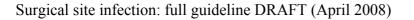
draft for consultation **Surgical site infection**

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

Commissioned by the National Institute for Health and Clinical Excellence

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page i of 165

Contents

Guide Ackno	eline Development Group membership and acknowledgements eline Development Group owledgements holder organisations	iv iv iv v
Abbro	eviations	ix
Gloss	ary of terms	xi
1 1.1 1.2 1.3 1.4 1.5 1.6 1.7 1.8	Introduction Surgical site infection Aim of the guideline Areas outside of the remit of the guideline For whom is the guideline intended? Who has developed the guideline? Other relevant documents Guideline methodology Schedule for updating the guideline	1 1 4 4 5 5 5 9
2 2.1 2.2 2.3 2.4 2.5	Summary of recommendations and care pathway Key priorities for implementation (key recommendations) Summary of recommendations Key priorities for research Summary of research recommendations Care pathway	10 10 11 14 15 16
3	Risk Factors	18
4	Information for patients	19
5 5.1 5.2 5.3 5.4 5.5 5.6 5.7 5.8 5.9 5.10	Preoperative phasePreoperative showeringHair removalPatient theatre attireNon-sterile theatre wearStaff leaving the operating area in non-sterile theatre wearNasal decontaminationMechanical bowel preparationHand decontamination (general)Hand jewellery, artificial nails and nail polishAntibiotic prophylaxis	21 23 26 26 27 28 30 32 32 33
6 6.1 6.2 6.3 6.4 6.5 6.6 6.7 6.8 6.9 6.10 6.11 6.12	Intraoperative phase Hand decontamination (scrubbing) Incise drapes Use of gowns Disposable drapes and gowns/ Reusable drapes and gowns Gloves Skin preparation with antiseptics prior to surgery Diathermy Maintaining patient homeostasis Intracavity lavage and Wound Irrigation Antiseptics and antimicrobials prior to wound closure Closure methods Wound dressings for SSI prevention	46 46 47 50 50 51 52 57 58 65 70 73 84
7 7.1 7.2 7.3 7.4 7.5	Postoperative phase Clean technique compared with aseptic non-touch techniques for dressing changes Postoperative cleansing of the wound Postoperative topical antimicrobials for prevention of SSI in surgical wounds healing by primary intention Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary Debridement	90 90 91 92 y intention93 95

Contents

Appendix A	Declarations of Interest	98
Appendix B	Clinical questions	99
Appendix C	Definitions of Surgical Site Infections	101
Appendix D	Wound dressings for SSI prevention	107
Appendix E	Cost-effectiveness of hair removal	108
Appendix F	Cost effectiveness of mupirocin nasal ointment to prevent surgical site infection caused by S. aureus	110
Appendix G	Cost-effectiveness of perioperative warming	117
Appendix H	Cost effectiveness of closure methods	119
Appendix I	Cost-analysis of wound dressings	121
Appendix J	General principles for hand hygiene (EPIC)	123
Appendix K	Postoperative cleansing of the wound	124
References		124
Index		
Search strate	ci	D-ROM
Evidence tables CD-RO		D-ROM
Excluded stu	dies CI	D-ROM

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Molnlycke Health Care MRSA Action UK NAASP Napp Pharmaceuticals National Council for Disabled People, Black, Minority and Ethnic Community (Equalities) National Nurses Nutrition Group National Patient Safety Agency National Public Health Service - Wales NCC for Cancer NCCHTA Neurological Alliance Newcastle PCT Newcastle Upon Tyne Hospitals NHS Foundation Trust NHS Direct NHS Quality Improvement Scotland NICE - Guidelines Coordinator - for info NICE - Guidelines HE for info NICE - Implementation Consultant Region East NICE - Implementation Consultant Region London/SE NICE - Implementation Consultant Region SW NICE - Implementation Consultant Region NW & NE NICE - Implementation Consultant Region West Midlands NICE - Implementation Co-Ordination for info NICE - R&D for info NICE - Technical Appraisals (Interventional Procedures) for info North Yorkshire and York PCT Nottingham City PCT Nottingham University Nottingham University Hospitals NHS Trust Nuffield Hospitals Acute Care Nuffield Orthopaedic Centre NHS Trust Nursing & Supportive Care Collaborating Centre Nutricia Ltd (UK) Pancreatic Cancer UK Park House Healthcare Limited Patient and Public Involvement Programme for NICE Pegasus Limited Pembrokeshire and Derwen NHS Trust PERIGON Healthcare Ltd Pfizer Limited Primary Care Collaborating Centre Princess Alexandra Hospital NHS Trust Queen Mary's Hospital NHS Trust (Sidcup) Queen Victoria Hospital NHS Trust Queens Hospital NHS Trust (Burton upon Trent) Regent Medical Relatives and Residents Association Rotherham Acute Trust Rotherham Primary Care Trust Royal Brompton and Harefield NHS Trust Royal College of Anaesthetists Royal College of General Practitioners Royal College of General Practitioners Wales Royal College of Midwives Royal College of Nursing Royal College of Obstetricians & Gynaecologists Royal College of Paediatrics and Child Health Royal College of Pathologists Royal College of Physicians of London Royal College of Radiologists Royal College of Surgeons of England Surgical site infection: full guideline DRAFT (April 2008)

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Abbreviations

AAS	Aqueous Alcohol Solution
Ab	Antibiotics
AHR	Alcohol-based Hand Rub
ASA grade	American Society of Anesthesiologists
BG	Blood Glucose
BGC	Blood Glucose Control
BMI	Body Mass Index
BNF	British National Formulary
CABG	Coronary Artery Bypass Graft
CDC	Centres for Disease Prevention and Control
CFUs	Colony Forming Units
CI	Confidence Interval
cm ²	Centimetres Squared
CNS	Coagulase Negative Staphylococcus
COPD	Chronic Obstructive Pulmonary Disease
d	Days
DAB	Solution containing 0.5g of neomycin sulfate, 0.1g of polymyxin B sulphate and 80mg of
2112	gentamicin sulphate per litre of normal saline
FDA	Food and Drug Administration
GDG	Guideline Development Group
GP	General Practitioner
h	hour
HAIs	Healthcare Associated Infections
HAP	Healthcare Associated Pneumonia
HE	Health economics
HCHS	Hospital and Community Health Services
ICER	Incremental Cost-Effectiveness Ratio
IV m ²	Intravenously Matrice Sequence
m ²	Metres Squared
MBP	Mechanical Bowel Preparation
ml	Millilitres
N	Number
NCC	National Collaborating Centre
NHS	National Health Service
NICE	National Institute of Health and Clinical Excellence
NINNS	Nosocomial Infection National Surveillance System
NNIS	National Nosocomial Infection Surveillance
02	Oxygen
OR	Odds Ratio
Р	Page
PI	Povidone Iodine
PU	Permeable Polyurethane
QALYs	Quality Adjusted Life Years
quasi-RCT	Quasi-randomised Control Trial
RCT	Randomised Controlled Trial
RTI	Respiratory Tract Infection
SD	Standard Deviation
Secs	Seconds
SENIC	Study on Efficacy of Nosocomial Infection Control
SHS	Surgical Hand Scrubbing
SR	Systematic Review
SSHAIP	Scottish Surveillance of Healthcare Associated Infection Programme
SSI	Surgical Site Infection
UK	United Kingdom
US	United States

Surgical site infection: full guideline DRAFT (April 2008)

UTI	Urinary Tract Infection
VAP	Ventilator Associated Pneumonia
vs	Versus
WMD	Weighted Mean Difference

Glossary of terms

Absolute risk reduction	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.
Amorphous	Describing an object that lacks a definitive visible shape or form, such as a gel.
Anaerobes	These are organisms which can multiply in atmospheres low in oxygen (facultative anaerobes) or in complete anoxia (strict anaerobes). They are often the cause of SSIs and may thrive in synergy with aerobic organisms such as the Gram negative bacilli (eg E.coli).
Anastomosis	An anastomosis is formed when bowel or vesseals are joined together during an operation using sutures, or in the case of bowel, staples as an alternative.
Antibiotic formulary	A local policy document produced by a multi-professional team, usually in a Hospital Trust or Primary Commisioning Group, combining best evidence and clinical judgement
Antibiotic prophylaxis	The preoperative use of antibiotics to prevent the development of infection at surgical sites (SSI).
Antibiotic treatment	The use of antibiotic treatment for SSIs following the recognition of invasive infection (see below)
АРАСНЕ	Acute Physiological and Chronic Health Evaluation provides a score for general patient risk factor assessment for SSI
ASEPSIS	This is a scoring system for SSIs and comprises the following factors Additional treatment (drainage, antibiotics, debridement), Serous discharge, Erythema, Purulent exudate, Separation of deep tissues, Isolation of bacteria, Stay in hospital >14 days.
Bias	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, e.g. 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 biases in their discussion and conclusions. See Blinding or masking and Double blind study.
Blinding or masking	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 bias . See also Double blind study .
CABG	A coronary artery bypass graft 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.
Case—control study	A study that starts with the identification of a group of individuals sharing the same characteristics (e.g. people with a particular disease) and a suitable comparison (control) group (e.g. people without the disease). All subjects are then assessed with respect to things that happened to them in the past, e.g. factors that might have increased their risk of getting the disease under investigation. Such studies are also called retrospective as they look back in time from the outcome to the possible causes.
Case report (or case study)	Detailed report on one patient (or case), usually covering the course of that person's disease and their response to treatment.
Case series	Description of several cases of a given disease, usually covering the course of the disease and the response to treatment. There is no comparison (control) group of patients, and so the conclusions of such series are subject to possible Bias .
Celsian (clinical signs)	Claudius 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 rested).
CDC definition of SSI	See Appendix C
Celsian signs of infection	Local heat, erythema (redness), pain and swelling (oedema).
Cholecystectomy	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.
Clinical effectiveness	The extent to which an intervention (for example, a device or treatment) produces health benefits (i.e. more good than harm). See Cost effectiveness .
Clinical trial	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 controlled clinical trials and randomised controlled trials .
Cochrane Collaboration	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 as CD-Rom or on the internet (www.cochranelibrary.com).
Cohort	A group of people sharing some common characteristic (e.g. patients with the same disease), followed up in a research study for a specified period of time.
Cohort study	An observational study 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, e.g. 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 'prospective' cohort study) or identified from past records and followed forward from that time up to the present (a 'historical' or 'retrospective' 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 Bias is minimised.
Co-interventions	Interventions or treatments, other than the treatment under study, which are applied to the treatment and/or control groups.
Collagen	The protein which is formed during the repair of a wound. It never reaches the pre-wounding strength of tissues and as it matures in a scar it turns white as the reparative blood vessels (angiogenesis) regress after successful healing.
Colony Forming Units (CFUs)	This is a measurement of viable bacterial numbers present in tissues or body fluids. It has limited value in the description of SSI.
Combine dressing pad	An integral central absorbent material that is attached and part of, not separate to, another wound management material such as a film membrane.
Co-morbidity	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.
Confidence interval	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.
Control group	A group of patients recruited into a study that receives no treatment, a treatment of known effect, or a placebo (dummy treatment), in order to provide a comparison for a group receiving an experimental treatment, such as a new drug.
Controlled clinical trial (CCT)	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 control group) receives an alternative treatment, a placebo (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 randomised controlled trial . See Blinding .

COPD	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
Cost benefit analysis	A type of economic evaluation where both costs and benefits of healthcare treatment are measured in the same monetary units. If benefits exceed costs, the evaluation would recommend providing the treatment.
Cost-consequences analysis	A type of economic evaluation, whereby both outcomes and costs of alternative interventions are described, without any attempt to compare the results.
Cost effectiveness	A type of economic evaluation that assesses the additional costs and benefits of doing something different. In cost effectiveness analysis, the costs and benefits of different treatments are compared. When a new treatment is compared with current care, its additional costs divided by its additional benefits is called the cost effectiveness ratio. Benefits are measured in natural units, for example, the cost for each surgical site infection prevented.
Cost-effectiveness analysis	A type of economic evaluation comparing the costs and the effects on health of different treatments. Health effects are measured in 'health-related units', for example, the cost of preventing one additional surgical site infection.
Cost-of-illness/economic burden study	An analysis of the total costs incurred by a society due to a specific disease.
Cost impact	The total cost to the person, the NHS or to society.
Cost-minimisation analysis	A type of economic evaluation used to compare the difference in costs between programs that have the same health outcome.
Costing study	The simplest form of economic study, measuring only the costs of given interventions.
Cost utility analysis	A special form of cost effectiveness analysis where benefit is measured in quality adjusted life years (see QALY). A treatment is assessed in terms of its ability to extend or improve the quality of life.
Crossover study design	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.
Cross-sectional study	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 longitudinal study , which follows a set of people over a period of time).
Cytokines	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

Debridement	The excision or wide removal of all dead or necrotic, damaged tissue which may develop in a surgical wound. In addition there are currently a number of other accepted methods available for wound debridement:
	Bio-surgery - the use of larvae (sterile maggots)
	<i>Surgery</i> – performed by an 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 within the United States of America but not a recommended debridement technique within the United Kingdom
	The use of wound dressing materials such as Hydrocolloids and
	Hydrogels – the use of amorphous hydrogel preparations which moisten and loosen adherent dead tissue to facilitate debridement but needs a covering secondary dressing
Diapedesis	This is the movement of white cells out of the circulation into an area of infection or tissue damage where the white cells help to combat infection and start the healing process predominantly under the influence of cytokines.
Discounting	The process of converting future cost and future health outcomes to their present value.
Double blind study	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 bias.
Dressings	Materials which are applied directly onto the wound:
	<i>a)</i> Passive - such as 'gauze like materials' that simply cover the wound, neither promoting or intentionally hindering the wound healing process. They have been associated with negative effects on the patients quality of life during the 30 day post operative period.
	b) Interactive - modern (post 1980) dressing materials which 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 (fibrous); hydrofibres; non-adherent wound contact materials and combinations of those listed below.
	<i>Alginates</i> – 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
	<i>Film Membranes</i> - 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.
	<i>Foams</i> – Foam dressings are usually made up of polyurethane and are available in a variety of different forms, for example simple foam sheets; film backed foam dressings; polyurethane membranes;

polyurethane foam gels (sometimes also referred to as hydropolymers) and silicone foams, the latter 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 contents dependent upon 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 (Povidine iodine) – an iodophor composed of elemental iodine and a synthetic polymer; and Cadexomer iodine – a polysaccharide starch lattice containing 0.9% elemental iodine which is released on exposure to wound exudate.

Both have different physical characteristics that relate to the component parts and the iodine concentration of available iodine that is released when used.

c) Active – These are dressings that, through their action, are designed to manipulate/alter the wound healing environment to either re-stimulate or further promote the wound healing process. Examples include Topical Negative Pressure Therapy; Larva therapy (sterile maggots), dressing materials which incorporate antimicrobial agents and dressings which contain biomaterials such as collagen or hyaluronic acid or cultured keratinocytes or bio-engineered skin.

