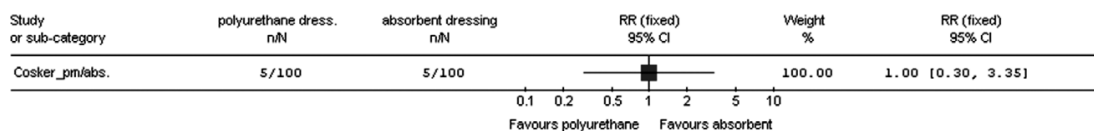
An RCT<sup>203</sup> ( $n = 494$  participants) compared the use of hydroactive dressings with the use of hydrocolloid dressings for the prevention of SSI. [EL = 1+] Participants were patients that had undergone cardiothoracic surgery. The study reported SSI as a main outcome. The difference found in SSI rates between the two groups was not statistically significant (RR 0.56, 95% CI 0.20 to 1.59) (Figure 6.57).



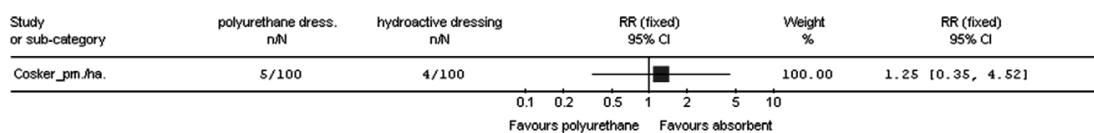
**Figure 6.57** Comparison of the effect on SSI incidence of using hydroactive dressings versus hydrocolloid dressings

Polyurethane membrane dressing compared with absorbent dressing and compared with hydroactive dressing:

One RCT<sup>205</sup> ( $n = 300$  participants) investigated the effect of different types of dressing (polyurethane membrane dressing, absorbent dressing and hydroactive dressing) in the incidence of SSI. [EL = 1-] Participants were orthopaedic surgical patients. Surgical site infection was a study outcome even though no definition criteria were given. The trial found no difference in the rates of SSI between the polyurethane membrane dressing group and the absorbent dressing group (RR 1.00, 95% CI 0.30 to 3.35) (Figure 6.58), and no statistically significant difference for the comparison between the polyurethane membrane dressing group and the hydroactive dressing group (RR 1.25, 95% CI 0.35 to 4.52) (Figure 6.59).



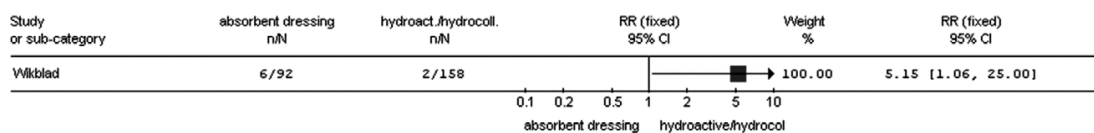
**Figure 6.58** Comparison of the effect on SSI incidence of using polyurethane membrane dressings versus absorbent dressings



**Figure 6.59** Comparison of the effect on SSI incidence of using polyurethane membrane dressings versus hydroactive dressings

Absorbent dressing compared with hydrocolloid dressing/hydroactive dressing:

One RCT<sup>207</sup> ( $n = 250$  participants) compared the use of absorbent dressings with the use of hydroactive and hydrocolloid dressing. [EL = 1–] Participants were undergoing heart surgery. The study reported the incidence of surgical wounds infected but a definition for SSI was not provided. The trial found a statistically significant difference favouring the use of hydroactive and hydrocolloid dressings against the use of absorbent dressings (RR 5.15, 95% CI 1.06 to 25.00) (Figure 6.60).



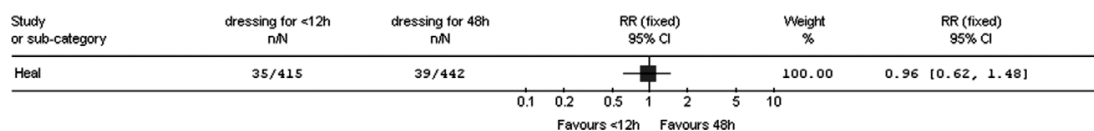
**Figure 6.60** Comparison of the effect on SSI incidence of using absorbent dressings versus hydrocolloid dressing or hydroactive dressings

The RCT<sup>207</sup> reported several outcomes other than the number of wound infection for each of the different dressing groups but this was not the case for the outcome of interest in this review. Therefore only the above comparison has been investigated.

*Duration 1 of dressing in place compared with duration 2 of dressing in place*

Wound covered for less than 12 hours compared with wound covered for 48 hours:

One multicentre RCT<sup>208</sup> ( $n = 857$  participants) investigated the effect on SSI of removing the wound dressing (Melolin® and tape) and leaving it uncovered within the first 12 postoperative hours. This was compared with keeping the wound dry and covered for 48 hours postoperatively. [EL = 1+] Participants were patients from a primary care setting who were undergoing minor skin excisions. The primary outcome was SSI defined by CDC criteria. The study found no statistically significant difference between the two groups (RR 0.96, 95% CI 0.62 to 1.48) (Figure 6.61).

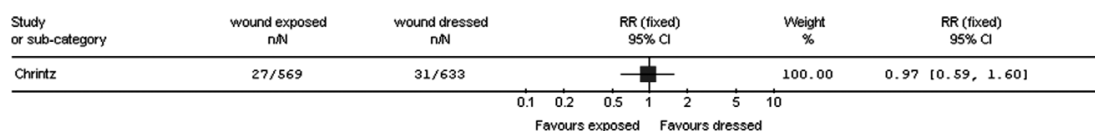


**Figure 6.61** Comparison of the effect on SSI incidence of covering the wound for less than 12 hours postoperatively versus covering the wound for 48 hours postoperatively

Wound covered for 24 hours compared with wound covered until suture removal:

One quasi-RCT<sup>209</sup> ( $n = 1202$  participants) examined the effect of leaving a post-surgical wound uncovered after the first 24 hours following surgery on the incidence of SSI. Leaving the post-surgical wound exposed after the first day was compared with keeping the wound dressed until removal of the sutures. [EL = 1–] Participants were surgical patients undergoing clean and clean-contaminated operations. The main outcome was SSI. The study found no statistically significant difference between the two groups (RR 0.97, 95% CI 0.59 to 1.60) (Figure 6.62).





**Figure 6.62** Comparison of the effect on SSI incidence of exposing the post-surgical wound after the first day versus keeping the wound dressed until suture removal

### Health economics overview of evidence

The published evidence identified<sup>203,204,207,210</sup> comprised costing analyses conducted in other countries that could not be used as evidence in a UK setting. A UK costing analysis was thus conducted (see Appendix G).

### Health economics conclusions

Although no clinical evidence was found to suggest that one type of dressing was more effective at prevention of SSI or was better for management of SSI, it was not possible to do a straightforward cost-minimisation analysis. There are many reasons for choosing a wound dressing depending on the surgery, type of wound and characteristics of the patient.

It is important to take into account the additional costs of changing dressings as well as the initial price of each dressing when choosing which dressings to use.

### Evidence statements

There is evidence from one RCT to show no difference between the use of a dry gauze dressing in the first 5 postoperative days and the use of a Vaseline ointment in the prevention of SSI. [EL = 1+]

There is evidence to suggest no difference between the use of hydrocolloid dressings and the use of absorbent dressings in the prevention of SSI. [EL = 1+]

There is evidence to support that there is no difference between the use of hydroactive dressings and the use of absorbent dressing in the prevention of SSI. [EL = 1+]

There is evidence from a single RCT to suggest that there is no difference between the use of hydrocolloid dressings and the use of hydroactive dressings in the prevention of SSI. [EL = 1+]

There is evidence from one poor-quality RCT to suggest that there is no difference between the use of polyurethane membrane dressings and the use of absorbent dressings, or compared with the use of hydroactive dressings, in the prevention of SSI. [EL = 1–]

There is limited evidence to suggest that there is a difference favouring the use of hydrocolloids or hydroactive dressings against the use of absorbent dressings in the prevention of SSI. [EL = 1–]

There is evidence to suggest that there is no difference between keeping a wound uncovered after the first 12 hours following surgery and keeping the wound covered for 48 hours following surgery in the prevention of SSI. [EL = 1+]

There is limited evidence to suggest that there is no difference between the use of a wound dressing until suture removal and the use of a wound dressing for only the first 24 hours following surgery in the prevention of SSI. [EL = 1–]

### GDG interpretation

There is no robust evidence to support the use of a dressing in the immediate postoperative period for the prevention of SSI. However, it is generally accepted good clinical practice to cover the wound with an appropriate interactive dressing for a period of 48 hours unless otherwise clinically indicated, for example, if there is excess wound leakage or haemorrhage.

There is no robust evidence to support the use of one dressing over another. However, in the majority of clinical situations a semi-permeable film membrane with or without an absorbent island is preferable.

The GDG consensus was that the use of gauze as a primary dressing should be avoided because of its association with pain and disruption of healing tissues at the time of dressing change.

### **Recommendation on wound dressings**

Cover surgical incisions with an appropriate interactive dressing at the end of the operation.

### **Research recommendation on wound dressings**

What is the benefit and cost-effectiveness of different types of post-surgical interactive dressing for reducing the risk of surgical site infection?

#### *Why this is important*

There are a huge number of dressings available for chronic wound care that could also be used for incisional sites. The use of island dressings compared with simple adhesive polyurethane transparent dressings is an example of a study that could be undertaken with outcomes of reductions in surgical site infections and also reductions in skin complications and improvements in final cosmetic outcomes. However, current studies are not adequate to show convincing differences. Research is also required on the effects of antiseptic-bearing dressings, placed at the end of an operation or at dressing changes. These antiseptics could include povidone-iodine, biguanides (such as chlorhexidine) or silver.

# 7 Postoperative phase

## 7.1 Changing dressings

### *Clinical question*

Is there any clinical evidence to support the use of a postoperative non-touch dressing change technique rather than the use of a clean dressing change technique in relation to the incidence of surgical site infection?

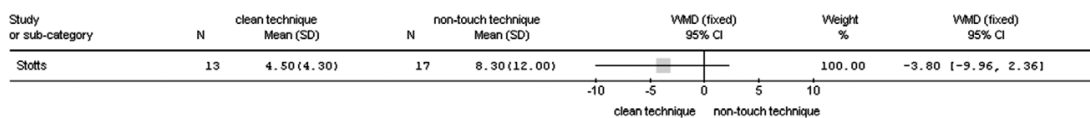
### Introduction

An 'aseptic' non-touch dressing technique is conventional and has been assumed to promote healing and prevent infection. As a consequence, it has been the gold standard for many years in the management of postoperative surgical wounds. This technique aims to prevent microorganisms on hands, surfaces and equipment from being introduced into the wound. When considering SSI incidence, it has to be asked whether there is a difference between the non-touch dressing technique and the less expensive clean dressing technique. The purpose of the review was to determine the clinical effectiveness of clean rather than non-touch dressing changing techniques for the prevention of SSI.

### Overview of evidence

A single RCT was identified.

A small pilot RCT<sup>211</sup> ( $n = 30$  participants) compared clean with non-touch dressing change techniques in the management of post-surgical wounds healing by secondary intention. [EL = 1–] The primary outcome was wound healing defined as a reduction in the wound volume. Participants were patients who had undergone elective gastrointestinal operations and who presented wounds healing by secondary intention. The trial found no statistically significant difference between the two groups (weighted mean difference  $-3.80$  cm<sup>3</sup>, 95% CI  $-9.96$  to  $2.36$ ) (Figure 7.1). However, the follow-up was only 4 days.



**Figure 7.1** Comparison of the effect on SSI incidence of clean versus non-touch dressing change techniques for management of wounds healing by secondary intention

### Evidence statement

There was insufficient evidence from a pilot study to show whether there is a significant difference in the rate of wound healing for a clean compared with an aseptic non-touch dressing change technique for healing by secondary intention. [EL = 1–]

### GDG interpretation

There is no high-quality evidence available that supports a change to the current clinical practice of using an aseptic non-touch technique. However, the GDG agreed that aseptic non-touch techniques for removing or changing surgical wound dressings can minimise the risk of contaminating the site with additional microorganisms.

**Recommendation on changing dressings**

Use an aseptic non-touch technique for changing or removing surgical wound dressings.

## 7.2 Postoperative cleansing

*Clinical question*

Is it clinically and cost-effective to use a wound cleansing solution for the management of a surgical wound healing by primary or secondary intention to reduce the incidence of surgical site infection?

### Introduction

The cleansing of surgical wounds with sterile saline solution is a common practice among healthcare practitioners (see Appendix I). As well as improving patient wellbeing, the practice is used to remove excess wound exudate or any mobile slough and wound debris. However, the impact this practice might have on SSIs needs more consideration. The purpose of the review was to examine the clinical and cost-effectiveness of using wound cleansing solutions for prevention of SSI in wounds healing by primary and secondary intention.