See Appendix D 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.
Endothelium	Endothelium is the single layer of cells which continuously line the inner side of all blood vessels
Epidemiological study	A study which looks at how a disease or clinical condition is distributed across populations, e.g. 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 which occurs when there is infection by enzyme or toxin producing bacteria (e.g. β -haemolytic streptococci). 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.
Evidence-based clinical practice	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.
Evidence table	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.
Exclusion criteria	See Selection criteria.
Experimental study	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. Controlled clinical trial and randomised controlled trial are examples of experimental study designs.
Extrinsic	Features which are external to the individual.
Fibroblasts	Cells involved in the wound repair process which leads to wound repair and the laying down of the scar protein collagen.
FiO2	The fraction of inspired oxygen in an inhaled gas. When breathing air the FiO2 is approximately 20%
Follow-up	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.
Gold standard	A method, procedure or measurement that is widely accepted as being the best available.
Granulation tissue	Vascular tissue which 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 (angiogenesis), fibroblasts and white cells which remove dead tissue and microorganisms and prepare the wound for repair by the laying dome of the scar protein collagen.
Haematogenous	Means spread through the blood stream. Microorganisms and cancer cells can spread by this route
Haemoglobin saturation	A measurement of the amount of oxygen carried in the blood measuredusung infra-red technology (oximetry). It is maintained as close to 100% as possible during anaesthesia and the postoperative period
Healing by primary intention	Occurs when a wound has been sutured after an operation and heals to leave a minimal, cosmetically acceptable scar. Healing by secondary intention 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
Health economics	A field of conventional economics which examines the benefits of healthcare interventions (e.g. medicines) compared with their financial costs.
Health professional	Includes doctors, nurses and allied health professionals such as physiotherapists.
Health Technology Assessment	The process by which evidence on the clinical effectiveness and the costs and benefits of using a technology in clinical practice is systematically evaluated.
Heterogeneity or lack of homogeneity	The term is used in meta-analyses and systematic reviews when the results or estimates of effects of treatment from separate studies seem to be very different. 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 variables or duration of follow up.
Homeostasis	The maintenance of normal physiological function.
Homogeneity	Means that the results of studies included in a systematic review or meta-analysis are similar and there is no evidence of heterogeneity . Results are usually regarded as homogeneous when any differences between studies could reasonably be expected to occur by chance. See also Consistency .
Humectant	A substance that promotes the retention of moisture.
Hypertrophic	The enlargement of an organ or tissue through an increase of cell size. A hypertrophic scar contains an excess of cells (hyperplasia) and also scar tissue that leads to a heaped up, red appearance.
IBD	Means inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
Incise drapes	These are transparent, adhesive polyurethane sheets which are placed over, operative (surgical) drapes to keep them in place. They may be impregnated with an antiseptic, such as iodophore. They may also be used as a postoperative wound dressing for the first few postoprative days as their transparency facilitates inspection.
Inclusion criteria	See Selection criteria.
Intervention	Healthcare action intended to benefit the patient, e.g. a surgical procedure.
Incidence	The number of new cases of illness commencing, or of persons falling ill, during a specified time period in a given population. Usually expressed as the number of new cases/100,000 population/year. The incidence of SSI is often expressed as number cases per days of post- op follow-up or number cases per procedure.See prevalence .
Intrinsic	Features present within the individual.
Keloid	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 which may be even more extensive.
Laparotomy	An exploratory, usually emergency, operation of the abdomen.
Leucocyte	Describes the group of white cells (primarily the neutrophils) which are involved in the first defence against infection and are involved in the early wound healing response.
Logistic regression analysis	This is a statistical method which allows identification of independent variables. For example this type of analysis may identify risk factors for infection, such as SSI, from a large data base of variables.
Longitudinal study	A study of the same group of people at more than one point in time. (This type of study contrasts with a cross-sectional study , which observes a defined set of people at a single point in time).
Lymphocyte	White cells involved in host response to infection. There are many types which confer protection through a hormonal route (B cells) or through the formation of antibodies (T cells)
Macrophages	Macrophages are formed from monocytes which 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.
Margination	Prior to diapedesis white cells become adherent to the endothelium of blood vessels, called margination, through a complicated process involving for example intercellular adhesion molecules
Masking	See Blinding.
Meta-analysis	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, e.g. because of differences in the study populations or in the outcomes measured, it may be inappropriate or even misleading to pool results. See also Systematic Review and Heterogeneity .
Metalloproteinases	There are several families of these enzymatic proteins which 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
Mitogenic	The description of a substance which can promote cell division.
Monocytes	A type of blood stream white cell. Once in the tissues in the inflammatory process they become macrophages
MRSA	Meticillin Resistant Staphylococcus aureus.
Myofibroblasts	The modified fibroblasts which produce the scar protein collagen and other components of repaired tissue during the wound healing process.
Neonates	Children up to one month of age.
Neutrophils	White cells of the leukocyte group.
Non-experimental study	A study in which its subjects are selected on the basis of their availability, with no attempt having been made to avoid problems of bias.
Number needed to treat (NNT)	This measures the impact of a treatment or intervention. 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 one, 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.
Observational study	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 (e.g. whether or not people received a specific treatment or intervention) are studied in relation to changes or differences in other(s) (e.g. whether or not they died), without the intervention of the investigator. These studies are easy to perform, but there is a greater risk of selection bias than in experimental studies .
Odds ratio	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 confidence interval) for the effect of a treatment. Odds are used to convey the idea of 'risk' and an odds ratio of one 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 relative risk (which uses actual risks and not odds) will be very similar.
Oedema	Swelling due to the accumulation of interstitial tissue fluid and frequently a result of bacterial infection in a wound. It is one of the Celsian signs of infection.
Operative (surgical) drapes	These are the drapes which 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 incise drapes . Operative drapes may be reusable or disposable and are usually self-adhesive; there have been significant advances in drape technology but disposable drapes should always be used in high-risk surgery (eg. when a patient has hepatitis).
Parenteral	The giving of a drug by intramuscular or intravenous route (i.e. not given through the gut, principally the oral route).
Peer review	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, patient and carer representatives.
Perfusion	Blood flow through tissues or organs. If not optimal can increase the risk of infectious complications (particularly SSI)
Pilot study	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.
Placebo	Placebos are fake or inactive treatments received by participants allocated to the control group in a clinical trial. 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 placebo effect due to receiving care or attention.
Placebo effect	A beneficial (or adverse) effect produced by a placebo and not due to any property of the placebo itself.

POSSUM	Physiological and Operative Severity Score for En(U)meration 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 co-morbidity.
Post discharge surveillance	Many SSIs present after discharge from hospital. Comparison of post- discharge surveillance data is difficult as it depends upon the methods used to detect SSIs The method of surveillance should be clear so that comparisons can be made between studies.
Power	See Statistical power.
Predictive validity	A risk assessment tool would have high predictive validity if the predictions it makes (say, of development of surgical site infection in a sample) became true (i.e. it has both high sensitivity and specificity).
Prevalence	The proportion of patients with a particular disease within a given population at a given time. Point prevalence is the number of patients affected/100,000 population.
Prospective study	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 retrospective .
Puerperal fever	Relates to uterine infection after giving birth. It follows poor obstetric hygiene and, if prevention or treatment is inadequate, has a high related mortality.
p value	If a study is undertaken to compare two treatments then the p 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 p-value for the study was 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 p is below 0.05 (i.e. less than 5%) the result is seen as statistically significant.
Qualitative research	Qualitative research is used to explore and understand people's beliefs, experiences, attitudes, behaviour and interactions. It generates non numerical data, e.g. 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.
Quality adjusted life years (QALYs)	A measure of health outcome which combines quantity and quality of life. To each year of life a weight is assigned, ranging from 0-1, 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.
Quantitative research	Research that generates numerical data or data that can be converted into numbers, for example clinical trials or the National Census, which counts people and households.

Random allocation	A method that uses the play of chance to assign participants to comparison.
Randomisation	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.
Randomised controlled trial	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 control group) receiving an alternative treatment, a placebo (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).
Relative risk	A summary measure which represents the ratio of the risk of a given event or outcome (e.g. 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 risk ratio .
Reliability	Reliability 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.
Retrospective study	A retrospective study deals with the present and past and does not involve studying future events. This contrasts with studies that are prospective .
Risk Factors	A risk factor is 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.
Risk ratio	Ratio of the risk of an undesirable event or outcome occurring in a group of patients receiving experimental treatment compared with a comparison (control) group. The term relative risk is sometimes used as a synonym of risk ratio.
Sample	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.
Scoring systems and definitions for SSI	There are many different definitions and scoring systems for SSI. The Center for Disease Prevention and Control (CDC) definition is the most commonly used. <i>See Appendix C for CDC definition</i>
Screening	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 persons who may have a disease from those who probably have not. A screening test is not intended to be diagnostic but should be sufficiently sensitive and

	specific to reduce the proportion of false results, positive or negative, to acceptable levels. Screening tests should be sensitive (less false negatives), but high specificity (less false positives) is less important. Patients with positive or suspicious findings in screening tests must be referred to the appropriate healthcare provider 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 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 (e.g. 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)	Can be defined as being present when there are multiplying pathogenic organisms in a wound giving rise to local signs and symptoms, e.g. heat, redness, pain and swelling, and (in more serious cases) with systemic signs of fever or a raised white blood cell count. <i>See Appendix C.</i>
	Surgical site (wound) infection (SSI):
	a) Superficial Incisional , affecting the skin and subcutaneous tissue;
	b) Deep Incisional , affecting the fascial and muscle layers;
	c) Organ or Space infection , This involves any part of the anatomy other than the incision which is opened or manipulated during the surgical procedure e.g. joint, peritoneum

Surgical site contamination	a) Clean : An incision in which no inflammation is encountered in a surgical procedure, without a break in sterile technique, and during which the respiratory tract, alimentary or genito-urinary tracts are not entered.
	b) Clean-contaminated : An operative wound in which the respiratory, alimentary, genito-urinary tract is entered under controlled conditions and with no encountered contamination.
	c) 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.
	d) Dirty or infected : An incision undertaken during an operation in which the viscera are perforated or when acute inflammation with pus is en countered during the operation (e.g. emergency surgery for faecal peritonitis), and for traumatic wounds where treatment is delayed, there is faecal contamination, or devitalised tissue present.
Sutures	Sutures are 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 which can be tailor made for their purpose of use. For example, the non- biodegradeable suture, polypropylene, is used for a permanent anastomosis between arteries, whereas the absobable suture polyglactin is 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.
Systematic review	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 meta-analysis .
Validity	Assessment of how well a tool or instrument measures what it is intended to measure.
Variable	A measurement that can vary within a study, e.g. 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.
Vasoconstriction	The shut down of blood vessels to an organ or tissue. It can lead to poor perfusion, an increased risk of infection or tissue death (gangrene).
Wound dressings	See Dressings
Wound separation	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, 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.
Wound dehiscence	After operations in general, wound dehiscence and wound separation 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

1.1 Surgical site infection

Infection in surgical wounds is generally referred to as surgical site infection (SSI). The precise definition of an SSI is important if the incidence or prevalence of infection is to be used in a research programme, or in measurements of standards or for inter-hospital comparisons. The majority of SSIs become apparent within 30 days of an operative procedure and most often between the 5th and 10th postoperative days, although a streptococcal SSI may present earlier than this as cellulitis. However, in procedures involving an implant, deep SSIs may still be seen months afterwards. The consensus is that in defining SSI for procedures that do not involve an implant the 30 day limit should be used, however, when an implant exists, infections affecting the deeper tissues can occur up to a year after surgery. This is why the Centre for Disease Control and Prevention (CDC) definition requires a 30 day surveillance for wounds in general and a year after prosthetic surgery.

SSIs are one of the healthcare associated infections (HAIs) which are broadly divided into four categories: respiratory tract infection (RTI); urinary tract infection (UTI); blood stream infection (bacteraemia); and SSI. HAI, or HCAI, (health care associated infection) has replaced the more limited term of nosocomial infection, because it recognises the continuum between hospital and community-based care. A 2007 prevalence survey in the UK suggested that approximately 8% of patients in hospital have an HCAI. Other European studies have estimated HCAI prevalence of up to 20%. Prevalence studies underestimate SSI because many of these infections occur after the patient has been discharged from hospital.

In a Hospital Infection Society/ Infection Control Nurses Association survey SSIs accounted for 14% of all HAIs; nearly 5% of patients who had undergone a surgical procedure were found to have developed an SSI. Since SSIs are diagnosed on the basis of clinical signs and symptoms, and their severity can range from trivial to life-threatening, studies may use different measures to identify them. Hence disparity in reported rates may often be due to variation in the definitions of SSI. SSIs are associated with considerable morbidity and increased costs of health care and can significantly extend hospital stay.

SSIs have been estimated to cost United States health care \$10b annually, ranging from \$44 for a superficial SSI to more than \$30k for a sternal or joint infection. A European perspective put the annual cost of SSIs between €1.47-€19.1b to the European health care system. These costs relate to extended length of stay, extra nursing care and interventions, and drug costs. In the UK, SSIs have been found to more than double the length of postoperative stay in hospital, this alone increasing the costs of care by between £814 and £6626 depending on the type of surgery and the severity of the infection. The indirect costs, due to loss of productivity, patient dissatisfaction and litigation, and reduced quality of life have been studied less extensively.

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 micro-organisms present, balanced against the host's immune response. In prosthetic surgery the presence of a 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 may also cause an opportunistic SSI. Operations on sites which are normally sterile ('clean') have therefore, relatively low rates of SSI (widely accepted as less than 2%), whereas after operations in 'contaminated' or 'dirty' sites rates may exceed 10%.

The micro-organisms that cause SSIs are usually derived from the patient, being present on their skin or from an opened viscus (endogenous infection). Exogenous infection follows contamination by micro-organisms from instruments or the theatre environment at operation, from a traumatic wound or later by introduction of micro-organisms after surgery, before the wound 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 at an operative site. In all these situations *Staphylococcus aureus* is the micro-organism most commonly cultured from SSIs, but in prosthetic surgery and implanted intravascular catheters, *Staphylococcus epidermidis* (coagulase negative staphylococcus, CNS) is also common. 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.

Signs and symptoms of SSI include:

- the classical Celsian signs of inflammation
- purulent drainage
- pain or tenderness, localised swelling, redness and heat at the site of the incision (Celsian signs)
- spontaneous separation of the incision edges to leave an open wound (the wound may need to be deliberately opened when there is a suspicion of a purulent collection)
- abscess or other evidence of infection found by direct examination during re-operation, or by histopathological or radiological examination

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

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. Spreading infections relating to wounds which do require antibiotics, usually administered parenterally, are relatively uncommon but in primary care it is likely that over 15% of postoperative wounds are treated with antibiotics, possibly inappropriately, something which can only lead to the development of further antibiotic resistance. It is possible that many of these wound complications are not infections but simply exudation from a gape in the wound edge, or represent an early failure to heal which is common in patients with a high body mass index (BMI). When there is gaping of a clean wound edge it is usually possible to undertake delayed primary or secondary suture or closure with adhesive tape (Steristrips), 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.