### Overview of evidence

*Wound cleansing*

No relevant studies were identified.

*Showering*

One systematic review was identified.

One well-conducted systematic review<sup>212</sup> (14 RCTs) was included that examined the evidence for postoperative wound cleansing and the solutions used. [EL = 1+] Only two included quasi-RCTs ( $n = 203$  participants) comparing showering with no showering were considered here.

In one quasi-RCT ( $n = 121$  patients), patients who had undergone inguinal hernia and abdomino-perineal excision were allocated to either showering on the first postoperative day or to keeping their wound dry for 14 days. Although there was one stitch abscess in each group, there were no wound infections in either group at an assessment 2 weeks postoperatively.

In the other quasi-RCT ( $n = 82$  patients), patients had undergone 'surgery with or without drains' and were allocated to either a showering (on the second postoperative day) or no-showering group. There were two wound infections in the showering group ( $n = 39$  patients) and four in the no-showering group ( $n = 43$  patients), which was not a statistically significant difference (OR 0.53, 95% CI 0.09 to 3.05).

*Clinical question*

Is it cost-effective to use a wound cleansing solution for the management of a surgical wound healing by secondary intention to reduce the incidence of surgical site infection?

### Health economics overview of evidence

One study from a Cochrane review was included.

An RCT<sup>213</sup> compared the effect of cleansing a wound with saline solution against cleansing a wound with tap water on the incidence of wound infection. Participants were patients with acute traumatic or chronic wounds. Since there was no difference in the incidence of wound infection between the two groups, a cost-minimisation analysis needed to be carried out showing that tap water was less expensive than normal saline.

### Health economics evidence statement

The price in the British National Formulary (BNF)<sup>107</sup> for sodium chloride solution (0.9%) as a skin cleanser was 95p for 1 litre.

### Evidence statements

There was no evidence available that examined the effects of wound cleansing solutions for the prevention of SSI.

Two quasi-randomised studies showed no evidence of a difference between showering or not showering to prevent SSI. [EL = 1+]

### GDG interpretation

There appeared to be no obvious difference between showering and not showering in terms of the incidence of SSI.

The GDG consensus was that only sterile cleansing solutions should be applied in the immediate postoperative period. However, where a surgical incision has separated or has been surgically opened to drain pus, several days after surgery, then the use of tap water may be considered for wound cleansing.

There is no evidence to show that postoperative showering during the hospital stay affects the rate of SSI. Therefore, patients can choose to shower safely according to local protocols.

### Recommendations on postoperative cleansing

Use sterile saline for wound cleansing up to 48 hours after surgery.

Advise patients that they may shower safely 48 hours after surgery.

Use tap water for wound cleansing after 48 hours if the surgical wound has separated or has been surgically opened to drain pus.

## 7.3 Topical antimicrobial agents for wound healing by primary intention

### Clinical question

What is the clinical effectiveness of topical antimicrobials to reduce surgical site infection?

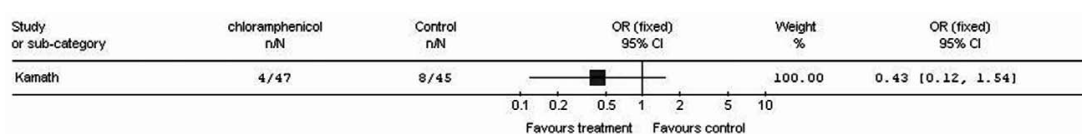
### Introduction

The use of topical antibiotics in wound healing by secondary intention is questionable because of the risks of unknown absorption and toxicity, allergy and antimicrobial resistance. Antiseptics have an established important role in chronic wound care, for example chlorhexidine (and other related compounds) and povidone-iodine with other antiseptics such as silver and even honey.

### Overview of evidence

One RCT was identified.

A single RCT<sup>214</sup> ( $n = 92$  participants) examined the effect on the prevention of SSI when applying a topical antimicrobial to the surgical wound. [EL = 1+] Patients underwent orthopaedic surgical procedures following a fractured neck of the femur. The outcome considered was SSI. The antimicrobial used was a chloramphenicol ointment applied to the incisional site at the end of the procedure and at the third day postoperatively. The trial found no statistically significant difference between the two groups (OR 0.43, 95% CI 0.12 to 1.54) (Figure 7.2).



**Figure 7.2** Comparison of the effect on SSI incidence of topical chloramphenicol ointment application to the surgical wound versus no application

### Evidence statement

There is evidence from a single RCT to suggest that there is no difference in the incidence of SSI when applying chloramphenicol to the incisional site in the postoperative period. [EL = 1+]

### GDG interpretation

There is insufficient evidence from one underpowered study to show any benefit of using topically applied chloramphenicol to prevent SSI.

### Recommendation on topical antimicrobial agents for wound healing by primary intention

Do not use topical antimicrobial agents for surgical wounds that are healing by primary intention to reduce the risk of surgical site infection.

## 7.4 Dressings for wound healing by secondary intention

### *Clinical questions*

Is it clinically effective to use topical antiseptics and antibiotics for the management of surgical wounds healing by secondary intention?

Which is the most clinically effective dressing in the management of surgical wounds healing by secondary intention?

### Introduction

This section updates recommendations within the NICE Technology Appraisal 24: 'Guidance on the use of debriding agents and specialist wound care clinics for difficult to heal surgical wounds'.

There are many types of antimicrobials and antimicrobial-impregnated dressings available for the management of surgical wounds healing by secondary intention. The efficacy of these dressings and topical agents has been considered in this review.

### Overview of the evidence

Four RCTs were identified.

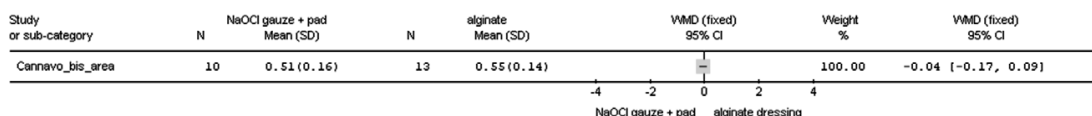
Four trials<sup>215-218</sup> ( $n = 226$  participants) investigated the effect on wound healing when using various types of dressing, with or without topical solutions, in post-surgical wounds healing by secondary intention. [EL = 1-] Participants were patients with surgical wounds left open to heal by secondary intention. The outcome of interest reported in the studies was wound healing expressed as time to complete healing, time to a clean wound, proportion of wounds healed during follow-up or wound size reduction. Definitions used varied among the studies.

#### *Sodium hypochlorite-soaked gauze plus combine dressing pad compared with combine dressing pad compared with alginate dressing*

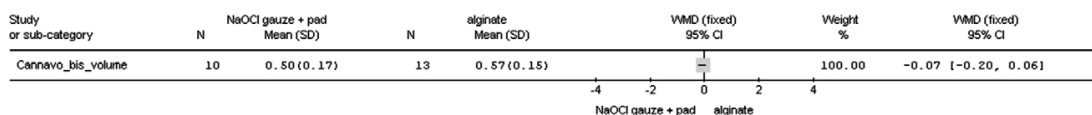
One RCT<sup>215</sup> ( $n = 36$ ) compared the use of a gauze soaked with sodium hypochlorite plus a combine dressing pad with the use of a combine dressing pad alone and with the use of an alginate dressing. [EL = 1-] The study included post-surgical abdominal wounds that had presented with a breakdown and followed size reduction of the wounds (surface and volume) for the three different groups. The trial found no statistically significant difference in the wound size reduction between the sodium hypochlorite gauze group and the alginate dressing group (Figures 7.3 and 7.4). It found, however, that the wound size reduction appeared to be significantly greater when using the combine dressing pad against the use of the sodium hypochlorite-soaked gauze or alginate dressing (Figures 7.5 and 7.6).

#### *Silicone foam dressing compared with gauze soaked in mercuric antiseptic solution dressing*

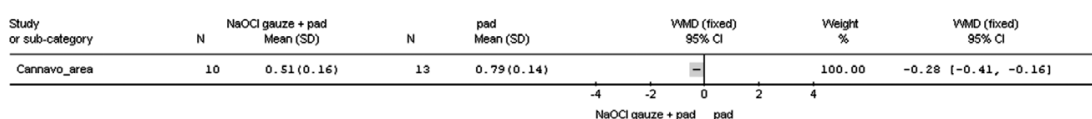
One RCT<sup>216</sup> ( $n = 50$  participants) examined the effect of using a silicone foam dressing compared with the use of a ribbon gauze soaked in a mercuric chloride solution in the management of



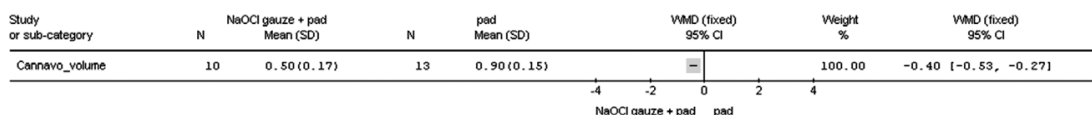
**Figure 7.3** Comparison of the reduction of the wound area using sodium hypochlorite-soaked gauze and a combine dressing pad versus alginate dressing for management of wounds healing by secondary intention



**Figure 7.4** Comparison of the reduction of the wound volume using sodium hypochlorite-soaked gauze and a combine dressing pad versus alginate dressing for management of wounds healing by secondary intention



**Figure 7.5** Comparison of the reduction of the wound area using sodium hypochlorite-soaked gauze and a combine dressing pad versus combine dressing pad for management of wounds healing by secondary intention



**Figure 7.6** Comparison of the reduction of the wound volume using sodium hypochlorite-soaked gauze and a combine dressing pad versus combine dressing pad for management of wounds healing by secondary intention

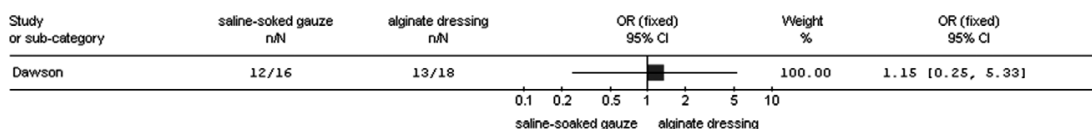
opened perineal wounds. [EL = 1–] The study did not find a statistically significant difference between the two groups when considering the time for a complete epithelialisation of the wound. However, the trial did report a statistically significant difference in the time needed for a wound to require only a dry dressing, favouring the use of the foam dressing (60.3 days ± 3.0 in the foam dressing group and 69.5 days ± 7.3 in the gauze group). However, insufficient information was given in the study to draw conclusions for this review.

*Moist cotton gauze dressing compared with polyurethane foam dressing containing hydroactive particles*

One RCT<sup>217</sup> (n = 43 participants) included patients with laparotomy or surgical incision of abscess. It examined the healing process of the opened wounds when two different dressings were used: moist cotton gauze compared with foam. [EL = 1–] The study reported the wound size reduction and the number of wounds completely healed by the fourth week. It found that the wound reduction and the proportion of wounds healed by the fourth week were higher in the foam dressing group. The authors reported these findings as statistically significant.

*Gauze packing soaked with saline compared with calcium alginate cavity pack*

One RCT<sup>218</sup> (n = 34 participants) explored the use of alginate dressings for incised abscess cavities compared with saline-soaked gauze packs. [EL = 1–] Wound healing was expressed as the proportion of patients with a completely healed wound after 2 weeks. It was found that the proportion of wounds healed was higher among the patients that received the saline-soaked gauze dressing but the result was not statistically significant (Figure 7.7).



**Figure 7.7** Comparison of wound healing rates using alginate dressings for incised abscess cavities versus saline-soaked gauze packs

### Evidence statements

There is insufficient high quality evidence to suggest any difference in the wound size reduction of surgical wounds healing by secondary intention when comparing the use of gauze with sodium hypochlorite with the use of a combine dressing pad or with the use of alginate dressing. [EL = 1–]

There is insufficient high quality evidence to suggest any difference in healing rates when comparing the use of silicone foam dressings with the use of ribbon gauze soaked in mercuric antiseptic solution in the healing process of open surgical wounds. [EL = 1–]

There is insufficient evidence to determine whether there is any difference in the healing process of post-surgical open wounds in patients presenting with abscesses when comparing the use of moist cotton gauze with polyurethane foam with the use of hydroactive particles dressings or when comparing the use of gauze packing with saline with the use of alginate cavity packs. [EL = 1–]

### GDG interpretation

Many of the trials identified are old and most of the materials used do not reflect the underlying principles of current wound management and may have a detrimental effect on the patient's experience (for example, pain).

A number of new dressings containing antimicrobials, such as honey, silver and cadexomer iodine, are now available and may be clinically appropriate. However, to date, there is no evidence to prove their efficacy in prophylaxis of SSI and further studies to prove their worth in treatment are needed (see Appendix C).

### Recommendations on dressings for wound healing by secondary intention

Do not use Eusol and gauze, or moist cotton gauze or mercuric antiseptic solutions to manage surgical wounds that are healing by secondary intention.