The appropriate treatment of established SSIs requires good surveillance and multidisciplinary communication between the 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, and the need for wound bed preparation, to encourage healing by secondary intention or facilitate secondary suture.

The 'normal' wound healing process has been identified as involving three overlapping major phases: inflammation, cascades of processes that can be further subdivided into early (first 24hrs) and late phases (normally up to 72 hrs), regeneration and maturation.

The <u>wound healing process</u> 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 is 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 to 72 hours) involves the release of vasodilators and other agents which 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 and repair 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, the final phase of wound healing – also known as the remodelling phase – can take up to two years to be 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 normal skin.

Since skin is normally colonised by a range of micro-organisms that could cause infection, defining an SSI requires evidence of clinical signs and symptoms of infection rather than microbiological evidence alone. Although the outcome measure for SSI used by many studies is based on standard definitions such as those described by the Centre for Disease Control, or the Surgical Site Infection Surveillance Service, other valid measures based on clinical signs and symptoms have been described. Studies may also report infections that affect any part of the incision, or focus only on those that affect the deeper tissues, particularly the long term surveillance of joint infection. Variation introduced by the definition used needs to be taken account when combining or comparing evidence from different studies.

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. Surveillance was first recognised as an important tool in reducing rates of infection in the 1980s. The Study on the Efficacy of Nosocomial Infection Control (SENIC) showed that surveillance and infection control programmes that included feedback of infection rates to surgeons were associated with significant reductions in rates of SSI. Since then many national surveillance systems have been established and reported reductions in rates of SSI. Consumer demand for information about the performance of healthcare providers has also led to compulsory public reporting of data on HAIs, including SSIs. In England, reporting of rates of SSI following orthopaedic surgery became compulsory in April 2004 and all 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 others such as the SSHAIP in Scotland, provide external benchmark rates of SSI which can be a powerful driver for change but if they are to be valid must be based on a standardised approach. This requires the use of standard definitions of SSI, defined methods of finding cases of SSI that are likely to consistently 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 and adjust rates of SSI by the risk index developed by the Centre for Disease Control, in the United States, which takes account of the underlying illness of the patient, the duration of the operation and the wound classification of the procedure but may not be relevant in international comparisons These differences need to be taken into account when comparing rates of SSI.

Since some SSIs may take many days to develop, many infections may not become apparent until after the patient has been discharged from hospital. Thus surveillance focused on detecting SSI during the inpatient stay is 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. 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 comparison of rates are to be made.

The accurate scoring of SSI severity is necessary for inter-hospital comparisons, and research in particular, with estimates of patients' co-morbidities. The Southampton and ASEPSIS methods have been widely used in research, for example, but not in routine clinical practice. Even simple scoring systems have not been taken up widely to judge SSI severity. It would be pointless to use data on SSIs for comparisons unless it was validated. There are also many methods of postoperative surveillance, none of which has proved to be widely taken up.

It is important to note that SSIs can range from a relatively trivial wound discharge with no other complications, to a life-threatening condition and to ignore such differences by placing SSI in a single category is inappropriate. It has been reported that over a third of postoperative deaths are related, at least in part, to an SSI, and that SSIs contribute to appreciable morbidity and mortality after surgery. In Europe there have been several prevalence studies, but they have not matched those of the national Nosocomial Infections Surveillance of the United States. A European perspective has attempted to calculate the incidence and economic burden of SSIs. Other clinical outcomes of SSIs include poor scars which are cosmetically unacceptable, spreading, hypertrophic or keloid; persistent pain and itching; restriction of movement, particularly when over joints; and a significant impact on emotional well being.

The protocol used by the Health Protection Agency should be used for surveillance of SSI.

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 surgical site infection.

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
- 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 is available, entitled 'Understanding NICE guidance: Surgical site infection'. It can be downloaded from the National Institute of Health and Clinical Excellence (NICE) website (<u>www.nice.org.uk/xxx</u>) or ordered via the NHS Response Line (0870 1555 455) quoting reference number xxx.

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
- theatre nurse
- surveillance co-ordinator
- · infection control specialist
- two patient/consumer representatives

Staff from the NCC-WCH provided methodological support for the guideline development process, undertook systematic searches, retrieval and appraisal of the evidence, health economics modelling and, together with the Guideline Leader, 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 surgical site infection 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:

- The guideline will update the NICE technology appraisal on wound care and debridement and the technology appraisal will be withdrawn on publication of the guideline.
- Multiple technology appraisal on topical negative pressure therapy.

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 (1966 onwards), Embase (1980 onwards), Cumulative Index to Nursing and Allied Health Literature (CINAHL; 1982 onwards), and PsycINFO (1967 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, 2007. 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 not applied to searches, although 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.

Towards the end of the guideline development process searches were updated and re-executed, thereby including evidence published and included in the databases up to XXXXX. Evidence published after this date has not been included in the guideline, except in the case of major international studies that were known to be ongoing during the development of the guideline and which were likely to report before the guideline was published. This date should 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 presented in Appendix X.

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. 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.

Table 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

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. For diagnostic tests, test evaluation studies examining the performance of the test were used if the effective (accuracy) of the test was required, but where an evaluation of the effectiveness of the test in the clinical management of patients and the outcome of disease was required, evidence from RCTs or cohort studies was optimal. For studies evaluating the accuracy of a diagnostic test, sensitivity, specificity, positive predictive values (PPVs) and negative predictive values (NPVs) were calculated or quoted where possible (see Table 2).

	Reference standard	Reference standard	Total
	positive	negative	
Test positive	a (true positive)	b (false positive)	a+b
Test negative	c (false negative)	d (true negative)	c+d
Total	a+c	b+d	a+b+c+d = N (total
			number of tests in
			study)

Table 2 '2 x 2' table for calculation of diagnostic accuracy parameters

Sensitivity = a/(a+c), specificity = d/(b+d), PPV = a/(a+b), NPV = d/(c+d)

The system described above covers studies of treatment effectiveness. However, it is less appropriate for studies reporting accuracy of diagnostic tests. In the absence of a validated ranking system for this type of test, NICE has developed a hierarchy of evidence that takes into account the various factors likely to affect the validity of these studies (see Table 3).

Level	Type of evidence
Ia	Systematic review (with homogeneity)* of level-1 studies+
Ib	Level-1 studies+
II	Level-2 studies++
	Systematic reviews of level-2 studies
III	Level-3 studies§
	Systematic reviews of level-3 studies
IV	Consensus, expert committee reports or opinions and/or clinical experience without
	explicit critical appraisal; or based on physiology, bench research or 'first principles'

Table 3 Levels of evidence for studies of the accuracy of diagnostic tests

*Homogeneity means there are minor or no variations in the directions and degrees of results between individual studies that are included in the systematic review.

+Level-1 studies are studies that use a blind comparison of the test with a validated reference standard

('gold' standard) in a sample of patients that reflects the population to whom the test would apply.

++Level-2 studies are studies that have only one of the following:

- narrow population (the sample does not reflect the population to whom the test would apply)
- use a poor reference standard (defined as that where the 'test' is included in the 'reference', or where the 'testing' affects the 'reference')
- the comparison between the test and reference standard is not blind
- case-control studies

§Level-3 studies are studies that have at least two or three of the features listed above

Clinical evidence for individual studies was extracted into evidence tables (see Appendix X) 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 not performed for this guideline because there were no clinical questions for which sufficient numbers of similar studies were identified to merit such analysis.

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 surgical site infection 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. 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 (see section 5.2)
- Nasal decontamination (see section 5.6)

- Perioperative warming (see section 6.8.3)
- Closure methods (see section 6.11)
- Wound dressings (see section 6.12)

The results of each economic analysis are summarised briefly in the guideline text with full costeffectiveness models presented in Appendices E-I.

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 approximately 10 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 and care pathway

2.1 Key priorities for implementation (key recommendations)

4 Information for patients

Patients and carers should receive clear and consistent messages about the risks and management of SSI and what measures are being undertaken to reduce them, throughout their patient journey.

Patients and carers should receive information on post-discharge wound care.

Patients and carers should be given information to help them recognise an SSI and who to contact if they are concerned.

5 Preoperative phase

5.2 Hair removal

Hair removal is not indicated for the prevention of SSI.

If hair has to be removed, electric clippers with single-use disposable heads should be used on the day of surgery.

If hair has to be removed, razors should not be used because of the increased risk of SSI.

5 Preoperative phase

5.10 Antibiotic prophylaxis

Antibiotic prophylaxis should be given to patients prior to clean surgery involving the placement of a prosthesis or implant, clean-contaminated and contaminated surgery. In addition to prophylaxis, patients undergoing surgery on a dirty/infected wound need antibiotic treatment

6 Intraoperative phase

6.1 Hand decontamination (scrubbing)

The operative team should decontaminate their hands prior to the first operation on the list using an antiseptic surgical scrub solution, with a brush for the nails. Between subsequent operations hands should be decontaminated using either an alcoholic hand rub/gel or antiseptic surgical scrub solution without scrubbing. If hands are soiled then they should be washed with an antiseptic surgical scrub solution.

6.6 Skin preparation with antiseptics prior to surgery

In adults the skin at the surgical site should be prepared immediately prior to the skin incision using an antiseptic preparation (aqueous or alcohol based) - povidone iodine or chlorhexidine are most suitable.

6.8.3 Perioperative warming

Perioperative patient warming should be undertaken to reduce SSI unless contraindicated in specific circumstances.

6.11 Closure methods

In general the choice of technique and material for skin closure should be guided by local protocol, costs and clinical needs.

6.12 Wound dressings for SSI prevention

Surgical incisions should be covered with an appropriate interactive dressing in the immediate postoperative period.

7 Postoperative phase

7.4 Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary intention

Surgical wounds healing by secondary intention should be managed using an appropriate interactive dressing.

2.2 Summary of recommendations

4 Information for patients

Patients and carers should receive clear and consistent messages about the risks and management of SSI and what measures are being undertaken to reduce them, throughout their patient journey.

Patients and carers should receive information on post-discharge wound care.

Patients and carers should be given information to help them recognise an SSI and who to contact if they are concerned.

5 Preoperative phase

5.1 Preoperative showering

Patients should shower or bathe (or be showered or bathed or bed bathed) either the day before, or on the day of, surgery.

5.2 Hair removal

Hair removal is not indicated for the prevention of SSI.

If hair has to be removed, electric clippers with single-use disposable heads should be used on the day of surgery.

If hair has to be removed, razors should not be used because of the increased risk of SSI.

5.3 Patient theatre attire

Specific patient theatre attire, appropriate for the procedure and clinical setting, should be worn but should have regard for patients' personal comfort and dignity, the provision of easy access both to the operative site and areas for the placement of devices.

5.4 Non-sterile theatre wear

Specific non-sterile theatre wear should be worn in all areas, by all staff, where operative procedures are undertaken.

5.5 Staff leaving the operating area in non-sterile theatre wear

Movement in and out of the operating theatre suite of healthcare personnel dressed in non-sterile theatre wear should be restricted.

5.6 Nasal decontamination

Routine use of nasal decontamination with topical antimicrobial agents aimed at eliminating *Staphylococcus aureus* is not recommended for the prevention of SSI.

5.7 Mechanical bowel preparation

Mechanical bowel preparation is not recommended solely for the prevention of SSI.

5.9 Hand jewellery, artificial nails and nail polish

The operative team should not wear hand jewellery, artificial nails and nail polish during operative procedures.

5.10 Antibiotic prophylaxis

Antibiotic prophylaxis should be given to patients prior to clean surgery involving the placement of a prosthesis or implant, clean-contaminated and contaminated surgery. In addition to prophylaxis, patients undergoing surgery on a dirty/infected wound need antibiotic treatment

Consider single dose administration for prophylaxis given IV at induction of anaesthesia but earlier in operations in which there is placement of a tourniquet

Consider timing and pharmacokinetics (e.g. serum half-life) of the drug when administering

Patients should always be informed that they have received antibiotics

For clean uncomplicated surgery, antibiotic prophylaxis may not be necessary

6 Intraoperative phase

6.1 Hand decontamination (scrubbing)

The operative team should decontaminate their hands prior to the first operation on the list using an antiseptic surgical scrub solution, with a brush for the nails. Between subsequent operations hands should be decontaminated using either an alcoholic hand rub/gel or antiseptic surgical scrub solution without scrubbing. If hands are soiled then they should be washed with an antiseptic surgical scrub solution.

6.2 Incise drapes

Non-iodophore impregnated incise drapes are not recommended for routine use in surgery

In cases where an incise drape is used, this should be iodophore impregnated (excluding those cases where the patient presents with an iodine allergy).

6.3 Use of gowns

Gowns should be worn by healthcare professionals in the operating theatre.

6.4 Disposable drapes and gowns/reusable drapes and gowns

As there is no recommendation that can be made from this evidence it is suggested that local trust protocols are implemented.

6.5 Gloves

Double gloving should be considered when there is a high risk of perforation.

6.6 Skin preparation with antiseptics prior to surgery

In adults the skin at the surgical site should be prepared immediately prior to the skin incision using an antiseptic preparation (aqueous or alcohol based) - povidone iodine or chlorhexidine are most suitable.

In neonates local practices for the use of skin preparation should be followed.

Appropriate care should be taken to ensure drying and avoid pooling when alcohol based preparations are used if diathermy is to be undertaken.

6.7 Diathermy

Diathermy as a method of surgical incision should not be used as a method to reduce SSI.

If diathermy is to be used, care should be taken when using inflammable skin preparations.

If an alcoholic skin preparation has been used then the operative area should be dried, and any pooled skin preparation removed, before the use of diathermy.

6.8 Maintaining patient homeostasis

6.8.1 Oxygenation

Oxygen should be administered to ensure a haemoglobin saturation of greater than 95% during major surgery and in the recovery period.

6.8.2 Perfusion

It is essential that a patient's physiological condition is maintained during surgery and this includes adequate perfusion.

6.8.3 Perioperative warming

Perioperative patient warming should be undertaken to reduce SSI unless contraindicated in specific circumstances.

6.8.4 Perioperative blood glucose control

Treatment to reduce raised blood glucose postoperatively, with the aim of reducing SSI should not be undertaken in patients who do not have diabetes, to prevent SSIs.

Overall, it is essential that optimal physiological homeostasis is maintained during surgery and this includes adequate perfusion, oxygenation and temperature control.

6.9 Intracavity lavage and wound irrigation

Wound irrigation during surgery should not be undertaken to reduce SSI.

Routine intracavity lavage during surgery to prevent SSIs should not be used.

6.10 Antiseptics and antimicrobials prior to wound closure

Single-use povidone iodine spray into the incision, prior to closure, should be considered in elective colorectal surgery and surgery for perforated gangrenous appendicitis in adults.

Collagen gentamicin implants into the sternal wound should be considered after cardiac surgery.

The use of intraoperative skin re-disinfection or topical cefotaxime is not recommended

6.11 Closure methods

In general the choice of technique and material for skin closure should be guided by local protocol, costs and clinical needs.