Use an appropriate interactive dressing to manage surgical wounds that are healing by secondary intention.

Refer to a tissue viability nurse (or another healthcare professional with tissue viability expertise) for advice on appropriate dressings for the management of surgical wounds that are healing by secondary intention.

### Research recommendation on dressings for wound healing by secondary intention

What are the most appropriate methods of chronic wound care (including alginates, foams and hydrocolloids and dressings containing antiseptics such as antimicrobial honey, cadexomer iodine or silver) in terms of management of surgical site infection as well as patient outcomes?

#### *Why this is important*

There are many small cohort studies which have examined the use of the wide range of dressings in surgical site infection management after an infected wound has been opened or after there has been separation of the wound edges after a surgical site infection. Differences are hard to see because the trials often include other wounds that are healing by secondary intention, such as chronic venous or diabetic ulcers and pressure sores. Specific studies using antiseptics (povidone-iodine, biguanides such as chlorhexidine, or silver) and other agents such as antimicrobial honey need to address this in powered randomised trials, specifically in the management of surgical site infection of an open wound. Similar questions need to be asked for the use of topical negative pressure, which has become widely used with or without antiseptic irrigation.



## 7.5 Antibiotic treatment of surgical site infection and treatment failure

### Introduction

Not all SSIs require antibiotic treatment: minor infections may respond to drainage of pus (for example, by removal of sutures) and topical antiseptics. Antibiotic therapy carries with it the risk of adverse drug reactions and the development of resistant bacteria with the associated risk of *C. difficile* diarrhoea.

### GDG consensus of good practice

Microbiological cultures (of swabs and/or samples of pus) should be sought from clinically serious infections, when patients are hypersensitive to first-line antibiotics and when antibiotic-resistant pathogens are suspected, for example in recent hospital inpatients or those returning from travel to countries with high rates of antimicrobial-resistant pathogens. The choice of second-line antibiotics is limited in such patients, and culture results can guide therapy should initial treatment fail.

First-line antibiotic therapy ('empirical' or 'blind' therapy) should cover the most likely infecting pathogens, the patient's clinical status – including recent antibiotic history and microbiology – and local antibiotic resistance patterns. Empirical therapy should be broad-spectrum and cover *S. aureus*, which is the most common cause of SSI after all types of operation.

SSIs after clean-contaminated surgery that involves mucosal surfaces should be treated with an empirical antibiotic regimen that includes activity against anaerobic bacteria (for example, metronidazole, co-amoxiclav, piperacillin-tazobactam or meropenem).

SSIs in patients known to have, or be at risk of methicillin-resistant *S. aureus* (MRSA) carriage should be treated with an empirical antibiotic regimen that includes activity against locally prevalent strains of MRSA.

All antibiotic therapy should be reviewed in the light of their clinical progress after culture results have been reported.

Recommendations for first- and second-line antibiotic therapy of SSI should be included in local hospital and community antibiotic prescribing guidelines and be consistent with local antibiotic formularies. These guidelines should include advice about special patient groups (for example, patients who are at higher risk locally of being carriers of resistant bacteria such as MRSA) and about particular organisms associated with SSI after specific and common types of surgical operation.

Antibiotic treatment guidelines should be reviewed regularly by microbiologists and, where appropriate, infectious diseases specialists (IDS) in response to local antibiotic sensitivity prevalence data. Microbiologists and IDS should also be available to provide expert advice for individual patients if indicated.

In the event of treatment failure, the patient should be reviewed clinically for evidence of non-infective reasons for wound breakdown, such as poor nutrition or underlying surgical problems (for example, a collection of pus, an anastomotic leak or a foreign body). It is imperative that the results of samples sent for microbiology are reviewed as soon as they are available and further samples obtained if required.

If, based on the microbiology results, a change of antibiotic is considered, it should cover a different spectrum of pathogens from the antibiotic treatment used previously.

### GDG interpretation

As no systematic searches were conducted for this section of the guideline, the GDG's recommendations are based on its consensus view reflecting good practice in the antibiotic treatment of SSIs.

#### **Recommendation on antibiotic treatment of surgical site infection and treatment failure**

When surgical site infection is suspected (i.e. cellulitis), either *de novo* or because of treatment failure, give the patient an antibiotic that covers the likely causative organisms. Consider local resistance patterns and the results of microbiological tests in choosing an antibiotic.

## 7.6 Debridement

### *Clinical question*

Is the use of debridement techniques clinically effective in the prevention and management of surgical site infection?

### Introduction

This section updates recommendations within the NICE Technology Appraisal 24: 'Guidance on the use of debriding agents and specialist wound care clinics for difficult to heal surgical wounds'.

The presence of dead (necrotic) or damaged (slough) tissue within a surgical wound healing by secondary intention almost certainly delays healing. Necrotic material or slough within the wound margin acts as a medium for bacterial proliferation and therefore should be removed (the process of debridement – see the Glossary of terms).

Most data from trials of dressings involve the management of chronic wounds, such as diabetic and venous leg and pressure ulcers healing by secondary intention. In general, data from chronic wound healing studies cannot be readily applied to surgical wounds healing by secondary intention (for example, where the wound edges have separated, owing to other confounding factors such as the patient's comorbidity, the presence of infection, or when the incision has electively been left open to heal by secondary intention because of severe intraoperative contamination as described previously). In this review, the clinical effect of various debridement techniques for the prevention and management of SSI was investigated.

### Overview of evidence

Four RCTs were identified.<sup>219–222</sup>

#### *Dextranomer compared with other dressings*

Three of the studies<sup>219,220,222</sup> ( $n = 110$  participants) examined the effect of dextranomer (paste or beads) in the management of postoperative infected wounds. [all EL = 1–]

An RCT<sup>219</sup> ( $n = 20$  participants) compared dextranomer (a debridement technique) with Eusol gauze in the healing process of postoperative wounds. [EL = 1–] Patients had open, infected surgical wounds following appendicectomy or bowel surgery. The main outcome was time to a clean wound bed ready for secondary wound closure. The authors reported that the mean time to wound closure was significantly shorter for the dextranomer group when compared with the control group but confidence intervals were not provided. The authors reported that the mean time to wound closure was 8.1 days in the dextranomer group and 11.6 days in the Eusol group.

An RCT<sup>222</sup> ( $n = 50$  participants) compared dextranomer beads with a silicone foam elastomer dressing in the treatment of post-surgical opened wounds. [EL = 1–] The participants had post-surgical wounds that had either broken down or had been left open postoperatively. Both outcomes, time to a clean wound bed and time to complete wound healing, were considered. Time to a clean wound bed was reported by the authors as similar in both groups but the time to complete healing was significantly longer in the group receiving the dextranomer treatment. However, not enough data were provided to confirm the findings. The study reported that the mean time taken to complete healing in the dextranomer group was  $41 \pm 4$  days and in the elastomer dressing group  $37 \pm 3$  days.

Another RCT<sup>220</sup> ( $n = 40$ ) compared the application of a dextranomer paste to the wound with the application of a gauze dressing soaked with polyvinylpyrrolidone 10%. [EL = 1–] The study included patients with post-surgical infected wounds. The primary outcomes were time to clean wound bed and time to complete wound healing. Time to clean wound bed was expressed as the disappearance or resolution of oedema, pus and debris, erythema, and necrotic tissue, and the presence of granulation tissue. None of the observed variables for the wound healing presented a statistically significant difference between the two groups; the only notable result showed that the dextranomer paste was more effective in cleansing those wounds with higher levels of pus and debris. However, the study reported insufficient data to support this result. Time to complete healing was not reported.

*Enzymatic dressing compared with dressing with saline*

A small RCT<sup>221</sup> ( $n = 18$  participants) examined the effects of an enzymatic dressing (streptodornase/streptokinase) against a dressing with saline for the management of post-surgical infected wounds. [EL = 1–] Participants had infected wounds following laparotomy. The primary outcome was time in days to a clean wound bed. The authors reported a statistically significant difference favouring the enzymatic dressing against the saline soaked dressing: mean time to a clean wound and eventual secondary closure  $5.0 \pm 2.2$  in the enzymatic dressing group and  $13.5 \pm 6.8$  in the dressing with saline group. There was not enough information provided to support the findings.

**Evidence statements**

There is insufficient evidence to decide whether there is an effect on the healing of postoperative open and infected wounds when comparing dextranomer beads treatment with Eusol gauze dressing. [EL = 1–]

The evidence from a small RCT suggesting that foam dressings favour the healing of postoperative open wounds when compared with dextranomer dressings is insufficient. [EL = 1–]

There is insufficient evidence to decide whether there is an effect on the healing of postoperative infected wounds when comparing dextranomer paste with polyvinylpyrrolidone 10%. [EL = 1–]

The evidence from a small RCT suggesting that enzymatic dressings (streptodornase/streptokinase) favour the healing of postoperative wounds when compared with saline-soaked dressings is insufficient. [EL = 1–]

**GDG interpretation**

Many of the trials identified are old and the materials used do not reflect the underlying principles of modern wound management and debridement techniques, and are no longer routinely used.

**Recommendation on debridement**

Do not use Eusol and gauze, or dextranomer or enzymatic treatments for debridement in the management of surgical site infection.

**Research recommendation on debridement**

What is the effectiveness of modern methods of debridement in surgical wounds healing by secondary intention?

**7.7 Specialist wound care services**

The recommendation below has been taken unchanged from NICE Technology Appraisal 24, 'Guidance on the use of debriding agents and specialist wound care clinics for difficult to heal surgical wounds'. The decision was made by the developers not to update the evidence review relating to specialist wound care services in NICE Technology Appraisal 24. This was on the grounds that it was of limited relevance to the revised scope of the guideline and was therefore not prioritised for review.

**Recommendation on specialist wound care services**

Although there is no direct evidence to support the provision of specialist wound care services for managing difficult to heal surgical wounds, a structured approach to care (including preoperative assessments to identify individuals with potential wound healing problems) is required in order to improve overall management of surgical wounds. To support this, enhanced education of healthcare workers, patients and carers, and sharing of clinical expertise will be required.

# Appendix A

## Declarations of interest

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<b>GDG member</b>	<b>Interest</b>
David Evans	<p>Member of the British Thoracic Society.</p> <p>Member of the RCP Acute Medicine Task Force.</p> <p>Wife was a Non-Executive Director of the Central Cornwall Primary Care Trust.</p>
Mark Farrington	<p>Employed by the Health Protection Agency.</p> <p>Provides occasional expert advice and commentary to various pharmaceutical companies, research organisations and healthcare equipment manufacturers. This has included 'Cambridge Healthcare and Biotech' on yet-to-be-marketed antibiotics.</p> <p>In the past, has performed research sponsored by laboratory/sampling equipment manufacturers and the National Blood Service.</p> <p>Previously an infection control doctor at the BUPA Cambridge Lea Hospital, lecturing regularly to BUPA nursing staff nationally on infection control.</p> <p>Has received educational travel grants to attend scientific meetings in the UK and abroad throughout career, from various pharmaceutical companies.</p>
Kate Gould	<p>Sponsorship of travel to International Society of Heart and Lung Transplantation, and Interscience Conference on Antimicrobial Agents and Chemotherapy – Novartis.</p> <p>Regional Microbiologist – HPA.</p> <p>DIPC and Consultant Microbiologist – Newcastle upon Tyne Hospitals NHS Foundation Trust.</p> <p>Sponsorship of travel to International Society for Heart and Lung Transplantation for other members of Laboratory team – Pfizer, Lederie, AstraZeneca.</p>
David Leaper	<p>Part-time medical advisor to Renovo who are in phase III trials of anti-scarring agents. Was given a small number of shares in the company when they went PLC. In the past, have acted in a similar capacity to Arizant and Inditherm who make warming products. In addition, advise Hutchinson in the USA with regard to the development and evaluation of a new device to measure tissue oxygen. Also an invited and honorarium-paid lecturer with Smith and Nephew and Ethicon.</p> <p>Clinical trials in conjunction with Ethicon, Hutchinson, and NitricBio. Trials involve sutures and wound care products.</p> <p>Cardiff/Swansea group have financial support to undertake trial work.</p> <p>New research group in Salisbury is in part funded by Convatec and financial support is pending from Ethicon, through a competitive grant from their Foundation, Tyco, Coloplast, Novartis and possibly Insense. Much of this work relates to topics in postoperative SSI care.</p> <p>In the past, have had many charitable and industry grants for research work which is now complete. This has been in the area of antibiotic prophylaxis and treatment, dressings research and tissue perfusion. Pecuniary support from several companies has been provided to attend and give papers to international societies and for educational activities. Most was related to the Surgical Infection Society and the European Wound Management Association of which I have been President and the European Tissue Repair Society of which I am currently on the board.</p>