6.12 Wound dressings for SSI prevention

Surgical incisions should be covered with an appropriate interactive dressing in the immediate postoperative period.

7 Postoperative phase

7.1 Clean technique compared with aseptic non-touch techniques for dressing changes

'Aseptic' non-touch techniques should be used for removing or changing surgical wound dressings.

7.2 Postoperative cleansing of the wound

If wound cleansing is indicated, sterile saline should be used.

Showering in the immediate postoperative period should not be undertaken specifically to reduce the rate of SSI.

When the surgical wound has separated or has been surgically opened to drain pus, then the use of tap water may be considered for wound cleansing.

7.3 Postoperative topical antimicrobials for prevention of SSI in surgical wounds healing by primary intention

Topical antimicrobial agents, such as the antibiotic chloramphenicol applied as a paste, should not be used in the postoperative management of wounds to prevent SSI.

7.4 Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary intention

Eusol and gauze, moist cotton gauze and mercuric antiseptic solutions should not be used in the management of surgical wounds healing by secondary intention.

Surgical wounds healing by secondary intention should be managed using an appropriate interactive dressing.

Healthcare professionals should refer to a tissue viability expert for advice on appropriate dressings for the management of surgical wounds healing by secondary intention.

There is a need to evaluate the modern methods of chronic wound care in terms of management of SSI including alginates, foams and hydrocolloids and dressings containing antiseptics such as honey, cadexomer, iodine or silver.

7.5 Debridement

Eusol and gauze, dextranomer and enzymatic treatments should not be used as debridement techniques in the management of SSI.

2.3 Key priorities for research

6.8.1 Oxygenation

Further research is needed both to investigate the value of supplemented oxygenation in the recovery room and to understand the mechanisms associated with the prevention of SSI.

Why this is important

There have been several randomised control trials which show a contradictory effect of supplemental oxygenation in the recovery room period. Two separate trials indicate that there could be a halving of SSI rates simply by increasing the amount of inspired oxygen but the claim that an FiO_2 of 0.8 can be reached using a face mask is not possible, and all patients are already given an FiO_2 to give a haemoglobin saturation of at least 95% by their anaesthetist during the operation and in the immediate postoperative period. The mechanism for this increase of FiO_2 to be able to presumably improve blood oxygen carriage is therefore physiologically not clear. Nevertheless, this simple cheap intervention, if it works, really does need further investigation.

6.8.4 Perioperative blood glucose control

Research should be undertaken into the possible benefits of improved glucose control postoperatively, with adequately powered RCTs in a broad range of surgical procedures.

Why this is important

There have been several large cohort studies in cardiac surgery that indicate that tight postoperative blood glucose control can reduce the dreaded complication of sternal incision SSI in particular. A rise of blood glucose outside the normal range is typical after major trauma and has been considered part of the 'normal' metabolic response. A randomised controlled clinical trial is needed, and in other fields of major surgery other than cardiac surgery alone, to show unequivocally that tight blood glucose control is acceptable (even if it lowers SSIs in general) as the lowering of glucose in the immediate peri-operative period may have unwanted complications and will require added careful surveillance. Again the physiological mechanisms why this intervention should lower SSI is not entirely clear.

6.11 Closure methods

Further research on sutures should be conducted and based on multi-centred adequately powered, single intervention RCTs.

Why this is important

Although there are many studies in the field of wound closure, there are still several areas which are unanswered. Natural suture materials such as catgut and silk should be replaced by tailor-made absorbable and non-absorbable polymers. However, it needs far more research to convince surgeons to stop using mass closure of the abdominal wall or subcuticular sutures for skin closure. The use of monofilaments or braids also depends on personal preference and further trials are unlikely to show differences in SSI. There are data

to show some techniques can allow more rapid closure, such as the use of staples or adhesive acrylate glues. Again this has other disadvantages which could only be proven in what would be large, single-intervention RCTs. The use of antiseptic-coated sutures offers a novel challenge to show if SSIs can be reduced or allow less use of antibiotics.

6.12 Wound dressings for SSI prevention

There should be further research on the benefit and cost effectiveness of different types of post-surgical interactive dressings.

Why this is important

There is a huge number of dressings which are available for chronic wound care which can be used for incisional sites. The use of island dressings compared with simple adhesive polyurethane transparent dressings is an example with outcomes of not just SSI but skin complications and final cosmetic outcomes for example. There are some studies but they do not yet have enough power to show convincing differences. Research into the effect of antiseptic-bearing dressings, placed at the end of an operation or at dressing changes, would be attractive as a lowering of SSIs might be found. These antiseptics could include povidone iodine, biguanides (such as chlorhexidine) or the recent popularity of silver.

7.4 Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary intention

There is a need to evaluate the modern methods of chronic wound care in terms of management of SSI including alginates, foams and hydrocolloids and dressings containing antiseptics such as honey, cadexomer, iodine or silver.

Why this is important

There are many small cohort studies which have examined the use of the wide range of dressings in SSI management after an infected wound has been opened or after there has been separation of the wound edges after an SSI. Differences are hard to see because the trials often include other wounds healing by secondary intention such as chronic venous or diabetic ulcers and pressure sores. Specific studies using antiseptics (povidone iodine, chlorhexidine biguanides or silver) and other agents such as honey do need to address this in powered randomised trials, specifically in the management of SSIs with 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

5 Preoperative phase

5.6 Nasal decontamination

There should be further research using larger numbers to test the cost effectiveness of mupirocin in nasal decontamination.

6 Intraoperative phase

6.4 Disposable drapes and gowns/reusable drapes and gowns

The new materials used in reusable and disposable operative drapes and gowns deserve further evaluation in RCTs which incorporate cost-effectiveness analysis

6.8 Maintaining patient homeostasis

6.8.1 Oxygenation

Further research is needed both to investigate the value of supplemented oxygenation in the recovery room and to understand the mechanisms associated with the prevention of SSI.

6.8.4 Perioperative blood glucose control

Research should be undertaken into the possible benefits of improved glucose control postoperatively, with adequately powered RCTs in a broad range of surgical procedures.

6.9 Intracavity lavage and wound irrigation

Irrigation with modern antiseptics, and saline under pressure with or without added antiseptics, should be repeated in a broader range of surgery, particularly as there is an increase in resistance that requires less reliance on antibiotics

6.10 Antiseptics and antimicrobials prior to wound closure

The use of povidone iodine spray and other antiseptic products applied to the wound prior to closure should be researched in elective, clean non-prosthetic surgery, particularly as there is an increase in resistance that requires less reliance on antibiotics

The use of other antiseptic products applied to the wound to reduce SSI should be considered

Further research should be undertaken into the use of collagen implants with antibiotics or antiseptics

6.11 Closure methods

Further research on sutures should be conducted and based on multi-centred adequately powered, single intervention RCTs.

6.12 Wound dressings for SSI prevention

There should be further research on the benefit and cost effectiveness of different types of post-surgical interactive dressings.

7 Postoperative phase

7.4 Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary intention

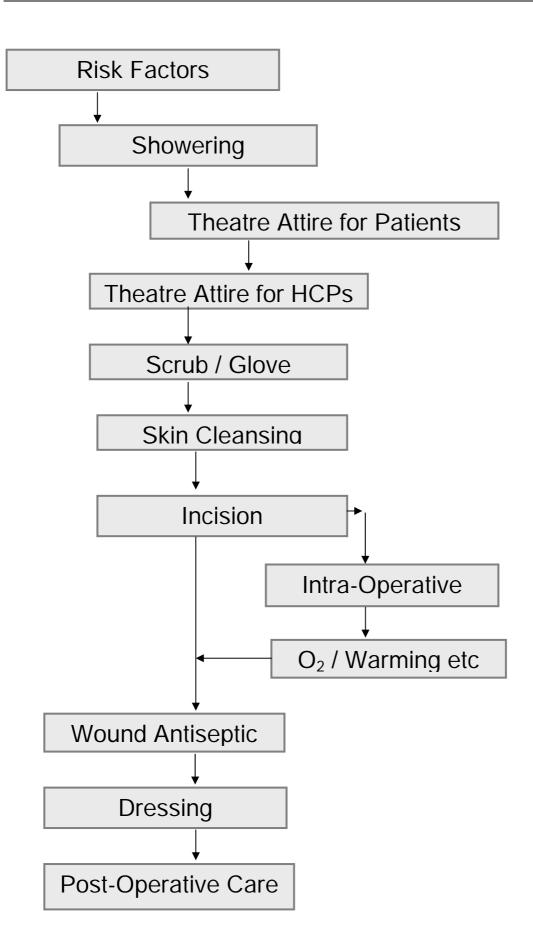
There is a need to evaluate the modern methods of chronic wound care in terms of management of SSI including alginates, foams and hydrocolloids and dressings containing antiseptics such as honey, cadexomer, iodine or silver.

7.5 Debridement

There is a need to evaluate the modern methods of debridement in surgical wounds healing by secondary intention.

2.5 Care pathway

The care pathway is taken from the NICE Quick Reference Guide version of this guideline (www.nice.org.uk/xxxxx).



3 Risk Factors

Risk factors

The risk of SSI is affected by the following factors:

- a) endogenous contamination (e.g. at surgical procedures which involve opening parts of the body that contain a dense normal flora, such as the bowel
- b) exogenous contamination (e.g. prolonged operations increasing the length of time that tissues are exposed or at dressing changes)
- c) reduced efficacy of the general immune response (e.g. diabetes, malnutrition, or immunosuppressive therapy with radiotherapy, chemotherapy or steroids) or local immune response (e.g. foreign bodies, damaged tissue, haematoma).¹

Practices to prevent surgical site infection are therefore aimed at

- a) minimising the number of micro-organisms introduced into the operative site (for example removing micro-organisms that normally colonise the skin)
- b) preventing the multiplication of micro-organisms at the operative site(for example using prophylactic antimicrobial therapy)
- c) enhancing the patients' defences against infection(for example minimising tissue damage and maintaining normothermia)
- d) preventing access of micro-organisms into the incision post-operatively by use of a wound dressings.

All the above topics are covered in this guideline. Whilst it is not likely to be possible to prevent all SSIs, studies have suggested that perioperative practice can help to minimise the risk.

Risk factors which may contribute to SSTs but which have not been assessed in RCTs include:

a) patient co-morbidity ¹ ²;³
b) high BMI ¹⁻⁴
c) low albumin, ⁵
d) age, ⁵ ³
e) ischaemia, ^{3;4}
f) diabetes mellitus ^{2-4;6}
g) anticancer therapies ¹
h) steroids
i) smoking ⁷ ¹ ²;³

The Study on Efficacy of Nosocomial Infection Control (SENIC) found that abdominal surgery lasting longer than two hours, contaminated procedures and three diagnoses at discharge from hospital, were three independent predictors of SSI. The National Nosocomial Infection Surveillance (NNIS) found that ASA grade, contaminated or dirty procedures and long operative procedures to be associated with SSI. Other trials have not concurred. Therefore it is critical that definitions and type of surveillance are considered when considering the findings from these studies which may not be applicable to all patients, types of surgery or in different health care settings.

Many risk factors for the development of SSIs have been identified, often without robust evidence. However, several of these pre-, intra- and post-operative factors have been the subject of randomised clinical trials, of varied quality, and these have been addressed.

4 Information for patients

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

4.1 Information for patients

Overview of evidence

Searches were run with no study-design filters.

One RCT⁸ was identified.

The searches failed to identify any studies investigating the role of patient-information in prevention of SSI. They did, however, identify one RCT ⁸ 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 ⁸ (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 against a 'non-educated' group in assessing the performance of SSI self-determination. (EL 1+) Participants were surgical patients who had undergone a range of different interventions. The main outcome of the study was the number of SSI events. There was no 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% wounds as being infected. This result was the same for the 'non-educated' group where also 83.3% wounds were correctly identified as being infected. On the other hand, the 'educated' group correctly identified 93.7% of the wounds as non-infected while for the 'non-educated' group the percentage of wounds correctly identified as non-infected was 98.1%. So, even if both groups identified correctly the same proportion of true SSI, the educated group over-estimated the number of SSI events.

Evidence statement

From a single RCT there is evidence to suggest that education provided before discharge will not improve patient self-diagnosis, but might lead to more false-positive SSI diagnoses.

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 giving information to patients on the recognition of SSI might lead to an overestimation of SSI events, it was agreed that it is preferable to deal with an over-estimation of cases than with missing ones. The GDG felt that as a minimum, patients and carers should be provided with information about the risk of SSI associated with their particular type of procedure.

GDG Recommendation

Patients and carers should receive clear and consistent messages about the risks and management of SSI and what measures are being undertaken to reduce them, throughout their patient journey.

Patients and carers should receive information on post-discharge wound care.

Patients and carers should be given information to help them recognise an SSI and who to contact if they are concerned.

5 Preoperative phase

5.1 **Preoperative showering**

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

Introduction

When the skin is incised, micro-organisms colonising the surface may contaminate the exposed tissues and subsequently proliferate and lead to an SSI. Interventions that reduce the number of micro-organisms on the skin surrounding the incision may therefore decrease the risk of SSI. The microbial flora on the skin is comprised of transient micro-organisms 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 is 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 surgical site infection.

Overview of evidence

One systematic review was identified.

One well-conducted systematic review 9 (6 RCTs, n=10,007 participants) examined the evidence for preoperative bathing or showering with antiseptics for the prevention of surgical site infection. (EL 1+)

Patients were undergoing orthopaedic, vascular, biliary tract, inguinal hernia, breast, vasectomy and other general surgical operations. The incidence of surgical site infection 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 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]), whilst the larger trial (n=978) found 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]).

Review: Comparison: Outcome:	Showering 03 chlorhexidine vs no washing 01 Surgical Site Infection				
Study or sub-category	chlorhexidine n/N	no washing n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Randall	12/32	9/32		28.91	1.33 [0.65, 2.72]
Wihlborg	9/541	20/437	_	71.09	0.36 [0.17, 0.79]
			0.1 0.2 0.5 1 2 5	10	
			Favours chlorhexidin Favours no w	vashing	

Five studies in the systematic review examined the effect of preoperative showering or bathing with 4% chlorhexidine solution compared to a detergent or bar soap. Three RCTs (n=7691 participants) used a detergent as a placebo intervention and three RCTs (n=1443) used bar soap as a comparator. It should be noted that one of these studies (Hayek 1987) used a placebo which was subsequently discovered to have antimicrobial properties.

A meta analysis 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 detergent or bar soap (487/4526) (RR = 0.90 [95%CI 0.79 to 1.02] $I^2 = 35.3\%$).

DRAFT FOR CONSULTATION

Showering

Review:

Study or sub-category	chlorhexidine n/N	detergent/bar soap n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Byrne	256/1754	272/1735		62.53	0.93 [0.80, 1.09]
Earnshaw	8/31	4/35		- 0.86	2.26 [0.75, 6.77]
Hayek	62/689	163/1326		25.49	0.73 [0.55, 0.97]
Randall	12/32	15/30		3.54	0.75 [0.42, 1.33]
Rotter	37/1413	33/1400		7.58	1.11 [0.70, 1.77]
Total (95% Cl)	3919	4526	•	100.00	0.90 [0.79, 1.02]
Total events: 375 (chlori	nexidine), 487 (detergent/bar soar))			
Fest for heterogeneity: (Chi ² = 6.18, df = 4 (P = 0.19), l ² = 3	5.3%			
Test for overall effect: Z	= 1.64 (P = 0.10)				

One included RCT (n=1093) found that total body washing with chlorhexidine produced a statistically significant reduction in SSI incidence compared to 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]).

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 ⁹ that examined the evidence for preoperative bathing or showering with antiseptics for the prevention of surgical site infection 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.

Are preoperative showers with antiseptics cost-effective?

Health economics overview of evidence

One RCT was identified.

One RCT 10 compared a chlorhexidine detergent shower three times before elective surgery with three showers using detergent. The average cost of both non-infected and infected patients was found to be higher in the chlorhexidine than the placebo group. The average cost of a non-infected chlorhexidine-treated patient was £847.95 compared with £804.60 for a non-infected placebo patient, whereas the average cost of an infected patient was £1459.70 (chlorhexidine) and £1414.22 (placebo). The authors concluded that preoperative whole-body disinfection with a chlorhexidine detergent was not a cost-effective treatment for reducing wound infection.

Evidence statements

There is evidence from one RCT that showering or bathing using chlorhexidine significantly reduces the rate of SSI compared to 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 (SR or RCT) evidence which examines the clinical effectiveness of the timing or number of preoperative showers to prevent surgical site infection.

Health economics evidence statement

There is evidence to indicate that preoperative showering with a chlorhexidine detergent is not a costeffective intervention to prevent surgical site infections when compared to preoperative showering with a placebo detergent or bar soap

GDG interpretation

One study demonstrated a significant reduction in SSI associated with a chlorhexidine preoperative shower compared to no showering or a partial body wash, and in one study, whole body showering with chlorhexidine was compared to 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, whilst there is evidence to support the efficacy of preoperative showering as a measure to reduce the rate of SSI, there is insufficient evidence to indicate whether chlorhexidine as a cleansing agent is more effective than plain detergent or soap.

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.

GDG Recommendation

Patients should shower or bathe (or be showered or bathed or bed bathed) either the day before, or on the day of surgery.

5.2 Hair removal

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 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 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 micro-organisms 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 minimize 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 surgical site infection.

Overview of evidence

One systematic review and one additional RCT were identified.

One well-conducted systematic review ¹¹ (11 RCTs, n=4,627 participants) was included that examined the evidence for preoperative hair removal for the prevention of surgical site infection. (**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, clipping and depilatory cream.

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

A recent RCT ¹² compared the effect of shaving 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, using a fixed effects model, shows that there was no statistically significant difference in SSI incidence between shaving and no hair removal (RR 1.82 [95% CI 0.93 to 3.59]).

DRAFT FOR CONSULTATION

Review:	Hair removal (Version 01)
Comparison:	01 shaving vs no shaving
Outcome:	01 Shaving vs no shaving and SSI incidence.

Study or sub-category	Shaving n/N	No shaving n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Court Brown Rojanapirom Celik	17/137 0/40 4/371	11/141 0/40 1/418		92.02	1.59 [0.77, 3.27] Not estimable 4.51 [0.51, 40.14]
Total (95% Cl) Total events: 21 (Shaving), 1 Test for heterogeneity: Chi ² Test for overall effect: Z = 1	= 0.80, df = 1 (P = 0.37), l ² = 0%	599	-	100.00	1.82 [0.93, 3.59]
			0.1 0.2 0.5 1 2 5	10 aving	

One trial (n=267 adults) reported in the systematic review compared SSI incidence in two groups randomised to hair removal with depilatory cream (10/126) or 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 to no hair removal.

Three RCTs (n=3193 participants) compared the relative effects of shaving vs clipping on the incidence rate of SSI. 2.8% (46/1627) of people who were shaved developed a SSI compared to 1.4% (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 and use of depilatory cream for hair removal. Meta analysis undertaken using a fixed effects model showed significantly more SSIs in patients who were shaved (65/670) compared to those who had hair removed with depilatory cream (38/543) (RR 1.54 [95% CI 1.05 to 2.24]).

There were no studies which compared clipping to depilatory cream.

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 11 (11 RCTs, n=4,627 participants) examined the evidence for the timing of preoperative hair removal for the prevention of surgical site infection. (**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 and clipping were investigated.

Shaving on day of surgery vs shaving one day preoperatively

14/271 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 finding 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 on day of surgery vs clipping one day preoperatively

10/250 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). This difference was not statistically significant (RR 2.26 [95%CI 0.72 to 7.11]).

At 30 days post operatively, 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 relative risk was not statistically significant (RR 2.30 [95% CI 0.98 to 5.41]).

What is the most cost-effective method of hair removal?

Health economics overview of evidence

Five studies were included ^{13 14 15 16 17}.

The studies examined and compared different techniques of preoperative hair removal (shaving, use of depilatory cream, clipping and, including as well, 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 different hair removal techniques in a UK context (*see Appendix E*). It showed that electric clippers were the most cost-effective method for preoperative hair removal.

Health economics evidence statement

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 to no hair removal, shaving using razors and shaving cream. The use of electric clippers was not only found to generate more QALYs but was also found to be less expensive than these three interventions.

Evidence statement

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

There is evidence that fewer SSIs occur following hair removal with clippers or depilatory creams compared to shaving. (EL 1+)

There is insufficient evidence to determine whether the timing of the preoperative shaving or clipping of hair at the operative site affects the incidence of surgical site infection. (EL 1+)

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

There is evidence that 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 with razors increases the risk of SSI.

There is insufficient evidence whether the timing of hair removal affects the risk of SSI but the consensus is 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.

GDG Recommendations

Hair removal is not indicated for the prevention of SSI.

If hair has to be removed, electric clippers with single-use disposable heads should be used on the day of surgery.

If hair has to be removed, razors should not be used because of the increased risk of SSI.

5.3 Patient theatre attire

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 operative team, little patient movement occurs during operations thus reducing the dispersal of micro-organisms from skin and clothing. The purpose of the review was to determine whether patient theatre attire can affect the incidence of surgical site infection.

Overview of evidence

No studies were identified which examined patient theatre attire and postoperative surgical site infection rates.

Evidence statement

There was no evidence identified to determine if patient theatre attire can affect the incidence of surgical site infection

GDG interpretation

There is no evidence concerning patient theatre attire, however 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.

GDG Recommendation

Specific patient theatre attire, appropriate for the procedure and clinical setting, should be worn but should have regard for patients' personal comfort and dignity, the provision of easy access both to the operative site and areas for the placement of devices.

5.4 Non-sterile theatre wear

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 operative 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, 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. Surgical site infection: full guideline DRAFT (April 2008) This well conducted systematic review (2 quasi-RCTs, n=1453 participants) was first published in 2002 and updated in May 2006¹⁸. (**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 due to clinical and methodological heterogeneity between the studies.

One quasi-RCT consisted of 3088 patients undergoing breast, vascular and acute surgery. In the review, data were presented for the 1429 patients undergoing clean surgery. 13/706 (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 are 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 surgical patients was discontinued because 3/10 (30%) SSIs occurred in the unmasked 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 statement

There is limited evidence to show that there is no difference in the rate of SSI when face masks are worn during clean or dirty surgery. (EL 1+)

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 surgical site infection.

GDG interpretation

Although there is limited evidence concerning the use of specific non-sterile theatre wear, there was a consensus view 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

Specific non-sterile theatre wear should be worn in all areas, by all staff, where operative procedures are undertaken.

5.5 Staff leaving the operating area in non-sterile theatre wear

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 surgical site infection.

Overview of evidence

No studies were identified which examined the effect of staff movement in and out of the operating room on surgical site infection rates.

Evidence statement

There is no evidence to determine whether staff exiting and re-entering the operating area has an influence on the incidence of surgical site infection.

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.

There is a consensus view 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.

GDG Recommendation

Movement in and out of the operating theatre suite of healthcare personnel dressed in non-sterile theatre wear should be restricted.

5.6 Nasal decontamination

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* (*S. aureus*) in the body, and *S. aureus* spreads from this site to other places on the skin surface. Up to a third of people carry *S. aureus* persistently in their nares and about a further third do so intermittently. *S. aureus* is the most common cause of SSI in all types of surgery, the micro-organism frequently being derived from the patients themselves. Hence measures to clear carriage of *S. aureus* from the anterior nares around the time of surgery have 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^{19 20-23} 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 ^{19 20 21}, although participants in one trial ²¹ were all *S. aureus* carriers. A further trial ²² compared mupirocin to no intervention and another ²³ compared the effect of chlorhexidine mouthwash and nasal gel to placebo on SSI incidence.

Two RCTs^{19 20} (n=4478 participants) examined whether there was any difference in SSI incidence following nasal decontamination with mupirocin and placebo. (EL 1+) Data were pooled in a meta analysis. There was no heterogeneity and no statistically significant difference in SSI incidence between the two groups (fixed effect OR 0.98 [95% CI 0.77 to 1.21]).

DRAFT FOR CONSULTATION

Review:	Nasal decontamination					
Comparison:	01 Nasal decontamination - mupirocin vs pla	cebo				
Outcome:	01 overall SSI in all participants					
Study	mupirocin	placebo		OR (fixed)	Weight	OR (fixed)
or sub-categor	y n/N	n/N		95% CI	%	95% CI
Kalmeijer	12/315	14/299			8.87	0.81 [0.37, 1.77]
Perl	152/1933	154/1931		- -	91.13	0.98 [0.78, 1.24]
Total (95% CI)	2248	2230		-	100.00	0.97 [0.77, 1.21]
Total events: 1	64 (mupirocin), 168 (placebo)			100		
Test for hetero	geneity: Chi ² = 0.23, df = 1 (P = 0.63), l ² = 0%					
Test for overal	effect: Z = 0.28 (P = 0.78)					
			0.1 0.2	0.5 1 2	5 10	
			Favour	s mupirocin Favou	irs placebo	

Two RCTs ^{20 21} examined the 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 [95% CI 0.55 to 1.28] n=891 and OR 1.88 [95% CI 0.83 to 4.25] n=157).

These two studies $^{20\ 21}$ 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 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 22 (n=395 participants) compared the SSI incidence following nasal decontamination with mupirocin or no nasal decontamination in patients undergoing abdominal digestive surgery. (EL 1+) There was no significant difference in SSI rate between treatment arms (OR 1.39 [95% CI 0.76 to 2.52]).

One trial 23 (n=954 participants) comparing the effects of chlorhexidine against placebo found no significant difference in SSI rates between groups (OR 0.88 [95% CI 0.58 to 1.33]). (EL 1+)

One trial ²³ 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.

Timing of nasal decontamination for SSI prevention

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 surgical site infection.

Cost-effectiveness of mupirocin nasal ointment to prevent surgical site infection caused by S. aureus

Health economics overview of evidence

Two full economic analysis papers ^{24 25} were included.

A cost-effectiveness analysis ²⁴ 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, \$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 ²⁵ compared the following strategies: screening patients for *S. aureus* colonization with nasal culture and treating carriers with mupirocin, no screening but treating all patients with mupirocin and 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 costeffectiveness of mupirocin nasal ointment to prevent surgical site infection caused by *S. aureus*. 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 a 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 probabalistic 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 F*.

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 surgical site infection caused by S. *aureus* is a cost effective strategy.

Evidence statement

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 significantly 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-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 surgical site infection caused by *S. aureus*, and the GDG did not think it should be recommended, especially as the potential harm of increased antibiotic resistance was not factored into the model.

GDG Recommendation

Routine use of nasal decontamination with topical antimicrobial agents aimed at eliminating *Staphylococcus aureus* is not recommended for the prevention of SSI.

Research Recommendation

There should be further research using larger numbers to test the cost effectiveness of mupirocin in nasal decontamination.

5.7 Mechanical bowel preparation (MBP)

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

Introduction

Most SSIs are acquired intraoperatively from the bacterial flora colonising the patients' 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 surgical site infection.

Overview of evidence

12 RCTs were identified.

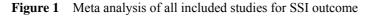
A systematic review (9 RCTs, n=1592 participants) published in 2005 was found that investigated SSI incidence (as a secondary outcome) following mechanical bowel preparation in patients undergoing colorectal surgery. All nine trials were included here, although two trial reports published after the Cochrane review was prepared were used as they contained fuller detail. A further three trials $^{26\ 27\ 28}$ published within the last two years were also identified. EL 1+

This gives a total of 12 included trials with patients who were all undergoing colorectal surgery. Different MBP solutions were administered in the studies: polyethylene glycol, mannitol, sodium picosulphate, 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 surgical site infection.

There was no heterogeneity and no statistically significant difference in SSI incidence between the treatment and control groups (I2 = 0% and (OR 1.08 [95% CI 0.88 to 1.32] - fixed effect model) see Figure 1.

		MBP		08.49.49	107-1-0-4	00.49.000
Study or sub-category		MBP N/N	No MBP n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
or sub-category		LINN	LINN	95% CI	70	35% CI
Brownson		5/86	7/93		3.54	0.76 [0.23, 2.49]
Bucher		10/78	3/75		1.49	3.53 [0.93, 13.37]
Burke		4/82	3/87		- 1.55	1.44 [0.31, 6.62]
Contant		41/670	45/684		23.39	0.93 [0.60, 1.43]
Fa-Si-Oen		9/90	7/95		3.43	1.40 [0.50, 3.92]
Fillman		1/30	2/30	<	- 1.08	0.48 [0.04, 5.63]
Jung		103/686	106/657	_ 	51.49	0.92 [0.68, 1.23]
Miettenen		5/138	3/129		- 1.67	1.58 [0.37, 6.74]
Pena-Soria		9/48	6/49		- 2.70	1.65 [0.54, 5.07]
Santos		17/72	9/77		- 3.72	2.34 [0.97, 5.65]
Tabusso		2/24	0/23		■ 0.26	5.22 [0.24, 114.87]
Zmora		12/187	11/193		5.67	1.13 [0.49, 2.64]
Total (95% Cl)		2191	2192	•	100.00	1.08 [0.88, 1.32]
Total events: 21	3 (MBP), 202 (No MBP	")				
Test for heterog	eneity: Chi² = 10.56, d	if = 11 (P = 0.48), I ² =	0%			
Test for overall (effect: Z = 0.74 (P = 0	(46)				



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 recognises 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 upon rates of SSI. The GDG recognises that there may be other indications where bowel preparation may be used in particular to minimise the risk of an anastomic 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.

GDG Recommendation

Mechanical bowel preparation is not recommended solely for the prevention of SSI.

5.8 Hand decontamination (general)

General hand decontamination is covered by EPIC 2 (See Appendix J). It refers to preoperative preparation and to any contact with the patient until discharge.

5.9 Hand jewellery, artificial nails and nail polish

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 surgical site infection.