# Appendix B

## Clinical questions

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1. When, how and what information should be provided for patients for the prevention surgical site infection?
2. What is the clinical effectiveness of preoperative showering to reduce surgical site infection?
3. What is the contribution to clinical effectiveness of the timing and number of preoperative washing for the prevention of surgical site infection?
4. Are preoperative showers with antiseptics cost-effective?
5. What is the clinical effectiveness of preoperative hair removal from the operative site to reduce surgical site infection?
6. Does the timing of preoperative hair removal affect the rate of surgical site infection?
7. What is the cost-effective method of hair removal?
8. Does patient theatre attire affect the incidence of surgical site infection?
9. What is the clinical effectiveness of theatre staff wearing non-sterile theatre wear (scrub suits, masks, hats, overshoes) for the prevention of surgical site infection?
10. Does staff exiting and re-entering the operating room affect the incidence of surgical site infection?
11. Does patient nasal decontamination to eliminate *Staphylococcus aureus* affect the rate of surgical site infection?
12. What is the contribution to clinical effectiveness of the timing of nasal decontamination for the prevention of surgical site infection?
13. What is the cost-effectiveness of mupirocin nasal ointment for the prevention of surgical site infection caused by *Staphylococcus aureus*?
14. Does mechanical bowel preparation reduce the rate of surgical site infection?
15. Does the removal of hand jewellery, artificial nails and nail polish reduce the incidence of surgical site infection?
16. What is the clinical effectiveness of parenteral or oral antibiotic prophylaxis for the prevention of surgical site infection compared with placebo or no antibiotic in patients undergoing surgery involving a skin incision?
17. For which types of surgery would prophylaxis be clinically and cost-effective? When should antibiotic prophylaxis be given – pre/peri/postoperatively?
18. What is the clinical hand decontamination strategy to use between subsequent surgeries?
19. What is the cost-effective hand decontamination strategy to use between subsequent surgeries?
20. Is the use of incise drapes clinically and cost-effective in reducing the incidence of surgical site infection?
21. Which incise drapes are clinically and cost-effective in reducing the incidence of surgical site infection?
22. Is the use of gowns clinically effective in reducing the incidence of surgical site infection?
23. Is the use of reusable or disposable surgical drapes and gowns related to surgical site infection?
24. Is there a difference between double- versus single-gloving affecting the incidence of surgical site infection?
25. Does the puncture rate of gloves correlate to the incidence of surgical site infection?
26. Is the use of preoperative skin antiseptics clinically effective in the prevention of surgical site infection?
27. Does use of diathermy for surgical incisions affect the rate of surgical site infection?
28. Is patient perioperative oxygenation clinically effective for the prevention of surgical site infection?
29. What is the clinical effectiveness of perioperative perfusion and hydration for the prevention of surgical site infection?

30. What is the clinical effectiveness of strict blood glucose control to reduce surgical site infection?
31. Is intracavity lavage or wound irrigation clinically effective for the prevention of surgical site infection?
32. Is the application of intraoperative topical antiseptics/antimicrobials before wound closure clinically effective in reducing surgical site infection rates?
33. Which type of suture is clinically effective as a closure method?
34. Which type of suture is clinically and cost-effective as a closure method?
35. Which type of dressing is advocated for immediate postoperative wound/incision coverage? Is it clinically and cost-effective to use interactive dressings in the immediate postoperative management of a surgical wound to prevent surgical site infection?
36. Is there any clinical evidence to support the use of a postoperative non-touch dressing change technique rather than the use of a clean dressing change technique in relation to the incidence of surgical site infection?
37. Is it clinically and cost-effective to use a wound cleansing solution for the management of a surgical wound healing by primary or secondary intention to reduce the incidence of surgical site infection?
38. Is it cost-effective to use a wound cleansing solution for the management of a surgical wound healing by secondary intention to reduce the incidence of surgical site infection?
39. What is the clinical effectiveness of topical antimicrobials to reduce surgical site infection?
40. Is it clinically effective to use topical antiseptics and antibiotics for the management of surgical wounds healing by secondary intention? Which is the most clinically effective dressing in the management of surgical wounds healing by secondary intention?
41. Is the use of debridement techniques clinically effective in the prevention and management of surgical site infection?

# Appendix C

## Wound dressings for surgical site infection prevention

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The majority of surgical wounds heal by primary intention (see Glossary of terms). However, on some occasions, it may not be advantageous to close the wound in this way owing to the presence of a persistent source of infection and the wound may therefore appear to have been left open. In these situations the wound will be being encouraged to heal from the base upwards by the use of appropriate dressings that promote healing by secondary intention (see Glossary of terms). Also, on occasions, a closed surgical wound may separate or may be opened intentionally to allow the drainage of excess fluid or infection (pus) and to assist the management of any underlying pathology.

The main purposes of a surgical dressing when used to cover a wound healing by primary intention are to control any postoperative bleeding, absorb exudate if anticipated, ease pain and provide protection for newly formed tissue.

For healing to take place at an optimum rate, all dressing materials used should ensure that the wound remains:

- moist with exudate but does not get macerated ('not too wet – not too dry')
- free from clinical infection and excessive slough or devitalised/necrotic tissue
- free from toxic chemicals, particles or fibres released from the dressing
- at an optimum temperature for healing to take place (around 37° C)
- undisturbed by frequent or unnecessary dressing changes
- at an optimum pH value.

It is generally considered best practice to cover all surgical incisions post-procedure and, when practical, this should involve low adherence, transparent polyurethane dressings, which protect the wound and give the opportunity to check the surgical incision site for any signs of wound infection without having to disturb the dressing itself. These dressings can be left in place for between 3 and 5 days, during which time the epithelialisation process may be completed in a wound healing by primary intention.

Dressings should incorporate an integral central pad of absorbent material (island dressings) if oozing of fluid (blood or exudate) from the incision site is anticipated in the immediate postoperative phase. These island dressings combine the advantages of transparent low-adherent polyurethane film dressings while also having the ability to absorb small amounts of excess exudate, aiding the normal debridement process (see Glossary of terms) in the wound and help to prevent any adverse effect on healing caused by surface cooling, for example.

The advantages of using low-adherent transparent polyurethane film dressings in general are as follows:

- they allow postoperative inspection of the wound without disturbance of the dressing
- they make the wound 'waterproof' to allow early showering or bathing while at the same time acting both as a barrier to possible external bacterial contamination and to prevent cross contamination to other patients
- their low adherence allows relatively painless and easy removal when there is a need for a dressing change, such as when there is a build-up and leakage of exudate (oozing) from the incision site
- they prevent any material from further contaminating the wound
- they maintain an optimal moist wound environment<sup>201</sup> without causing maceration of the surrounding skin as the dressing material is permeable to moisture and gas

- they prevent heat loss from the wound and maintain the optimal wound temperature
- they provide a cost-effective approach to wound management as they reduce the number of dressing changes required and the pain experienced by the patient. The overall cost-effectiveness is further improved, even if the dressing is replaced once during the healing process, since when alternative conventional dressings are used, additional medication such as analgesia may also be required.

Table C.1 lists the various types of dressing available for surgical wounds and their main clinical indications.

**Table C.1** Classification of dressings available for surgical incision care (sutured wounds healing by primary intention) and management of open wounds with or after surgical site infection (healing by secondary intention).

Dressing classification	Healing intention	Main clinical indications
Cotton wool and gauze (absorbent pads)	Primary – not generally recommended Secondary – occasionally	Additional absorbency over another primary dressing or a low-adherent wound contact layer (see below)
Alginates	Secondary	Absorbency, maintaining a moist wound surface and the removal of cellular debris/slough from the wound surface
Semi-permeable films (may or may not incorporate an island dressing)	Primary	Facilitating the optimum healing environment and providing a barrier to bacteria/protect the incision site
Polyurethane foams	Secondary Occasionally primary	Absorbency, maintaining the optimum healing environment and minimising the risk of trauma at the wound surface at the time of dressing change
Hydrocolloids [wafer and fibrous (hydrofibre)]	Primary – wafers may be used Secondary – fibrous	Facilitating the optimum healing environment and protecting the incision site Absorbency, maintaining a moist wound surface
Hydrogels	Secondary	Rehydration of tissues and some absorption
Low-adherent wound contact layers	Secondary	Minimising the risk of trauma at the wound surface and the patient's pain experience at the time of dressing change.
Combinations of the above dressing materials – various	Secondary	Will depend on dressing chosen, primarily considered for the management of specific symptoms associated with wound infection such as the production of excess exudate, pain, associated wound odour
Antimicrobial-carrying dressings (cadexomer iodine and silver)	Secondary	Wound cleansing; wound bed preparation – the stimulation and influence of specific cells involved with the immune system and the management of wound infection in conjunction with appropriate systemic therapy
Antiseptic wound irrigation (povidone-iodine and chlorhexidine)	Secondary – occasionally	For the prevention/management of wound infection in conjunction with appropriate systemic therapy

Additional wound management products / therapies that may be considered:

- topical negative pressure (TNP) therapy
- growth factors (such as platelet-derived growth factor)
- antibacterial honey
- larva therapy (maggots)
- anti-scarring agents (such as transforming growth factors)
- antiseptic-impregnated sutures (such as triclosan coating).



# Appendix D

## Cost-effectiveness of hair removal

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### D.1 Literature survey

Five studies were identified in the cost-effectiveness review.<sup>39–43</sup>

A series of case studies in a descriptive pilot study<sup>41</sup> undertaken in Belgium compared the cost-effectiveness of three preoperative skin preparation protocols – razor, clipper and depilatory cream – in conjunction with whole-body disinfection with chlorhexidine in patients undergoing coronary artery bypass graft (CABG) surgery.

What appeared to be a prospective cohort study<sup>42</sup> undertaken in the USA compared preoperative hair removal with disposable razors, clipper and depilatory cream, as well as no hair removal.

#### D.1.1 Methodological quality of published health economic studies

It was difficult to assess from these studies which methods of hair removal (i.e. shaving using razors, depilatory cream or clipping) were most cost-effective. Furthermore, nearly all of these studies were undertaken more than 20 years ago. Three studies<sup>39,40,42</sup> had very limited cost analyses. Two studies<sup>40,42</sup> did not include the staff costs associated with hair removal, which is important as the time spent by the healthcare professional removing hair from the patient will vary among the different preoperative hair removal interventions. One study<sup>39</sup> only included the costs of treating SSI in the analysis and did not include the costs of preoperative hair removal.

#### D.1.2 Results of published studies

Two studies<sup>40,42</sup> compared shaving using razors with no preoperative hair removal. As these two studies only included the costs of preoperative hair removal, they found that shaving was more costly than no hair removal.

Four studies<sup>40–43</sup> compared shaving using razors with the use of depilatory cream. One study<sup>40</sup> found that the costs of consumables per 100 patients were approximately £14 for shaving and £22 for the depilatory cream. One study<sup>41</sup> found no statistically significant difference in depilation costs for the two groups, with median costs per patient for the razor and cream depilation groups being \$6.13 and \$8.16, respectively ( $P = 0.10$ ). One study<sup>42</sup> found that the use of depilatory cream was more expensive than shaving using razors (\$56.70 and \$11.40/m<sup>2</sup>/1000 patients/year, respectively). The authors reported that, despite the depilatory cream being the most expensive intervention, the additional costs could be offset by the time and labour saved. However, the authors did not provide any estimates of these savings. One study<sup>43</sup> found that the mean cost to prepare an area of 250 cm<sup>2</sup> (average hernia repair) cost £0.25 when using the depilatory cream compared with £0.80 when shaving, after taking into account staff time and the disposable equipment used.

Two studies<sup>40,42</sup> examined depilatory cream with no preoperative hair removal. As these two studies only included the costs of preoperative hair removal, they found that depilatory cream was more costly than no hair removal.

It is difficult to assess from these studies, three of which were undertaken more than 20 years ago, which method of hair removal (i.e. depilatory cream or clipping) is most cost-effective. Additional economic analysis was thus conducted to inform the GDG on the cost-effectiveness of the various hair removal practices, including no hair removal, as an intervention to prevent SSIs.

## D.2 Economic modelling

### D.2.1 Method

A decision-analytic economic model was developed to assess the cost-effectiveness of the various methods of preoperative removal of patients' hair. The analysis was undertaken from the perspective of the National Health Service (NHS), and all costs were updated to 2004 prices using the Hospital and Community Health Services (HCHS) pay and price inflation index. The model structure is illustrated in Figure D.1 and the comparisons in this analysis were:

1. no hair removal
2. hair removal by shaving using razors
3. hair removal using depilatory cream
4. hair removal using an electric clipper.