Overview of evidence

One systematic review ²⁹ was identified that examined the effect of the surgical scrub team removing finger rings and nail polish on postoperative SSI rates.

No trials were found that compared the wearing of finger rings with the removal of finger rings. No trials were found that compared the removal/wearing of nail polish with SSI.

One well-conducted systematic review 29 (1 RCT, n=102 participants) looked at the effects of removing finger rings and nail polish in 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 finger nails before and after surgical scrubbing expressed as the number of 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 statements

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 and artificial nails. However there is GDG concern that in certain circumstances artificial nails and jewellery may conceal underlying soiling and impair hand decontamination.

GDG Recommendation

The operative team should not wear hand jewellery, artificial nails and nail polish during operative procedures.

5.10 Antibiotic prophylaxis

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

Introduction

Antibiotic prophylaxis has been used effectively to prevent postoperative patient 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 which entails a course of antibiotics over a period of time. In this review the clinical effectiveness of antibiotic prophylaxis for different types of surgical procedures in the prevention of SSI was examined.

Searches were run for 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 30 (8 RCTs, n=2075 participants) examined the evidence for antibiotic prophylaxis in patients who received a craniotomy. The antibiotics used were clindamycin, vancomycin/gentamicin, cefazolin/gentamicin, vancomycin, piperacillin, cloxacillin, oxacillin, and cefotiam and these were compared to placebo. (EL 1+)

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

Spinal Surgery

One systematic review was included.

A systematic review ³¹ was found (5 RCTs, 1 quasi-RCT, n=843 participants) that examined antibiotic prophylaxis in patients who all had spinal operations in trials of general neurosurgery, orthopaedic and spinal surgery. (EL 1+) The antibiotics used were cephaloridine, 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 to controls although none reached statistical significance. The meta-analysis conducted of the six studies drew the same conclusion of a statistically significant protective effect of antibiotics (10/461) against wound infection compared to control (23/392) (OR = 0.37 [0.17 to 0.78]).

Open reduction and internal fixation of compound mandibular fractures

One systematic review was included.

A systematic review was identified ³² (4 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 treatment. 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 of the four studies found significantly fewer wound infections in participants given antibiotic prophylaxis compared to those given placebo or no treatment (OR=0.18 [0.10 to 0.32]). Removal

of the trial that mixed open and closed reduction of fractures did not remove significance (OR=0.25 [0.08 to 0.30]).

Review: Comparison: Outcome:	antibiotic prophylaxis 04 Compound mandibular fractures 01 antibiotic vs placebo or no treatment					
Study or sub-category	Antibiotic n/N	Placebo/no treatment n/N		(fixed) % Cl	Weight %	OR (fixed) 95% Cl
Zallen	2/32	16/30	←		27.82	0.06 [0.01, 0.29]
Aderhold	6/80	8/40	_	-	17.73	0.32 [0.10, 1.01]
Chole	5/37	18/42	← ■		26.20	0.21 [0.07, 0.64]
Gerlach	8/151	11/49	← ■		28.26	0.19 [0.07, 0.51]
Test for heterog	300 (Antibiotic), 53 (Placebo/no treatment) eneity: Chi² = 3.00, df = 3 (P = 0.39), l² = 09	161	•		100.00	0.18 [0.10, 0.32]
Test for overall (effect: Z = 5.89 (P < 0.00001)			l		
			0.1 0.2 0.5	1 2 5	5 10	
			Favours antibiotic	Favours plac	ebo/notx	

Ear Nose and Throat

Clean, malignant, neck dissection head and neck surgery

One RCT was identified

An RCT ³³ (n=20 patients) was included that examined the effect of cefamandole prophylaxis compared to 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. Results are 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 [0.05 to 1.94]).

Contaminated/clean-contaminated head and neck surgery

One systematic review was included.

A systematic review ³⁴ (12 RCTs) investigating antibiotic prophylaxis compared to placebo or to 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 to 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 of these three trials found that there were significantly fewer wound infections in patients who received antibiotics (19/155) than those who received placebo (35/82) (OR= 0.06 [0.02 to 0.18]).

Study or sub-category	antibiotic n/N	placebo n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Becker	12/32	20/23	_ _	42.37	0.09 [0.02, 0.37]
Johnson	7/71	7/9	← ■	32.63	0.03 [0.01, 0.18]
Dor	0/52	8/50	← ∎───	25.00	0.05 [0.00, 0.85]
Total (95% Cl) Total events: 19 (antibiot	155 ic), 35 (placebo)	82	-	100.00	0.06 [0.02, 0.18]
Test for heterogeneity: (Test for overall effect: Z	hi ² = 0.88, df = 2 (P = 0.65), l ² = 09 = 5.14 (P < 0.00001)	6			

Breast cancer surgery

One systematic review and an RCT were identified

One Cochrane systematic review ${}^{35}(6 \text{ RCTs}, n=1302 \text{ participants})$ was identified that included people with breast cancer undergoing breast surgery with or without immediate re-construction as part of their treatment. (EL 1+) The antibiotics used were azithromycin, cefonicid (two trials), clarithromycin, co-amoxiclav and cefazolin.

Five RCTs compared antibiotic to placebo and found significantly fewer infections in the group receiving prophylaxis (RR = 0.66 [0.48 to 0.89]).

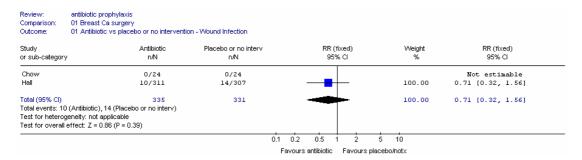
Surgical site infection: full guideline DRAFT (April 2008)

page 34 of 165

Study or sub-category	Antibiotic n/N	Placeboor nointerv n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Platt	20/303	37/303	_	41.99	0.54 [0.32, 0.91]
Wagman	3/59	5/59		5.67	0.60 [0.15, 2.40]
Amland	3/42	4/34		5.02	0.61 [0.15, 2.53]
Bold	3/69	10/72 🔶		11.11	0.31 [0.09, 1.09]
Gupta	29/156	32/157	-	36.20	0.91 [0.58, 1.43]
Total (95% Cl)	629	625	•	100.00	0.66 [0.48, 0.89]
Total events: 58 (Antibiotic),	38 (Placebo or no interv)		-		
Test for heterogeneity: Chi2 =	3.96, df = 4 (P = 0.41), l ² =	0%			
Test for overall effect: Z = 2.	56 (P = 0.008)				

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

A further, subsequently published trial (n=618 participants) was identified 36 . (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 each group (OR 0.71 [0.32 to 1.56]).



Immediate breast reconstruction with or without implants

One systematic review was found.

A systematic review 35 did not identify any eligible studies evaluating prophylactic antibiotics for reconstructive surgery (with or without implants) for inclusion. (EL 1+)

Cardiac pacemaker insertion

One systematic review was identified.

A systematic review ³⁷ (7 RCTs, n=2023 participants) of antibiotic prophylaxis for permanent pacemaker insertion was identified. (EL 1+) All trials compared antibiotics to '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/amoxycillin and ampicillin/flucloxacillin, cefazolin, cefazedon and flucloxacillin alone. 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 treatment (5/1011) compared to no antibiotic treatment (37/1012) (OR=0.256 [0.10 to 0.656]) for infection.

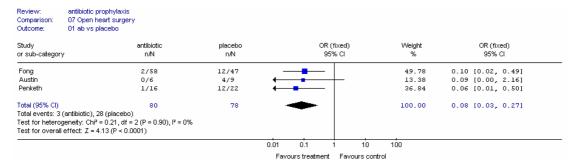
Open heart surgery

Three RCTs were identified.

Two trials were identified that examined the effect of antibiotic prophylaxis compared to placebo in CABG³⁸ ³⁹ and one trial in aorto-coronary bypass operations ⁴⁰. (EL 1-, EL 1+, EL 1+ respectively). The antibiotics used were methicillin, cephradine, and cephalothin. All studies were halted to examine infection rates in both groups. One study ³⁹ was re-started with placebo still given, whilst the other two had protocols modified.

A meta-analysis of these three RCTs showed that antibiotic prophylaxis reduced the rate of wound infections compared to placebo (OR=0.08 [0.03 to 0.27]).

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General Thoracic Surgery

Two RCTs were identified.

Two trials of patients undergoing operations in general thoracic surgery units were found.

One RCT ⁴¹ randomised participants (n=211 participants) to receive either cephalothin 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 [0.08 to 0.50]).

One RCT ⁴² randomised participants (n=127 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 significantly fewer wound infections in the antibiotic group (2/70) than in the placebo group (8/57) (OR=0.18 [0.04 to 0.89]).

A meta analysis of these two studies that included a total of 238 participants also found that there were significantly fewer wound infections with antibiotic prophylaxis compared to placebo (OR = 0.20 [0.09 to 0.43]).

Comparison: 08 Th	iotic prophylaxis noracic surgery rtibiotic vs placebo					
Study or sub-category	antibiotic n/N	placebo n/N	OR (f 95%		Weight %	OR (fixed) 95% Cl
llves Aznar	7/118 2/70	22/93 8/57			72.99 27.01	0.20 [0.08, 0.50] 0.18 [0.04, 0.89]
Total (95% Cl) Total events: 9 (antibio Test for heterogeneity Test for overall effect:	: Chi ² = 0.02, df = 1 (P = 0.90), l ² = 0%	150	-		100.00	0.20 [0.09, 0.43]
			0.1 0.2 0.5 1 Favours antibiotic	2 5 Favours place		

Abdomen Upper GI

Stomach and duodenal surgery

Four RCTs were found

Four trials ⁴³ ⁴⁴ ⁴⁵ ⁴⁶ were found that compared the use of antibiotic prophylaxis to placebo to no antibiotic in stomach and duodenal surgery. Three reported wound infections outcomes for patients and one reported wound infections as a proportion of the overall number of wounds ⁴³.

This study ⁴³ included patients undergoing general surgery randomising them to either cephaloridine (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 significant (OR= 0.13 [0.01 to 1.11]).

One RCT ⁴⁴ included 83 patients undergoing surgery for high risk gastroduodenal disease who were divided into two treatment arms, one of which received two doses of cephaloridine, the other no antibiotic. (EL 1+) A further low risk treatment arm was not considered here. No wound infections were found in the cephaloridine group (n=41 patients) compared to 11 in the no antibiotic group (n=42 patients). This difference was significant (OR = 0.03 [0.00 to 0.58]).

One RCT ⁴⁵ 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 significant (OR = 0.10 [0.01 to 0.94]).

One RCT ⁴⁶ 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 significant (OR = 0.03 [0.00 to 0.61]).

A meta-analysis 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 to placebo or no antibiotics (OR = 0.05 [0.01 to 0.22]).

Review: Comparison: Outcome:	antibiotic prophylaxis 09 Stomach and duodenal 02 antibiotics vs no antibiotics or placebo				
Study or sub-category	Antibiotics n/N	no abs/placebo n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Polk Lewis	0/32 0/41	11/36 11/42		37.64 39.58	0.03 [0.00, 0.61] 0.03 [0.00, 0.58]
Nichols Total (95% Cl)	1/19 92	7/20 98		22.78	0.10 [0.01, 0.94] 0.05 [0.01, 0.22]
Test for heteroge	Antibiotics), 29 (no abs/placebo) eneity: Chi² = 0.56, df = 2 (P = 0.75), l² = 0% .ffect: Z = 3.98 (P < 0.0001)		-		
			0.01 0.1 1 10 Favours antibiotics Favours no	100 ab/placeb	

Hepatobiliary Bile duct surgery

One systematic review was identified

42 RCTs of biliary tract operations comparing the effects of antibiotic prophylaxis to 'control' for wound infection were pooled in a meta-analysis in a systematic review ⁴⁷. (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 choledochoenterostomy.

Control interventions varied (e.g. 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 10 were excluded.

Overall the difference in wound infection incidence in the antibiotic prophylaxis group compared to the 'control' group was in favour of the antibiotic group (OR=0.30 [0.23 to 0.38]).

Laparoscopic gall bladder surgery

One systematic review and two RCTs were found.

One relevant systematic review ⁴⁸ and two more recently published RCTs from India ⁴⁹ and Taiwan ⁵⁰ were included.

The systematic review (6 RCTs, n=974 patients) that compared the effect of antibiotic prophylaxis to placebo on wound infection in patients undergoing low risk laparoscopic cholecystectomy. (EL 1+) The pooled OR was 0.82 [0.36 to 1.86] 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 ⁴⁹ included 93 patients of ASA grade I and II diagnosed as having gall stone disease undergoing laparoscopic cholecystectomy. (EL 1+) 40 patients were randomised to receive 1.5g cefuroxime in 100ml saline at anaesthesia induction whilst 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 significant (OR = 0.65 [0.06 to 7.47]).

One trial ⁵⁰ included 277 patients with symptomatic gallbladder stones or polyps disease with or without acute cholestasis who were candidates for laparoscopic cholecystectomy. (EL 1+) 141 patients were randomised to receive 1g cefazolin given at anaesthetic induction and 136 received 10ml isotonic sodium chloride solution similarly. There were two infections, both of which occurred in the placebo group. This finding was not significant (OR = 0.19 [0.01 to 4.00]).

Surgical site infection: full guideline DRAFT (April 2008)

page 37 of 165

A meta-analysis of all participants wound infection outcomes was performed that yielded a similar non-significant result (OR = 0.63 [0.30 to 1.32]).

	ophylaxis copic cholecystectomy c vs placebo					
Study or sub-category	Antibiotic n/N	Placebo n/N		OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Catarci	12/567	12/407			76.45	0.71 [0.32, 1.60]
Chang	0/141	2/136	←		14.18	0.19 [0.01, 4.00]
Kuthe	1/40	2/53			9.38	0.65 [0.06, 7.47]
Total (95% Cl) Total events: 13 (Antibiotic), '		596		+	100.00	0.63 [0.30, 1.32]
Test for heterogeneity: Chi² = Test for overall effect: Z = 1.	: 0.68, df = 2 (P = 0.71), I ² = 09 22 (P = 0.22)	6				
			0.01	0.1 1 10	100	
			Favo	ours antibiotic Favours pl	acebo	

Lower GI Appendicectomy

One systematic review was identified.

A Cochrane systematic review was identified ⁵¹ that investigated the use of antibiotics compared to placebo or no treatment 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.

Results

Statistically significant results favouring the use of systemic antibiotics compared to placebo were found in meta-analyses for both clinical and pathoanatomical descriptions of appendicitis ((Peto OR 0.33 [0.29 to 0.38]) and (Peto OR 0.32 [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 treatments (Overall (Peto OR 0.34 [0.25 to 0.45]) and Overall (Peto OR 0.14 [0.05 to 0.39]) respectively.