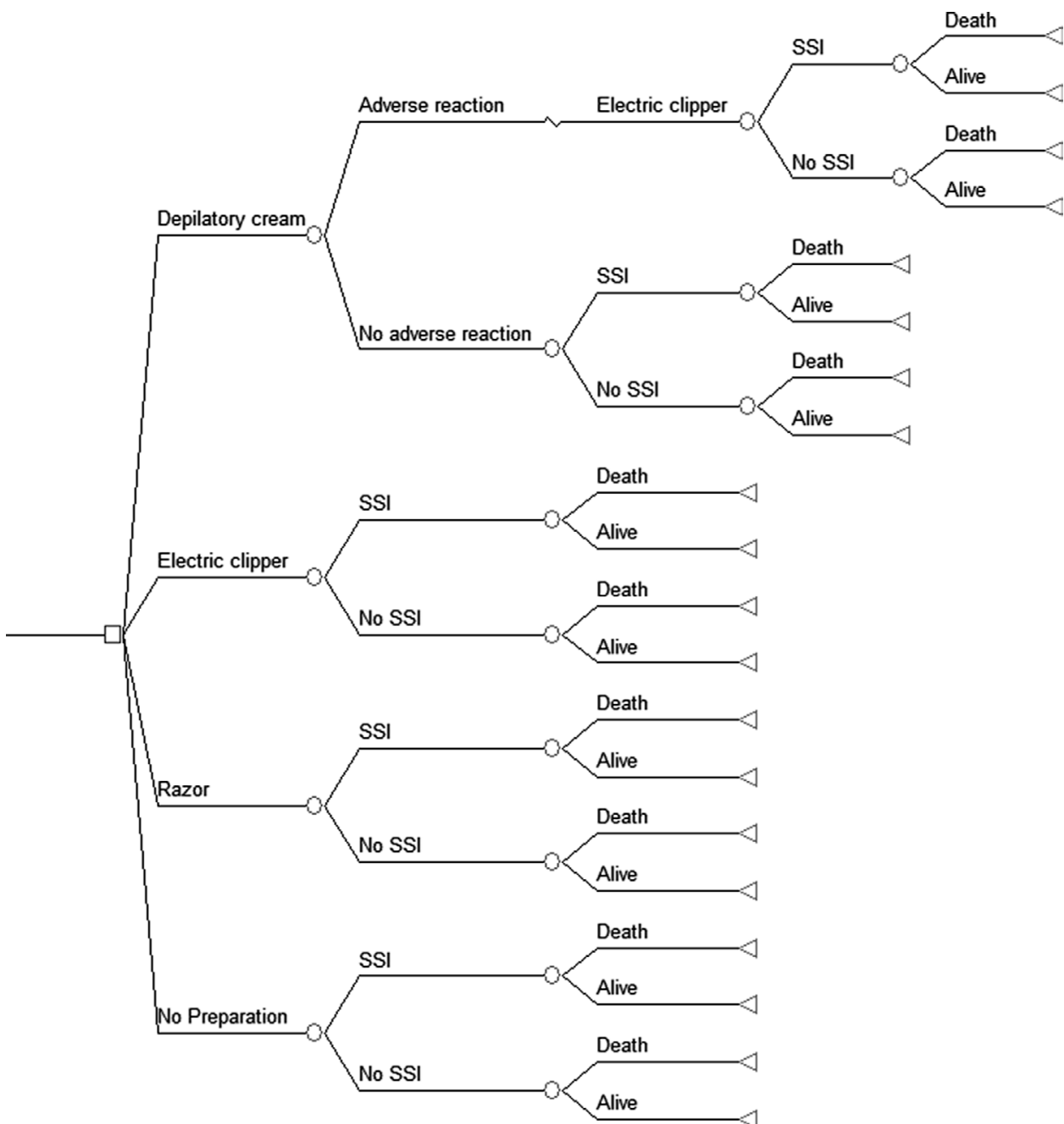


Figure D.1 Decision-analytic hair removal model

In a hypothetical cohort of 1000 patients undergoing surgery, the probability of acquiring an SSI after surgery and the associated mortality risk for patients with or without SSI for each group was modelled. Some patients have adverse reactions to depilatory cream and this was incorporated into model with the assumption that such patients undergo hair removal with an electric clipper instead. Outcomes were measured both in terms of the number of SSIs prevented and the number of quality-adjusted life-years (QALYs) gained. As quality of life information was only available for 1 year after surgery, the time horizon of the model was 1 year after surgery.

## D.2.2 Data

### *Effectiveness data*

Data from the clinical literature review was used to derive the proportion of SSIs in each of the preoperative hair removal groups. The literature reported that depilatory cream could cause adverse skin reactions in some cases and, as such, patients should be tested before full hair removal by applying some cream on an inconspicuous part of the skin. From the literature, the rate of adverse skin reactions to depilatory cream was found to be 7.8%.<sup>41</sup>

Mortality rates after surgery were derived from the Nosocomial Infection National Surveillance System (NINNS) study.<sup>4</sup> This study found that in those patients who did not acquire an SSI following their operation the risk of death was 2.6% (95% CI 2.5% to 2.7%), compared with a significantly higher risk of death in those patients acquiring an SSI, who faced a 6.6% (95% CI 5.7% to 7.6%) risk of dying following surgery (Table D.1).

**Table D.1** Effectiveness data for hair removal methods in the literature

Parameter	Baseline	Minimum/lower	Maximum/upper	References
SSIs:				
Rate of SSIs razor	9.42%	6.91%	11.93%	39,225 226
Relative risk electric clipper versus razor	0.58	0.36	0.92	39,225 226
Relative risk depilatory cream versus razor	0.61	0.36	1.02	40,227,228
Relative risk no preparation versus razor	0.69	0.39	1.25	40,256
Mortality rate after surgery:				
Patients with SSI	6.64%	5.72%	7.56%	4
Patients with no SSI	2.56%	2.44%	2.68%	4
Adverse skin reaction using depilatory cream	7.76%	3.5%	12.8%	41
Utility values:				
Patients with SSI	0.57	0.51	0.64	4,224
Patients with no SSI	0.64	0.57	0.71	4,224

Quality of life data in patients undergoing surgery were derived from a case–control study that compared the impact of SSIs following orthopaedic surgery on quality of life.<sup>223</sup> In this study, case-patients (i.e. those with an SSI) and matched controls were interviewed 1 year after detection of SSI or after initial surgery, respectively. Quality of life was measured using the short form of a questionnaire containing 36 items (SF-36). Results of the SF-36 were then converted to utility values using a published algorithm.<sup>224</sup>

### *Resource use and cost data*

The costs included in the analysis were the direct costs of the various hair removal methods (i.e. staff time associated with removing patients' hair and the hospital costs associated with treating a wound infection). The costs of the actual surgical procedure were not included as it was assumed they would be similar between the four different patient groups.

The time required to remove patients' hair prior to surgery was derived from a 1996 study<sup>41</sup> that found that the median time required for hair removal (after standardisation of hair growth between groups) was:

- 8 minutes and 32 seconds for a shaving area of 1.78 m<sup>2</sup> using razors
- 16 minutes and 13 seconds for an area of 1.83 m<sup>2</sup> using clippers
- 6 minutes and 20 seconds for an area of 1.80 m<sup>2</sup> using depilatory cream.

Using these data, the time required to remove hair in an area of 0.25 m<sup>2</sup> was estimated for each of the three removal methods. The time taken was then multiplied by the average wage for a band E nurse.<sup>229</sup>

**Table D.2** Resource use and costs for hair removal methods

Parameter	Baseline	Minimum/lower	Maximum/upper	References
Depilation time (seconds per 1.0 m <sup>2</sup> ):				
Clipper	417	206	628	41
Razor	319	110	527	41
Depilatory cream	238	150	325	41
Average wage for a band E nurse (per minute)	£0.31	£0.29	£0.41	229
Cost of clipper:				
Annual cost	£55.75	£30.50	£96.03	230
Price of disposable clipper blade	£1.92	£1.73	£2.11	231
Number of operations per year	1000	800	1200	Assumption
Cost of depilatory cream:				
Price of 100 ml of depilatory cream	£4.69	£3.75	£5.63	Personal communication
Number of operations per 100 ml	2	1	3	Personal communication
Price of disposable razor	£0.12	£0.11	£0.13	231
Costs of treating SSI:				
Additional days in hospital if SSI	11.37	9.43	13.66	4
Cost per bed day due to SSI	£306.58	£229.94	£383.23	4

The price of an electric clipper (£94.91) and its charger (£73.88) were derived from a healthcare provider's catalogue,<sup>230</sup> with the price of the disposable blades (£1.92 per blade) used in the electric clipper being derived from the NHS Purchasing and Supply Agency catalogue.<sup>231</sup> It was assumed that one clipper could be used during a 3 year period. Based on a 3.5% interest rate, the yearly cost of the clipper and charger was £55.75, using the equivalent annual cost method.<sup>8</sup> Assuming an average of 1000 operations per year,<sup>41</sup> the cost per patient for using the clipper was estimated at £1.98 per patient.

The price of a single disposable razor blade (£0.12) was derived from the NHS Purchasing and Supply Agency catalogue.<sup>231</sup>

It was assumed that Veet® depilatory cream would be used for patients' hair removal. Using price data from Veet's preferred supplier in the UK, the price of a 100 ml package was £4.69, and it was assumed that 100 ml of depilatory cream was enough for two patients (personal communication with Veet's customer care).

The hospital costs associated with treating SSIs were derived from the NNINS.<sup>4</sup> The survey found that patients who acquired an SSI had an additional length of stay in hospital of 11.4 days more than patients with no SSI. The study also found that the cost per extra day spent in hospital due to SSI, in 2004 prices, was £307. This translates to an additional £3,500 per patient for treating an SSI.

### D.2.3 Results

The decision tree model predicted the number of SSIs prevented, the number of deaths prevented and the number of QALYs gained with each hair removal strategy. Each of the methods was then ranked by costs (i.e. from the least to the most costly) and an incremental cost-effectiveness ratio (ICER; i.e. additional cost per QALY gained) was then estimated by comparing each hair removal method with its next best alternative.

#### *Cost-utility analysis*

Despite shaving using razors being one of the less costly options for hair removal, once the costs of treating SSI were included in the analysis, this option became the most expensive. After including the costs of treating SSIs in the analysis, the use of clippers for preoperative hair removal was found to be the cheapest option and was also found to generate the highest number

of QALYs (Table D.3). As a result, when hair removal using electric clippers was compared with no preparation, with depilatory cream, or with shaving using razors, it was found to be dominant (i.e. it was both more effective and less costly).

**Table D.3** QALYs gained and total costs for each hair removal method for 1000 patients undergoing surgery

Hair removal method	QALYs gained	No. of SSIs	Costs of hair removal	Costs of treating SSI	Total costs	ICER (cost per QALY gained)
Electric clipper	618.79	55	£2,516	£190,610	£193,126	
Depilatory cream	618.60	57	£2,250	£198,311	£200,561	Dominated by electric clipper
No preparation	617.86	65	£0	£227,699	£227,699	Dominated by electric clipper
Razors	615.35	94	£530	£328,355	£328,865	Dominated by electric clipper

#### D.2.4 Sensitivity analysis

A probabilistic sensitivity analysis showed that the use of electric clipper for preoperative hair removal was the intervention most likely to be cost-effective at both a £20,000 and a £30,000 threshold for willingness to pay for a QALY. Furthermore, the results of the analysis also showed that, irrespective of the cost-effectiveness threshold, the use of electric clippers was always the option most likely to be cost-effective. Hair removal with depilatory cream was the next most likely option to be cost-effective. Hair removal using razors and no preparation were found to be the interventions with the lowest probabilities of cost-effectiveness.

### D.3 Discussion

The results of both the cost-effectiveness and the cost-utility analysis showed that hair removal with electric clippers was the most cost-effective method for preoperative hair removal. It was shown to be both more effective (in terms of SSIs prevented and QALYs gained) and less costly than its alternatives. These results were further strengthened in the sensitivity analysis, which showed that hair removal with electric clippers was the hair removal option most likely to be cost-effective, irrespective of the cost-effectiveness threshold (i.e. the amount the decision maker is willing to pay per unit of effect, in this case an extra QALY).

The results of this model are in line with the results from other studies evaluating the costs of different hair removal methods, which also did not recommend the use of razors for preoperative hair removal.<sup>39-43</sup> As with other studies, the model showed that, although the use of razors was one of the cheapest interventions in terms of material costs,<sup>39,41</sup> once the costs of treating SSIs were included in the analysis this intervention generated higher costs than the other methods of hair removal, and was also associated with the highest rates of SSIs.

However, the model had several limitations. Firstly, the price of the electric clipper and charger were not identified in the NHS Purchasing and Supply Agency catalogue and thus had to be derived from the catalogue of a healthcare provider, which might not be the actual price paid by the NHS as it is likely that the NHS would pay substantially less. Secondly, only the costs of treating SSI in hospital, and not in the community, were included. As SSI may also be treated in the community, the costs in the model of SSI treatment are likely to be an underestimate. Thirdly, the time horizon of the model was limited to just 1 year, owing to limited data on the quality of life of patients who acquired an SSI.

# Appendix E

## Cost-effectiveness of mupirocin nasal ointment to prevent surgical site infection caused by *Staphylococcus aureus*

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### E.1 Literature review

Two full economic analyses<sup>50,51</sup> were identified.