Single or multiple antibiotics given as a single dose peroperatively resulted in statistically significantly fewer wound infections than peroperative placebo treatments

(Overall (Peto OR 0.43 [0.34 to 0.55]) and Overall (Peto OR 0.43 [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 treatments (Overall ((Peto OR 0.16 [0.07 to 0.36]) and Overall (Peto OR 0.46 [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 treatments (Overall (Peto OR 0.18 [0.11 to 0.27]))

In children there was no significant difference in SSI rates with systemic antibiotics or placebo (Overall (Peto OR 0.64 [0.37 to 1.10])) except in complicated (gangrenous or perforated) appendicitis (Peto OR 0.31 [0.12 to 0.77])

Colorectal surgery

A systematic review ⁵² of antibiotic prophylaxis in colorectal surgery was found. It examined antibiotic prophylaxis compared with no antibiotic administration. (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 [0.13 to 0.43]).

One systematic review and one RCT were identified.

A recently updated Cochrane systematic review ⁵³ (12 RCTs, n=6705 participants) was found that evaluated antibiotic prophylaxis compared to 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 (herniorraphy).

Hernioplasty

There were 17 wound infections amongst the participants who received prophylaxis (n=1196 participants) compared to 37 in those receiving placebo (n=1240 participants). This difference in wound infection incidence was statistically significant (OR =0.48 [0.27 to 0.85]).

Herniorraphy

There were 103 wound infections amongst the participants who received prophylaxis (n=2932 participants) compared to 66 in those receiving placebo (n=1337 participants). This difference in wound infection incidence did not quite reach significance. Overall for both hernia repair methods there were 120 wound infections amongst the participants who received prophylaxis (n=4128 participants) compared to 103 in those receiving placebo (n=2577 participants). This was a statistically significant finding (OR =0.64 [0.48 to 0.85]) favouring antibiotic prophylaxis.

A further RCT ⁵⁴ 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 to 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 to nine in the placebo group (n=189 participants). This was not a statistically significant difference (OR= 0.54 [0.18 to 1.64]).

Adding this study to the review of hernioplasty narrowed the confidence interval and reduced the point estimate of the odds ratio (OR = 0.49 [0.30 to 0.81]).

Pelvis

Abdominal hysterectomy

One systematic review was identified

A systematic review ⁵⁵ (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 vs placebo or no antibiotic' and no quality assessment of methodology is provided. The group treated with cephalosporin showed a significantly lower infection rate compared with the control group (9.8% vs 23.4% OR = 0.35 [0.3 to 0.4] p<0.0001)'.

Caesarean section

One systematic review was identified

A Cochrane review ⁵⁶ (81 trials) was included 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 rate 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 treatment 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 to 86/1130 in the control group. 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 to 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 to 468/4905 in the control group. The RR was 0.41 [95% CI 0.29 to 0.43].

Limb Open fracture

antibiotic prophylaxis

Review:

One systematic review was identified

A Cochrane review 57 (7 trials, n=913 participants) was included that investigated the effect of antibiotics compared to 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.

Significantly fewer wound infections were found in the participants treated with antibiotic compared to 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 was included ⁵⁸ which 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 vs placebo were included.

This left five trials available for inclusion in this review.

A meta-analysis of three trials that considered the deep and superficial infection rates following multiple doses of a single antibiotic compared to placebo found that statistically fewer wound infections occurred in the antibiotic group in comparison to the placebo 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.

Study or sub-category	multidose ab n/N	placebo n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
01 Deep wound infection					
Bergman	0/117	2/63	d	38.17	0.11 [0.01, 2.23]
Gatell	2/134	4/150	-	44.45	0.56 [0.10, 3.01]
Paiement	0/60	1/62	• • •	17.38	0.34 [0.01, 8.29]
Subtotal (95% Cl)	311	275		100.00	0.35 [0.10, 1.24]
Total events: 2 (multidose ab),	7 (placebo)				
Test for heterogeneity: Chi ² = 0 Test for overall effect: Z = 1.62).88, df = 2 (P = 0.64), l² = 0%				
02 Superficial wound infection					
Bergman	12/117	6/63		46.30	1.08 [0.42, 2.73]
Gatell	0/134	7/150	←───┼	42.03	0.07 [0.00, 1.29]
Paiement	1/60	2/62	▲ ■ ↓	- 11.68	0.52 [0.05, 5.55]
Subtotal (95% Cl)	311	275		100.00	0.59 [0.27, 1.27]
Total events: 13 (multidose ab) Test for heterogeneity: Chi² = 3 Test for overall effect: Z = 1.35	3.63, df = 2 (P = 0.16), l ² = 45.	0%			
03 All wound infection					
Bergman	12/117	8/63	_	43.82	0.81 [0.35, 1.87]
Gatell	2/134	11/150	← ∎ ────	43.74	0.20 [0.05, 0.90]
Paiement	1/60	3/62	← ■	12.43	0.34 [0.04, 3.22]
Subtotal (95% Cl)	311	275		100.00	0.49 [0.25, 0.96]
Total events: 15 (multidose ab)	I, 22 (placebo)		_		
Test for heterogeneity: Chi ² = 2	2.81, df = 2 (P = 0.25), l ² = 28.	8%			
Test for overall effect: Z = 2.09	P = 0.04)				

A meta-analysis of two trials that considered the deep and superficial infection rates following single dose of one antibiotic as prophylaxis compared to placebo found that statistically fewer wound infections occurred in the antibiotic group in comparison to the placebo 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.

Study or sub-category	single dose ab n/N	placebo/no tx n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl	
01 Deep wound infection						
Boxma	13/1105	40/1090		100.00	0.32 [0.17, 0.60]	
Hughes	0/25	0/29	_		Not estimable	
Subtotal (95% CI)	1130	1119		100.00	0.32 [0.17, 0.60]	
Fotal events: 13 (single dose ab),	40 (placebo/no tx)		-			
est for heterogeneity: not applica	able					
est for overall effect: Z = 3.60 (F	° = 0.0003)					
02 Superficial wound infection						
Boxma	23/1105	39/1090		92.36	0.58 [0.35, 0.97]	
Hughes	0/25	3/29	< - −	7.64	0.16 [0.01, 3.04]	
Subtotal (95% CI)	1130	1119		100.00	0.55 [0.33, 0.90]	
fotal events: 23 (single dose ab),	42 (placebo/no tx)		-			
est for heterogeneity: Chi ² = 0.70	0, df = 1 (P = 0.40), l ² = 0%					
est for overall effect: Z = 2.35 (F	° = 0.02)					
03 All wound infection						
Boxma	36/1105	79/1090		96.07	0.45 [0.31, 0.66]	
Hughes	0/25	3/29	<	3.93	0.16 [0.01, 3.04]	
Subtotal (95% CI)	1130	1119	→	100.00	0.44 [0.30, 0.64]	
fotal events: 36 (single dose ab),	82 (placebo/no tx)		-			
est for heterogeneity: Chi ² = 0.45	5, df = 1 (P = 0.50), l ² = 0%					
Fest for overall effect: Z = 4.24 (F	P < 0.0001)					

Hip fracture

One systematic review was identified

This systematic review ⁵⁹ investigated the effect of antibiotic prophylaxis administered pre, peri and/or post operatively 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 with a total of 2417 participants investigated at wound infection and found that significantly fewer wound infections occurred in those patients given antibiotics compared to those given placebo (OR = 0.55

[0.35 to 0.85])

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

Lower limb amputation

One systematic review was identified

One RCT (n=152 participants) conducted in Denmark was identified ⁶⁰ that examined the use of cefoxitin (five doses of 2g during first 24h, starting 30mins before amputation and then every 6h) compared with placebo (no further details) in patients admitted for amputation due to arteriosclerosis. (EL 1+) There were significantly more wound infections in the placebo group compared to 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 ⁶¹ was identified (35 RCTs) which sought to determine the effectiveness of perioperative strategies to prevent infection in patients undergoing peripheral arterial reconstruction. (EL 1+)

All patients undergoing peripheral arterial reconstruction. Ten studies compared antibiotic prophylaxis against placebo. A meta analysis of these 10 studies demonstrated that prophylactic systemic antibiotics reduced the risk of wound infection (RR 0.25 [0.17 to 0.38]) compared to placebo or no treatment.

Health economics overview of evidence

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

Four studies were identified ^{62 63 64 65}.

Three studies compared no antibiotic prophylaxis to antibiotic therapy. One study found no significant difference in SSI rate in patients undergoing neck dissections ⁶² although this was based on retrospective data from 1977 to 1989. One study found a significant difference in SSI rate in patients undergoing appendicectomies and colorectal operations ⁶⁴. One study was underpowered ⁶³. As none of these studies was carried out in the UK the costs were not generalisable to this setting.

One study compared a 24 hour prophylactic antibiotic regime to a one dose regimen administered at anaesthesia induction. No significant difference was found between SSI rate (2% and 2.1%, P=0.67). Therefore a cost-minimisation analysis was carried out and using 1 dose of antibiotics was the lowest cost intervention. If similar SSI rates could be applied to a UK setting with reduced antibiotic prophylaxis then a one dose antibiotic prophylaxis protocol will be cost saving compared to a 24 hour antibiotic regimen.

Health economics evidence statement

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

Clean surgery – evidence statements

There is evidence that administration of antibiotics in craniotomy results in fewer wound infections compared to placebo treatment. (EL 1+)

There is evidence that administration of antibiotics in spinal surgery results in fewer wound infections compared to placebo treatment. (EL 1+)

There is evidence that pre or peri operative antibiotic used as prophylaxis for breast cancer surgery results in fewer wound infections than placebo, although there is insufficient evidence to determine whether this effect is also true when antibiotics are compared with no treatment. (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 than when patients are given no antibiotic treatment. (EL 1+)

There is evidence that antibiotic prophylaxis reduces wound infection incidence in open heart surgery compared to placebo. (EL 1+)

There is evidence that antibiotic prophylaxis reduces wound infection incidence in thoracic surgery compared to placebo.

There is evidence that antibiotic prophylaxis reduces the incidence of wound infection compared to 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 herniorraphy. (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 treatment 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 rate 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 to 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 insufficient evidence available (due to poor reporting) to determine the effect on wound infection in abdominal hysterectomy of antibiotic prophylaxis compared to placebo or no treatment. (EL 1-)

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

There is currently evidence of fewer wound infections occurring when antibiotic prophylaxis is given in elective caesarean delivery compared to placebo/no treatment. (EL 1+)

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

Clean-contaminated surgery – evidence statements

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

There is evidence that antibiotic prophylaxis reduces wound infection incidence in gastroduodenal surgery compared to placebo or no antibiotic. (EL 1+)

There is evidence that antibiotic prophylaxis reduces wound infection incidence in biliary tract surgery compared to placebo or no antibiotic. (EL 1+)

There is evidence of no difference of effect of antibiotic prophylaxis compared to 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 to 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 preoperatively compared to 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 to 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 to placebo. (EL 1+)

There is evidence that in children there is no difference of effect of antibiotic prophylaxis for noncomplicated 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+)

Contaminated surgery - evidence statements

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

Dirty surgery - evidence statements

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 to no other antibiotic treatment or to 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+)
- Long bone and other unspecified closed fractures (EL 1+)
- Hip fractures (EL 1+)
- Open limb fractures (EL 1+)
- Amputation (EL 1+)
- Emergency and elective Caesarean (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 to no other antibiotic treatment or to placebo in:

- Breast reconstruction with/without implants (EL 1+)
- Abdominal hysterectomy (clean contaminated) (EL 1+)
- Uncomplicated appendicectomy in children (EL 1+)

Health economics overview of evidence

19 papers were identified for further review; only three compared antibiotic prophylaxis to no antibiotic prophylaxis. One study was identified that compared a 24 hour prophylactic antibiotic regimen to a one dose regimen.

One study (39600) compared no antibiotic prophylaxis to antibiotic therapy. One study found no significant difference in SSI rate in patients undergoing neck dissections (39384) although this was based on retrospective data from 1977 to 1989. One study found a significant difference in SSI rate in patients undergoing appendicectomies and colorectal operations (39600). One study was underpowered (39388). As none of these studies was carried out in the UK the costs are not generalisable to this setting.

The most recent study (39383), was a Brazilian study which used historical controls. A 24 hour prophylactic antibiotic regimen was compared to 1 dose antibiotic prophylaxis given at anaesthesia induction. No significant difference was found between SSI rate (2% and 2.1%, P=0.67). Therefore a cost-minimisation analysis was 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 to a 24 hour antibiotic regimen.

Health economics evidence statement

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

GDG interpretation

Many of these studies used antibiotics which 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 (orthopaedic prosthetic surgery, for example) the GDG felt that even in the absence of adequate studies, antibiotic prophylaxis would be appropriate:

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

The only indications for repeating an antibiotic prophylaxis dose in these groups is 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 treatment

The GDG felt that the lack of evidence on the effectiveness of prophylaxis in the following procedures is insufficient to withhold antibiotic prophylaxis:

- Breast reconstruction with/without implants
- Abdominal hysterectomy (clean contaminated)
- Elective Caesarean
- Uncomplicated appendicectomy in children

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

GDG Recommendation

Antibiotic prophylaxis should be given to patients prior to clean surgery involving the placement of a prosthesis or implant, clean-contaminated and contaminated surgery. In addition to prophylaxis, patients undergoing surgery on a dirty/infected wound need antibiotic treatment.

Consider single dose administration for prophylaxis given IV at induction of anaesthesia but earlier in operations in which there is placement of a tourniquet.

Consider timing and pharmacokinetics (e.g. serum half-life) of the drug when administering.

Patients should always be informed that they have received antibiotics.

For clean uncomplicated surgery, antibiotic prophylaxis may not be necessary.

6 Intraoperative phase

6.1 Hand decontamination (scrubbing)

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

Introduction

Hand decontamination prior to surgery is required to minimize the risk that either the resident flora of microorganisms that normally colonise the skin or transient organisms acquired by touch contaminate the surgical wound. Whilst transient micro-organisms 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 micro-organisms, it does not physically remove organic material and it should, therefore, not be used when the hands are visibly soiled. The operative team must decontaminate their hands many times a day. Hence the regimen chosen should 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 stick. 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

scrubbing

A cluster RT ⁶⁶ was identified.

The trial (n=4823 participants) looked at incidence of SSI when comparing hand-rubbing with 75% aqueous alcohol solution (AAS) against hand-scrubbing with 4% povidone-iodine or 4% chlorhexidine before surgery (EL 1+). Participants were patients undergoing clean or clean-contaminated surgery. The outcome of interest was the incidence of surgical site infection. 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 1.

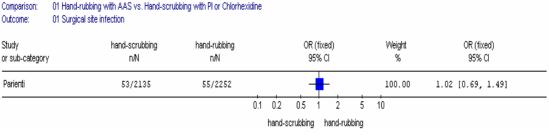


Figure 1

Review.

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

Health economics overview of evidence

One study was included 67

A study ⁶⁷ 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 surgical hand rubbing (SHR) was equivalent to surgical hand scrubbing 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 (39045) SHR was found to be cost-saving, this 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 statements

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.

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

GDG Recommendation

The operative team should decontaminate their hands prior to the first operation on the list using an antiseptic surgical scrub solution, with a brush for the nails. Between subsequent operations hands should be decontaminated using either an alcoholic hand rub/gel or antiseptic surgical scrub solution without scrubbing. If hands are soiled then they should be washed with an antiseptic surgical scrub solution.