A cost-effectiveness analysis conducted in the Netherlands<sup>50</sup> compared mupirocin calcium ointment treatment with no preventative treatment in cardiothoracic surgery patients. This analysis was based on a study of 1796 patients using a historical control. The analysis was conducted from the perspective of the healthcare system (only including costs to the healthcare system), with the time frame for the analysis not stated. The outcome used was cost per SSI prevented. The authors reported that treating 1000 surgical patients with mupirocin would lead to a cost saving of \$747,969, which was \$16,633 saved per SSI prevented. The incidence of SSIs was 7.3% in the historical control and 2.8% with the intervention. Mupirocin led to a 62% reduction in SSIs, which was calculated to prevent 45 SSIs per 1000 patients undergoing surgery. Sensitivity analyses were carried out on the incidence of SSIs (1% to 100%), effectiveness of mupirocin (1% to 100%), SSI-attributable costs (0% to 200%) and cost of mupirocin treatment (\$0 to \$1000). Mupirocin treatment remained cost saving except when SSI-attributable costs dropped below \$245 per patient with an SSI. No staff costs were considered for the application of mupirocin, which would make using mupirocin ointment more expensive.

A US cost-effectiveness analysis compared the following strategies:<sup>51</sup>

1. screening patients for *S. aureus* colonisation with nasal culture and treating carriers with mupirocin
2. screening no patients and treating all with mupirocin
3. no screening and no preventative treatment.

The patient group in this analysis had multiple coexisting illnesses and underwent non-emergency cardiothoracic, neurologic, general and gynaecological surgery. The outcomes of the analysis were cost per infection avoided and cost per life year saved. The analysis was based on one large RCT for mupirocin effectiveness in 3864 surgical patients and was conducted from the perspective of society, including patient expenses as well as the costs to the healthcare system. The time frame for the analysis was 90 days. The study concluded that both mupirocin strategies were cost saving: \$102 per patient undergoing surgery in the screen and treat strategy, and \$88 per patient in the treat-all strategy. Mupirocin led to a 51% reduction in SSIs. If mupirocin efficacy was less than 16.1% effective, then the screen and treat strategy was no longer cost saving. If *S. aureus* carriage rate was greater than 42.7%, then the treat-all strategy was more cost-effective.

As neither published analysis was conducted in the UK, a new model was developed for the purpose of this guideline.

### E.2 The decision tree model

A simple decision-analytic model was developed in Microsoft Excel® (see Figure E.1) to assess the cost-effectiveness of preventing SSI caused by *S. aureus* using mupirocin nasal ointment. Costing was calculated from the perspective of the NHS and the analysis considered a time frame of 1 year, meaning that no discounting of costs or benefits was undertaken.

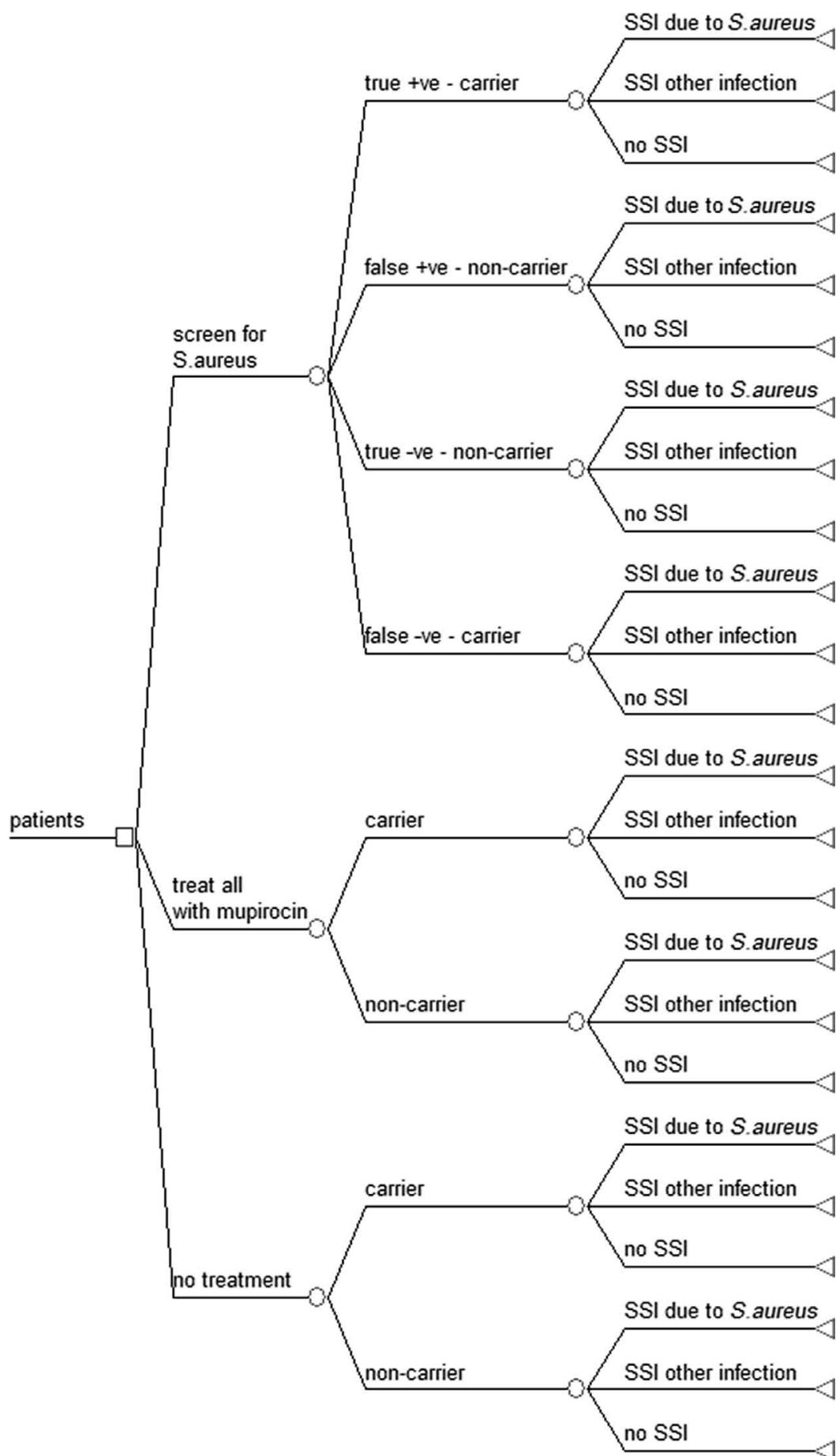


Figure E.1 Decision tree for the three treatment strategies

The model compared the following three strategies:

1. no nasal decontamination
2. treat all patients with mupirocin
3. screen all patients and treat patients identified as *S. aureus* carriers.

The analysis was based on a modelling exercise carried out in the USA<sup>51</sup> where the population was men and women, mean age 54 years, with multiple coexisting illness who underwent non-emergency cardiothoracic, neurological, general and gynaecological surgery. The model was not applicable to orthopaedic patients or patients with few comorbidities undergoing low-risk procedures. This model looked at all healthcare-associated infections caused by *S. aureus* and other pathogens, including pneumonia and bacteraemia. As the scope for this guideline is SSIs, the model has been simplified to consider only these infections. This may underestimate the benefits of using mupirocin as cases of pneumonia and bacteraemia may be reduced owing to mupirocin use.

The clinical evidence (see Section 5.6) showed no statistically significant difference in the rate of SSI overall in all patients treated with mupirocin compared with placebo. In *S. aureus* carriers there was a reduction in SSIs caused by *S. aureus* when mupirocin was used, although this reduction did not achieve statistical significance at the 5% level. This model does not take into account antibiotic resistance to *S. aureus*, which would require a more complex model to be developed.

### E.2.1 Model inputs

**Table E.1** Probabilities used in the mupirocin decision tree model

Variable	Value	Minimum	Maximum	Source	Notes
Prevalence of <i>Staphylococcus aureus</i> nasal colonisation	0.23	0.19	0.55	Young (2006) <sup>51</sup>	
Screening sensitivity	0.96	0.682	0.98	Ritchie (2007) <sup>232</sup>	The base case for this model used the sensitivity and specificity for detecting MRSA, a conservative assumption
Screening specificity	0.95	0.945	0.998	Ritchie (2007) <sup>232</sup>	
Mortality with SSI	0.066	0.057	0.076	Coello (2005) <sup>4</sup>	See hair removal model in Appendix D
Mortality without SSI	0.026	0.025	0.027	Coello (2005) <sup>4</sup>	See hair removal model in Appendix D
No treatment – <i>S. aureus</i> carrier:					
<i>S. aureus</i> infection	0.059			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Other SSI	0.058			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
No treatment – non-carrier:					
<i>S. aureus</i> infection	0.014			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Other SSI	0.062			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Mupirocin – <i>S. aureus</i> carrier:					
<i>S. aureus</i> infection	0.029			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Other SSI	0.060			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Mupirocin – non-carrier:					
<i>S. aureus</i> infection	0.019			Perl (2002) <sup>46</sup>	Beta distribution used for PSA
Other SSI	0.056			Perl (2002) <sup>46</sup>	Beta distribution used for PSA

MRSA = methicillin-resistant *Staphylococcus aureus*; PSA = probabilistic sensitivity analysis

**Table E.2** Utility values used in the mupirocin decision tree model

Outcome	Value	Minimum	Maximum	Notes
Patients with SSI	0.57	0.51	0.64	See hair removal model in Appendix D
Patients with no SSI	0.64	0.57	0.71	See hair removal model in Appendix D
Dead	0			



**Table E.3** Costs used in the mupirocin decision tree model

Resource item	Cost	Minimum	Maximum	Source	Notes
Real-time PCR swab	£5.18	£7.45	£19.40	GDG	Traditional culture nasal swab, 24–48 hours, full cost plus overheads
Time to take swab	£2.55	£1.28	£3.83	Ritchie (2007) <sup>232</sup>	Costs associated with taking patient samples: <ul style="list-style-type: none"> <li>• staff nurse (grades D–G) spending approximately 5 minutes</li> <li>• providing information to patient, taking two swab samples</li> <li>• completing related administration such as labelling samples and sending them to the lab</li> </ul>
1 hour of nurse time	£22.00	£16.50	£27.50	Curtis (2006) <sup>233</sup>	Nurse, day ward, cost per hour including qualifications
Nurse time – mupirocin (application only)	£9.17			Ritchie (2007) <sup>232</sup>	Assuming 5 minutes per application for 5 days
Mupirocin	£5.80	£2.90	£8.70	BNF 54 <sup>107</sup>	Bactroban® Nasal (GSK) 3 g 0.2% mupirocin per patient
Bed day due to SSI	£307	£230	£383	Coello (2005) <sup>4</sup>	
SSI treatment per patient	£3,486	£2,168	£5,235	Coello (2005) <sup>4</sup>	Assuming 11.37 (minimum 9.43 days, maximum 13.66 days) additional hospital days to treat SSI

BNF = British National Formulary; PCR = polymerase chain reaction

## E.2.2 Results

As is shown in Tables E.4 and F.5, treating all patients with mupirocin is the dominant strategy resulting in the least number of SSIs and the lowest cost. In the model, application of mupirocin has low costs, with five applications taking 25 minutes of a nurse's time (£9.17) plus the cost of the ointment (£5.80). The screening is also relatively low cost, at £2.55 for the nurse's time and £5.18 for the screening itself, but this is still higher than the cost of applying the mupirocin. However, it is because of the high 'downstream' costs of treating SSI that the most efficacious strategy is also the cheapest.

**Table E.4** Cost per SSI prevented

Strategy	Number of SSIs	Cost
No nasal decontamination	85.36	£297,555
Screen for <i>S. aureus</i> and treat identified carriers	81.42	£295,431
Treat all patients with mupirocin	79.18	£290,963

**Table E.5** Cost per QALY

Strategy	QALYs	Cost
No nasal decontamination	615.59	£297,555
Screen for <i>S. aureus</i> and treat identified carriers	615.95	£295,431
Treat all patients with mupirocin	616.16	£290,963

## E.2.3 Sensitivity analysis

Considerable uncertainty surrounds the data inputs of the model and therefore one-way sensitivity analysis was used to assess how robust the baseline conclusions would be given different assumptions. In particular, the clinical evidence would not cause a null hypothesis that mupirocin conferred no benefit in terms of reduced SSI to be rejected at the 5% level.

Table E.6 shows the effect of assuming that mupirocin does not lead to any changes in SSI.

**Table E.6** Sensitivity analysis showing cost and QALY with no treatment effect

Strategy	QALY	Cost
No nasal decontamination	615.59	£297,555
Screen for <i>S. aureus</i> and treat identified carriers	615.59	£309,179
Treat all patients with mupirocin	615.59	£312,522

A sensitivity analysis with a lower SSI treatment cost is shown in Table E.7. This is an important driver of the conclusions in the baseline analysis as it is this that causes treatment to be cost saving relative to no treatment.

**Table E.7** Sensitivity analysis showing incremental cost per QALY with a lower SSI treatment cost (£2,168)

Strategy	QALYs	Cost	Incremental QALYs	Incremental cost	ICER
No nasal decontamination	615.59	£185,093			
Screen for <i>S. aureus</i> and treat identified carriers	615.95	£188,165	N/A, dominated	N/A, dominated	N/A, dominated
Treat all patients with mupirocin	616.16	£186,649	0.57	£1,556	£2,730

A threshold analysis showed that the cost of treating an SSI would have to fall to below £600 before the ICER for the treat all patients with mupirocin strategy exceeded £20,000 per QALY, the threshold used by NICE to determine cost-effectiveness.

In this model, there is uncertainty over more than one parameter value. One technique to address this is multi-way sensitivity analysis where a number of parameter values are varied from their baseline value simultaneously. However, in a model with many parameter values, the number of possible permutations to test can be daunting. So, instead, a probabilistic sensitivity analysis (PSA) was undertaken using Monte Carlo simulation, which is an alternative way of addressing uncertainty across many parameter values simultaneously. In the baseline deterministic model, the results are determined by the point estimates entered as parameter values. However, the point estimates of the SSI rate in different patients and with different treatments are based on a sample of patients who participated in a particular study. If that study was well designed these point estimates provide the best estimate of the true SSI rate but they are nevertheless subject to sampling error. In PSA, the parameters are made probabilistic, which involves specifying a distribution around that point estimate. A simulation exercise is then undertaken that involves 'running' the model many times. In each 'run', the parameter values are sampled from the probability distribution, which means that the model output varies on each run while still being informed by the best estimates from the evidence. It is by sampling from the probability distribution that the inherent uncertainty in the data is handled.

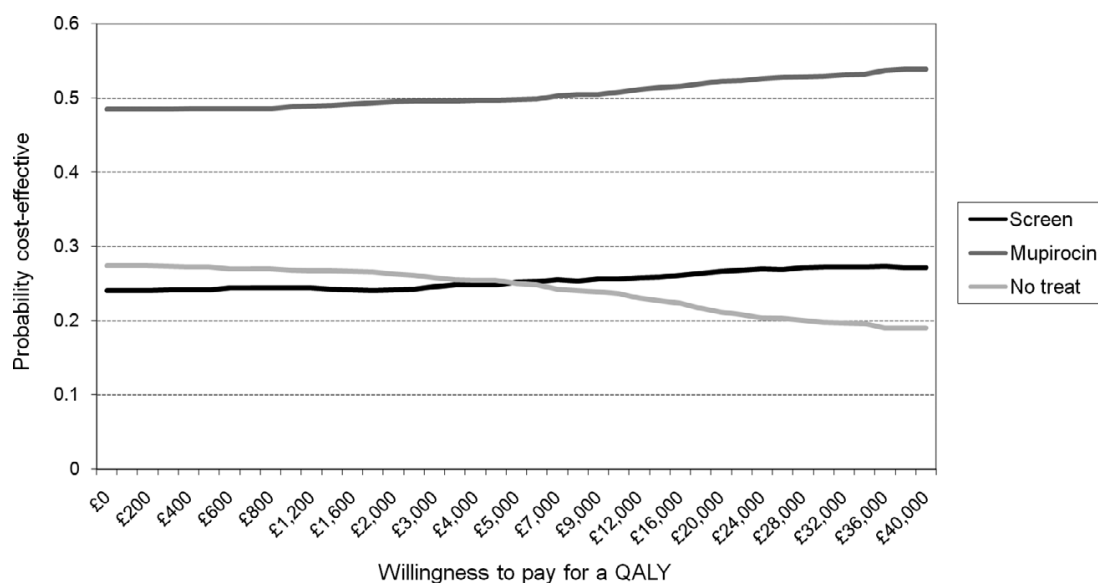
In this PSA for this model, only the SSI rates have been made probabilistic. In other words, the costs, the prevalence of *S. aureus* carriers, the accuracy of screening and the utility associated with states with and without an SSI do not change. However, to reflect the importance of treatment costs of SSI to the model, two Monte Carlo simulations were undertaken, one with treatment costs for SSI at their baseline level (£3,486) and one with a lower treatment cost for SSI (£2,168).

Each Monte Carlo simulation consisted of running the model 1000 times. For each run, the strategy that is the most cost-effective is recorded. This is straightforward where a strategy is the cheapest and most effective. However, when a strategy is more effective and more costly then its cost-effectiveness will depend on the willingness to pay for a QALY. NICE uses a willingness-to-pay threshold of £20,000 per QALY (with interventions with an ICER of less than this considered cost-effective). However, the model calculates for each run which would be the most cost-effective strategy at a range of willingness-to-pay thresholds.

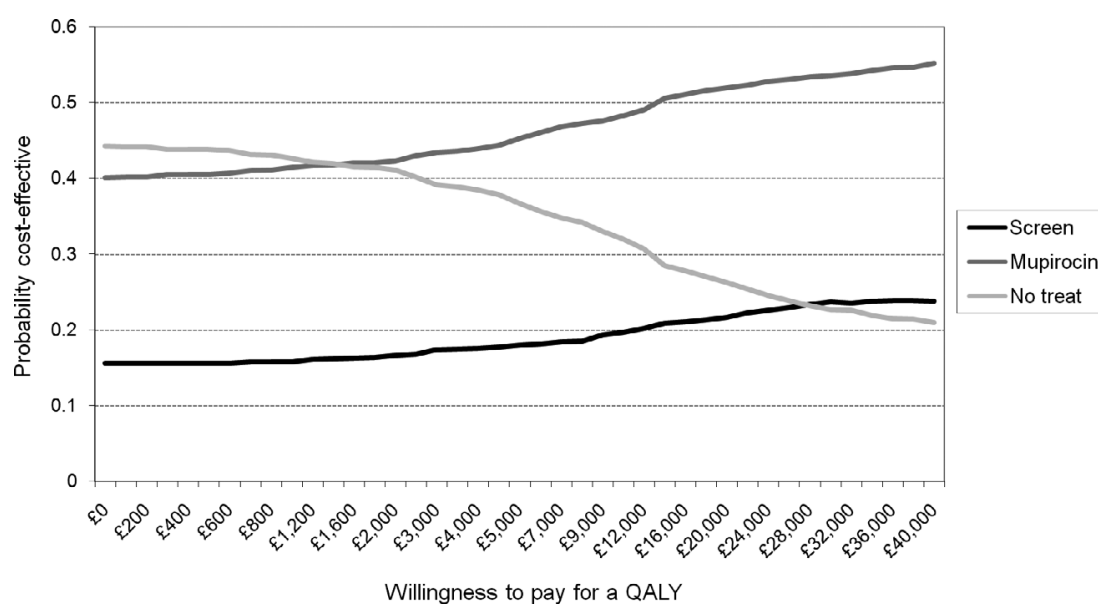
The results of the PSA are shown in Figures E.2 and E.3.

### E.3 Discussion

The results with the baseline analysis suggest that treating all patients with mupirocin is a cost-effective strategy. This is driven by the model inputs that assume that mupirocin does confer



**Figure E.2** Cost-effectiveness acceptability curve with the cost of treating SSI = £3,486



**Figure E.3** Cost-effectiveness acceptability curve with the cost of treating SSI = £2,168

benefits in terms of reduced SSI and that the initial costs of treatment are offset to some extent by reduced 'downstream' costs of SSI treatment. Sensitivity analysis suggested that as long as treating SSI infections incurs a cost per patient of greater than £6,000, treating all patients with mupirocin would remain a good use of scarce NHS resources.

However, there are a number of caveats that need to be borne in mind when interpreting this analysis. The cost-effectiveness of mupirocin is driven by the point estimates derived from just one trial and, although SSI rates are lower with mupirocin, the difference is not statistically significant at the 5% level. Clearly, if the results are a chance finding then mupirocin will not be cost-effective. Both PSA analyses suggest that there is about a 50% chance that treating all patients with mupirocin is the most cost-effective strategy at a £20,000 per QALY willingness-to-pay threshold. In fact, treating all patients with mupirocin is usually the most cost-effective strategy regardless of the willingness-to-pay threshold. The only exception to this was in the analysis where a lower cost of treating an SSI was assumed, where no treatment was more likely to be cost-effective if the willingness to pay for a QALY was £800 or less.

Treating all patients with mupirocin carries a potential harm in that it may increase antibiotic resistance, which has public health implications and costs in the longer term. This analysis does not model any impact on increased antibiotic resistance but it may be that, even if there were genuine benefits in treating all patients with mupirocin in terms of reduced SSI, these would be outweighed by the downside of increased antibiotic resistance. It might very reasonably be decided that, although the PSA suggests that treating all patients with mupirocin is more likely to be cost-effective than the other strategies, the probability of it being so is too small given the harms and risks that have not been incorporated into the model.

In the review of the clinical evidence (Section 5.6), two studies were included and the evidence pooled in a meta-analysis. This meta-analysis did not form the basis of the point estimates entered into the model because it compared all SSIs whereas the trial data used in the model allowed SSIs to be broken down into *S. aureus* and non-*S. aureus* infections. It should be noted that, in terms of all SSIs, the point estimates of these studies contradict each other. However, both results were not statistically significant at the 5% level and are thus consistent with no treatment effect, as the forest plot of the meta-analysis suggests (Figure E.4).

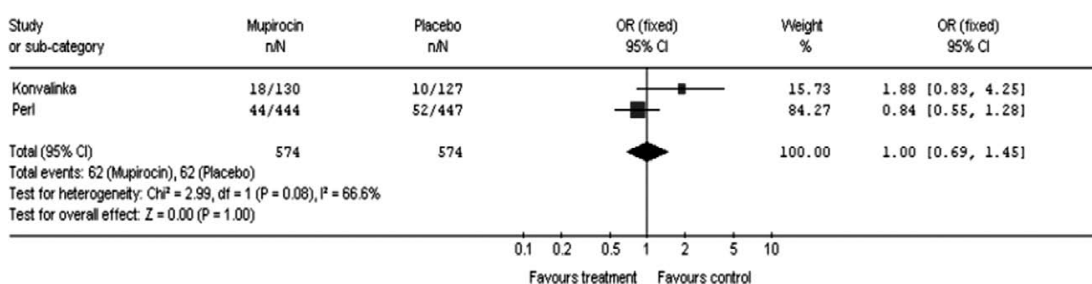


Figure E.4 All infections in *S. aureus* carriers: mupirocin compared with placebo

Nevertheless, some caution may also be required in interpreting this meta-analysis. It is likely that mupirocin would only be effective in preventing *S. aureus* infections in *S. aureus* carriers. Therefore, by including all SSI infections in the analysis, any treatment effect will be diluted and the 'noise' will lead to wider confidence intervals. Indeed, in the trial that informed the point estimates, the effect size was closer to being statistically significant (although still not) in a comparison of *S. aureus* infections in *S. aureus* carriers. Another of the potential harms of treating all patients with mupirocin, in addition to the possible impact on antibiotic resistance, is that it may increase the patient's susceptibility to non-*S. aureus* infections. In the study that informed the model, there was no evidence to support this, with non-*S. aureus* SSI virtually identical. However, it should be noted that the other included paper might be considered to show evidence, albeit weak, of such an effect.

Further research may be required to establish whether mupirocin does indeed reduce *S. aureus* SSI in *S. aureus* carriers and whether this is achieved at the expense of more non-*S. aureus* infections and/or antibiotic resistance.

# Appendix F

## Cost-effectiveness of closure methods

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Six cost studies<sup>163,166,194,198,199,200</sup> of wound closure methods were included in the economic review. Where closure methods are equally effective, the cheapest method is the most cost-effective.

### F.1 Characteristics of included studies

The six studies<sup>163,166,194,198,199,200</sup> included material costs and costs for use of operating rooms and medical personnel time. No costs for treating wound infection were included.

A study<sup>198</sup> included a cost analysis alongside a clinical study conducted in Italy. Tissue adhesive (octylcyanoacrylate) was compared with standard sutures in breast surgery. No SSIs were reported for either closure method.

Another study<sup>163</sup> compared the closure of laparoscopic trocar wounds with tissue adhesive (octylcyanoacrylate), adhesive paper tape or suture (poliglecaprone) in The Netherlands. The wound infection rate was highest in the octylcyanoacrylate group but the difference between the groups was not statistically significant. The costs of materials used and the costs for use of an operating room and medical personnel were included. No costs for treatment of wound infections were included.

A third study<sup>166</sup> compared skin closure after phlebectomy with monofilament sutures, tape or tissue adhesive (octylcyanoacrylate) in Austria. No statistically significant difference was found in the clinical outcomes.

A fourth study<sup>194</sup> compared absorbable suture with tissue adhesive (octylcyanoacrylate) for closure of trocar sites in a US study. Wound complication rates were similar for the two groups.

A fifth study<sup>199</sup> undertaken in the USA in patients undergoing elective laparoscopic surgery compared octylcyanoacrylate adhesive with suturing, and was based on a quasi-randomised trial. No statistically significant difference was found between wound infection rates in the two groups.

The last study<sup>200</sup> compared clips with subcuticular Vicryl® sutures in patients with fracture neck of femur. This was a small, non-randomised, prospective study carried out in the UK.

### F.2 Findings

The first study<sup>198</sup> reported that the total mean costs were lower for tissue adhesives than for sutures for wound closure in breast surgery. The material cost for tissue adhesive was higher than for standard sutures. However, the cost of postoperative visits increased the overall cost for sutures, compared with no visits for the tissue adhesives.

Adhesive paper tape was found to be significantly cheaper than the tissue adhesive (octylcyanoacrylate) and suture (poliglecaprone) in the second study.<sup>163</sup> The material cost of octylcyanoacrylate was €13.90 for one ampoule, one package of poliglecaprone was €2.47, and one package of adhesive paper tape was €1.15. The time needed to close a wound was significantly less for adhesive paper tape and tissue adhesive than suture (26 seconds and 33 seconds, respectively, versus 65 seconds).

Adhesive tape was found to be the lowest costing closure method in the third analysis.<sup>166</sup> It was the fastest method of wound closure (58 seconds versus 64 seconds for sutures and 1 minute and 14 seconds for tissue adhesive). The material costs were also lowest for adhesive tape.<sup>166</sup>

The fourth study<sup>194</sup> comparing absorbable suture with tissue adhesive reported that the mean closure time for tissue adhesives was shorter than with sutures (3 minutes and 42 seconds

compared with 14 minutes and 5 seconds). Although the costs of suture materials were much less than for the tissue adhesive (\$4.12 versus \$20.30), the operating room cost was high, at \$35 per minute, and so tissue adhesive was the least expensive option.

The fifth study<sup>199</sup> comparing octylcyanoacrylate adhesive with suturing reported that the median time to close the wound was less with tissue adhesive than sutures (2.5 minutes versus 6 minutes,  $P < 0.001$ ). Although the material cost of tissue adhesive was higher, as less time was required in the operating room tissue adhesive was cost saving compared with sutures.

The last study<sup>200</sup> comparing clips with subcuticular Vicryl sutures reported that dressing changes were needed less frequently in the suture group: on average five changes were needed compared with three for clips. Three infections were identified, all in patients where clips were used, but the number was too small to test any statistical significance. The costs for sutures were lower at £5, compared with £18.10 for the clips. These costs included application, removal and dressings.

### F.3 Conclusion

Tissue adhesive was consistently the most expensive for material costs. On the other hand, adhesive tape was consistently the cheapest for material costs and closure also takes the least time. Sutures require the greatest time for wound closure and also require a postoperative outpatient visit for removal.

There is evidence that wound closure using tissue adhesives generates cost savings when compared with sutures for skin closure owing to shorter time for wound closure and no need for a postoperative outpatient visit. Furthermore, there is evidence that wound closure with adhesive tape generates cost savings when compared with tissue adhesives or sutures, as adhesive tape was found to be faster to apply and less costly.

Finally, there is evidence that sutures are less expensive than clips.

# Appendix G

## Cost analysis of wound dressings

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### G.1 Costing analysis assumptions

The only published evidence available was costing analyses conducted in other countries and which could not be used as evidence in a UK setting. Therefore the GDG felt that a UK costing analysis should be conducted. The dressings listed in the BNF were divided into categories, with the main categories being interactive, active and passive dressings. These were further subdivided by type of dressing, such as alginate, foam, etc.

As there were a large number of wound dressings available, of different types and of different sizes, it was difficult to compare the dressings. The costs reported below are a comparison of each category of dressing for moderate to heavily exuding wounds (as described in the BNF September 2007).<sup>107</sup>

The costs included the cost of the dressing (10 cm × 10 cm)<sup>107</sup> and a nurse's time to change a dressing.<sup>234</sup> It was assumed that each dressing change would require 10 minutes of a nurse's time, with a cost per hour for a nurse of £22.<sup>234</sup> For comparison, 10 cm by 10 cm wound dressings were used or the next available size above (or 15 g for hydrogel dressings). This dressing size was chosen because it allowed inclusion of the majority of brands.

A suggested range for number of changes that would be required for each dressing type was decided by expert opinion:

- alginate dressings were assumed to be changed every 2–3 days
- foam dressings every 3–4 days
- hydrogel dressings every 1–2 days
- hydrocolloid dressings every 3–4 days
- vapour-permeable films and membranes every 5–7 days
- wound contact materials every 4–7 days
- passive dressings once a day to 4 times a day.

Hydrogel dressings and wound contact materials required an additional dressing; the lowest cost foam dressing of the same size was used for this. It was assumed that both dressings, in the majority of clinical situations, would be changed at the same time.

### G.2 Results

A 10 cm × 10 cm dressing for a moderate to heavily exuding wound cost on average from £6.14 for a vapour-permeable dressing that needs to be changed every 5–7 days, to £83.84 for a passive dressing that needs to be changed 2–3 times per day (Tables G.1 and G.2).

A further analysis was conducted for hydrocolloid dressings to compare products for different types of wound, from lightly exuding to heavily exuding wounds (Table G.3).

### G.3 Conclusions

Although no clinical evidence was found to suggest that one type of dressing was more effective at prevention of SSI or was better for management of SSI, it was not possible to do a straightforward cost-minimisation analysis. There are many reasons for choosing a wound dressing and these depend on the surgery, type of wound and characteristics of the patient.

**Table G.1** Costing analysis of a 10 cm × 10 cm dressing by dressing type for a moderate to heavily exuding wound

Dressing type	Frequency of change	Mean cost/week	Minimum cost/week	Maximum cost/week
Alginate	2–3 days	£16.32	£13.90	£21.78
Topical antimicrobials	2–3 days	£25.22	£13.96	£57.39
Capillary	2–3 days	£14.35	£13.17	£15.54
Foam	3–4 days	£13.57	£9.69	£26.90
Hydrogel	1–2 days	£38.87	£32.06	£56.42
Hydrocolloid	1–2 days	£33.46	£24.50	£54.23
Fibrous hydrocolloid	2–3 days	£17.81	£17.81	£17.81
Vapour-permeable	5–7 days	£6.14	£5.26	£12.08
Wound contact materials	4–7 days	£11.12	£9.25	£12.40
Odour-absorbing	4–7 days	£8.33	£7.23	£9.35
Protease-modulating matrix	4–7 days	£11.77	£11.77	£11.77
Passive dressings	2–3 per day	£83.84	£65.22	£137.14

**Table G.2** Costing analysis of a 10 cm × 20 cm dressing by dressing type for a moderate to heavily exuding wound

Dressing type	Frequency of change	Mean cost/week	Minimum cost/week	Maximum cost/week
Alginate	2–3 days	£21.28	£18.66	£30.94
Topical antimicrobials	2–3 days	£32.32	£17.08	£49.19
Capillary	2–3 days	£18.51	£18.51	£18.51
Foam	3–4 days	£19.91	£13.61	£56.12
Hydrogel	1–2 days	£64.08	£46.29	£80.83
Hydrocolloid	1–2 days	£46.08	£34.79	£58.05
Fibrous hydrocolloid <sup>a</sup>	2–3 days	–	–	–
Vapour-permeable	5–7 days	£6.97	£6.14	£7.44
wound contact materials	4–7 days	£19.67	£17.44	£21.06
Odour-absorbing	4–7 days	£11.41	£8.00	£13.92
Protease-modulating matrix	4–7 days	£28.35	£28.35	£28.35
Passive dressings	2–3 per day	£106.10	£65.57	£241.97

<sup>a</sup> No fibrous hydrocolloid dressings were available in this size or larger.

**Table G.3** Costing analysis of hydrocolloid dressings by type of wound

Wound type	Frequency of change	Minimum cost/week	Lowest cost dressing
Light to moderate	1–2 days	£16.30	Suprasorb® H (Vernon-Carus) without adhesive border, thin
Light to moderate – adhesive	1–2 days	£16.89	DuoDERM® Extra Thin (ConvaTec)
Moderate to heavy	1 day	£24.50	Askina® Biofilm Transparent (Braun)
Heavy	2 days	£35.96	CombiDERM® (ConvaTec)

Wound type	Frequency of change	Maximum cost/week	Highest cost dressing
Light to moderate	1–2 days	£35.44	Contreet® Hydrocolloid (Coloplast)
Light to moderate – adhesive	1–2 days	£35.44	Contreet® Hydrocolloid (Coloplast)
Moderate to heavy	1 day	£40.78	Comfeel® Plus (Coloplast)
Heavy	2 days	£56.33	Versiva® (ConvaTec)



Both the vapour-permeable dressings and the passive dressings have a very low price for each dressing (the minimum price of a vapour-permeable dressing was 27p, and 6p for a passive dressing). The passive dressings become the most expensive option because they have to be changed so often and this requires additional nursing time.

The main conclusion of this analysis is that it is important to take into account the additional costs of changing dressings as well as the initial price of each dressing when choosing which dressings to use.

# Appendix H

## General principles for hand hygiene (epic2)

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Department of Health-commissioned guidance on healthcare-associated infection is available in the 2006 epic2 guideline.<sup>255</sup> The section on principles of hand hygiene is outlined below.

Hands of staff are the most common route by which microorganisms are transferred between patients. Pathogens are frequently acquired on the hands by contact with patients and their environment. To prevent cross-infection these need to be removed, especially prior to contact with susceptible sites such as wounds or invasive devices. Hands should be decontaminated before every episode of care that involves direct contact with patients' skin, their food, invasive devices or dressings. They should also be decontaminated after completing such an episode of care. While gloves protect the hands from gross contamination with body fluid, the skin may still become contaminated through perforations or as gloves are removed. Hands should therefore be decontaminated after gloves are removed.

Transient microorganisms acquired by touch are readily removed by soap and water, and by alcohol-based hand rubs or gels. Alcohol rapidly kills transient microorganisms and reduces the resident flora that normally colonises the skin. However, since alcohol does not physically remove organic material, it should not be used when the hands are visibly soiled. It is also not effective against some microorganisms such as *C. difficile*. The main advantage of alcohol-based hand rubs is that they are quicker and easier to use than soap and water and hence encourage staff to wash their hands more frequently. However, repeated use of alcohol-based hand rubs may cause residues to accumulate on the skin and hands should therefore periodically be washed with soap.

Repeated hand decontamination may remove the natural oils that lubricate the skin and cause them to become dry and cracked. This problem is exacerbated if hands are not properly dried. Damaged skin not only discourages hand decontamination but may increase the number of microorganisms colonising the skin. Emollients added to handwashing solutions may help to reduce their damaging effects on skin.

### Recommendations

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

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

Hands should be decontaminated between caring for different patients or between different care activities for the same patient, including after removal of gloves. For convenience and efficacy, an alcohol-based hand rub is preferable unless hands are visibly soiled.

Hands should be washed with soap and water after several consecutive applications of alcohol-based hand rub.

An effective technique for routine handwashing involves three stages: preparation, washing and rinsing, and drying. Preparation requires wetting hands under running tepid water before applying the recommended amount of liquid soap or an antiseptic detergent. The handwash solution should come into contact with all surfaces of the hands. The hands should be rubbed together vigorously for a minimum of 10–15 seconds, paying particular attention to parts that are easily missed such as the tips of the fingers. Hands should be rinsed thoroughly prior to drying with good-quality paper towels.

Clinical staff should be aware of the potentially damaging effects of hand decontamination products and use emollient hand cream regularly to maintain the integrity of the skin.

Near-patient alcohol-based hand rub should be made available in all healthcare facilities.

Hand hygiene resources and individual practice should be audited at regular intervals and the results fed back to healthcare workers.

Education and training in risk assessment, effective hand hygiene and glove use should form part of all healthcare workers' annual updating.

# Appendix I

## Postoperative cleansing of the wound

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Observations of current clinical practice would suggest that the majority of healthcare practitioners continue to use sterile normal saline for the cleansing of acute (for example, surgical) wounds, while tap water is normally reserved for the cleansing of chronic wounds or for the initial cleansing of traumatic injuries while in the accident and emergency department.

The reasons for cleansing surgical wounds (not dry surgical incision sites) and the surrounding wound areas on a regular basis are generally accepted as being for the:

- removal of excess wound exudates (reducing the risk/effects of both excoriation and maceration)
- removal of 'mobile' slough
- removal of foreign bodies, including residues from other wound management products
- removal of wound crusts (generally these are made up of a combination of fibrin, dehydrated exudates and dressing residue, and are most likely to be found at the wound edge)
- psychological wellbeing of the patient.

Issues of source and quality of tap water used as a wound cleansing solution need to be carefully considered, as although it is acknowledged that hospital tap water can be delivered at a constant temperature (having firstly gone through a process ensuring that all harmful bacteria have been killed) the same cannot be said for tap water within the homes of patients.

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