6.2 Incise drapes

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 micro-organisms 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 ⁶⁸ and an RCT ⁶⁹ were identified.

Incise drape (without added antimicrobial properties) versus no incise drape

Five trials (n=3082) from a well-conducted systematic review ⁶⁸ 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 surgical site infection even if the definition criteria varied among the studies. A meta-analysis was performed pooling all the trials together (I²=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 1.

Review:	Drapes
Comparison:	01 incise drape (without added antimicrobial properties) vs. no incise drape
Outcome:	01 surgical site infection

n/N	no incise drape n/N		Г	R (fixe) 95% C	r .		Weight %	RR (fixed) 95% Cl
67/473	52/448				_		30.95	1.22 [0.87, 1.71]
8/51	10/47			•	_		6.03	0.74 [0.32, 1.71]
58/337	43/354				-		24.30	1.42 [0.98, 2.04]
41/325	31/324			+	-		17.99	1.32 [0.85, 2.05]
6/65	5/55			-			3.14	1.02 [0.33, 3.15]
34/305	30/298			+	_		17.59	1.11 [0.70, 1.76]
1556	1526			•	•		100.00	1.23 [1.02, 1.48]
171 (no incise drape)				1				. , .
D, df = 5 (P = 0.79), I ² = 09	%							
P = 0.03)								
		0.1 0.2	2 0.5	1	2	5		
						-		
ļ	67/473 8/51 58/337 41/325 6/65 34/305 1556 171 (no incise drape)	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0%	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0% P = 0.03) 0.1 0/2	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0% P = 0.03) 0.1 0.2 0.5	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0% P = 0.03) 0.1 0.2 0.5	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0% P = 0.03) 0.1 0.2 0.5 1 2	67/473 52/448 8/51 10/47 58/337 43/354 41/325 31/324 6/65 5/55 34/305 30/298 1556 1526 171 (no incise drape) 0, df = 5 (P = 0.79), P = 0% P = 0.03) 0.1 0.2 0.5 1 2 5	67/473 52/448 30.95 8/51 10/47 6.03 58/337 43/354 24.30 41/325 31/324 17.99 6/65 5/55 3.14 34/305 30/298 17.59 1556 1526 100.00 171 (no incise drape) 0.1 0.2 0.5 1 2 5 10

Figure 1

One RCT 69 (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]; (I2 0%)) when added to the previous meta-analysis, Figure 2.

Study or sub-category	incise drape n/N	no incise drape n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Jackson	67/473	52/448		30.20	1.22 [0.87, 1.71]
Psaila	8/51	10/47		5.88	0.74 [0.32, 1.71]
Alexander	8/310	4/267		- 2.43	1.72 [0.52, 5.66]
Cordtz_no skin redis	58/337	43/354		23.71	1.42 [0.98, 2.04]
Cordtz_skin redisinf	41/325	31/324	_ ⊢∎	17.55	1.32 [0.85, 2.05]
Chiu	6/65	5/55	_	3.06	1.02 [0.33, 3.15]
Ward	34/305	30/298		17.16	1.11 [0.70, 1.76]
Fotal (95% CI)	1866	1793	•	100.00	1.24 [1.03, 1.50]
lotal events: 222 (incise drag	e), 175 (no incise drape)				
Fest for heterogeneity: Chi ² =	2.71, df = 6 (P = 0.84), l ² = 0	%			
Fest for overall effect: Z = 2.	29 (P = 0.02)				

Figure 2

Incise drape (without added antimicrobial properties) versus no incise drape

Two RCTs from the above systematic review 68 were included under this comparison. The studies (n=1113 participants) investigated whether the use of incise drapes impregnated with iodophore had an effect in the incidence of surgical site infection when compared to when no incise drapes were used. (EL 1+) Participants were patients undergoing abdominal and cardiac surgical procedures. In both studies surgical site infection was reported. The data from the two trials were combined in a meta-analysis (I²=0%), Figure 3. The analysis showed no statistically significant difference, RR 1.03[95%CI 0.66 to 1.60].

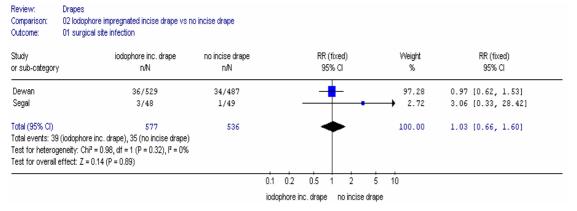


Figure 3

Incise drapes without added antimicrobial properties and iodophore-impregnated incise drapes versus no incise drapes

All the trials were pooled together in a meta-analysis. A statistically significant difference was found that favoured the non use of incise drapes in the prevention of SSI when compared to the use of an incise drape (impregnated with antimicrobial or not) (RR 1.20, [95% CI 1.02 to 1.43]), Figure 4.

Study r sub-category	incise drape n/N	no incise drape n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Jackson	67/473	52/448		25.03	1.22 [0.87, 1.71]
Psaila	8/51	10/47		4.88	0.74 [0.32, 1.71]
Alexander	8/310	4/267		- 2.01	1.72 [0.52, 5.66]
Dewan	36/529	34/487	_ _	16.59	0.97 [0.62, 1.53]
Cordtz_no skin redis	0/1	0/1			Not estimable
Cordtz_skin redisinf	99/662	74/678		34.26	1.37 [1.03, 1.82]
Chiu	6/65	5/55	_	2.54	1.02 [0.33, 3.15]
Ward	34/305	30/298	_ _	14.22	1.11 [0.70, 1.76]
Segal	3/48	1/49		→ 0.46	3.06 [0.33, 28.42]
fotal (95% Cl)	2444	2330	•	100.00	1.20 [1.02, 1.43]
iotal events: 261 (incise	drape), 210 (no incise drape)				
lest for heterogeneity: C	hi ² = 4.20, df = 7 (P = 0.76), l ² = 0%				
est for overall effect: Z	= 2.14 (P = 0.03)				

Figure 4

Evidence statement

There is evidence to suggest that the use of non-iodophore 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 iodophore impregnated incise drape and no incise drape. EL 1+

GDG interpretation

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

GDG Recommendation

Non-iodophore impregnated incise drapes are not recommended for routine use in surgery

In cases where an incise drape is used, this should be iodophore impregnated (excluding those cases where the patient presents with an iodine allergy).

6.3 Use of gowns

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

Overview of evidence

No studies were found that examined the use of gowns in the prevention of SSI

Evidence statements

There is insufficient evidence to determine if the use of gowns is clinically effective in the incidence of SSI.

GDG interpretation

It is good practice to use 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.

There is a consensus view that staff should wear 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.

GDG Recommendation

Gowns should be worn by healthcare professionals in the operating theatre.

6.4 Disposable drapes and gowns/ Reusable drapes and gowns

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

Overview of evidence

Two RCTs were identified 70;71.

The two studies (n=496 participants) ⁷¹; (n=505 participants) ⁷⁰ looked at the effects of using disposable drapes and gowns compared to reusable drapes and gowns in the incidence of SSI. (EL1+) Participants in one trial were booked for isolated coronary artery surgery ⁷¹; in the other trial 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 both studies. None of the two RCTs found a statistically significant difference between the use of disposable or reusable drapes and gowns ⁷⁰ (RR 0.99, [95% CI 0.30-3.28], p=0.98) Figure 1; ⁷¹ (RR 1.02[95% CI 0.46-2.29]), Figure 2 and (RR 0.78 [95% CI 0.45-1.35] p=0.37), Figure 3.

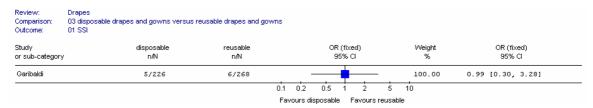


Figure 1

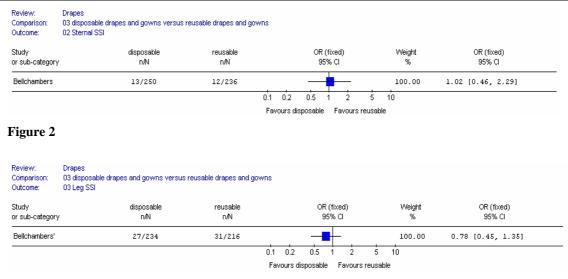


Figure 3

Evidence statements

There is evidence of no difference between the use of reusable drapes and gowns when compared to the use of disposable drapes and gowns in the incidence of SSI. 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 recognise 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 which may invalidate this interpretation.

GDG Recommendation

As there is no recommendation that can be made from this evidence it is suggested that local trust protocols are implemented.

Research Recommendation

The new materials used in reusable and disposable operative drapes and gowns deserve further evaluation in RCTs which incorporate cost-effectiveness analysis.

6.5 Gloves

Is there a difference between double vs single gloving affecting the incidence of surgical site infection? Does the puncture rate of gloves correlate to the incidence of surgical site infection?

Overview of evidence

Double gloving vs single gloving

No studies were found that investigated the use of double gloving versus single gloving in the prevention of SSI.

Gloves puncture

From a well-conducted systematic review two RCTs were identified ^{72 73}.

Two RCTs⁷² (n=50 participants)⁷³ (n=71 participants) examined the correlation between the use of different double-gloving techniques, 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. In both trials no SSI case was reported.

Evidence statements

There is insufficient evidence to determine if 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 recognises 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.

GDG Recommendation

Double gloving should be considered when there is a high risk of perforation.

6.6 Skin preparation with antiseptics prior to surgery

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

Introduction

When the skin is incised micro-organisms colonising the surface may contaminate the exposed tissues and subsequently cause SSI. Skin antiseptics are therefore used to reduce the number of micro-organisms on the skin around the incision. The resident flora that normally resides 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 surgical site infection.

Overview of evidence

One systematic review and four further RCTs were identified

One well-conducted systematic review (6 trials, n=2850 participants) was identified that examined the effects of pre-operative skin antiseptics for prevention of SSI in clean surgery only. EL 1+ Three trial reports from this review were included – one report describing two trials - preliminary and definitive.

A range of operations were undertaken in the 8 included trials: coronary artery bypass graft, 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 different concentrations and chlorhexidine.

Antiseptic vs no antiseptic

One quasi-RCT $^{74}(E \ 1-)$ examined the effects of showering with soap then saline irrigation of operative site vs showering with soap and PI scrub and paint of operative site. Although this study was adequately powered, no SSIs were found in either treatment arm.

Antiseptic 1 vs antiseptic 2

Chlorhexidine vs Iodine

Two trials that examined chlorhexidine compared to iodine were identified in the systematic review. One preliminary trial ⁶⁹ compared chlorhexidine in alcohol to 2% iodine in three different concentrations (50%, 70% and 90%) of alcohol, although an iodophor incise drape was used in all operations. The number of participants in each treatment arm was small (total n=70) and no significant findings were reported (RR 0.30 [0.03 to 3.10], RR 1.34 [0.06 to 30.86] and RR 0.46 [0.03 to 6.86] respectively). EL 1+

The other trial 75 (n=737 participants) compared the use of chlorhexidine spray to scrubbing and painting with iodine soap and aqueous povidone-iodine paint. No statistically significant difference in SSI rate between the two groups was found (RR 1.74 [0.65 to 4.66]). EL 1+

Surgical site infection: full guideline DRAFT (April 2008)

Review: Comparison: Outcome:	antiseptics 02 Antiseptic 1 vs antisepti 01 Chlorhexidine vs lodine	ic 2					
Study or sub-category		nexidine NN	lodine n/N		R (fixed) I5% Cl	Weight %	RR (fixed) 95% Cl
01 1 min scrub v	with chlorhexidine in alcohol	(Hibitane) vs 1 min s	crub with 2% iodine	e in 50% alcohol	0		
Alexander preli	im 1,	/28	2/17	← ■		100.00	0.30 [0.03, 3.10]
Subtotal (95% C	0)	28	17			100.00	0.30 [0.03, 3.10]
Total events: 1 ((Chlorhexidine), 2 (lodine)				17420		
Test for heterog	geneity: not applicable						
Test for overall	effect: Z = 1.01 (P = 0.31)						
	with chlorhexidine in alcohol	(Hibitane) vs 1 min s	scrub with 2% iodin	ne in 70% alcohol	Tanana II		
Alexander preli		/28	0/12	+		→ 100.00	1.34 [0.06, 30.86]
Subtotal (95% C		28	12		-	100.00	1.34 [0.06, 30.86]
Total events: 1 ((Chlorhexidine), 0 (lodine)						
Test for heterog	geneity: not applicable						
Test for overall	effect: Z = 0.19 (P = 0.85)						
031 min scrub v	with chlorhexidine in alcohol	(Hibitane) vs 1 min s	crub with 2% iodine	e in 90% alcohol			
Alexander preli		/28	1/13				0.46 [0.03, 6.86]
Subtotal (95% C		28	13			- 100.00	0.46 [0.03, 6.86]
	(Chlorhexidine), 1 (lodine)						
	geneity: not applicable						
	effect: Z = 0.56 (P = 0.58)						
04 0.5% Chlorhe	exidine spray in 70% alcohol	vs 6 min scrub with	soap (0.75% iodine	e) then aqueous povide	one-iodin		
Brown		/378	6/359			100.00	1.74 [0.65, 4.66]
Subtotal (95% C		378	359			100.00	1.74 [0.65, 4.66]
	(Chlorhexidine), 6 (lodine)				30000		
	geneity: not applicable						
	effect: Z = 1.10 (P = 0.27)						
				0.1 0.2 0.5	1 2	5 10	
				Favours chlorhex			
				r avours chiomex	a ravoursiou	ine -	

Alcohol vs chlorhexidine

One preliminary trial ⁶⁹ compared a one minute scrub with 70% alcohol vs a one minute scrub with chlorhexidine in alcohol (Hibitane). Both arms used iodophor polyester incise drape. This comparison was underpowered and there were no significant differences in SSI rate (RR 1.24 [0.12 to 13.10]). EL 1+

Comparison: Outcome:	02 Antiseptic 1 vs antiseptic 2 02 Alcohol vs chlorhexidine				
Study or sub-categor	Alcohol y n/N	Chlorhexidine n/N	RR (fixed) 95% Cl	VVeight %	RR (fixed) 95% Cl
01 1 min scrub	with 70% alcohol vs 1 min scrub with cł	lorhexidine in alcohol (Hibitane)			
Alexander pre	im 2/45	1/28 —		→ 100.00	1.24 [0.12, 13.10]
Culstatel (OCOL)	CI) 45	28 —		100.00	1.24 [0.12, 13.10]
Subtotal (95%)			30 00 <u>00 00 00</u> 00		
	(Alcohol), 1 (Chlorhexidine)				
Total events: 2	(Alcohol), 1 (Chlorhexidine) geneity: not applicable				

Iodine 1 vs Iodine 2

Iodine in alcohol vs iodine in different concentrations of alcohol

One preliminary trial ⁶⁹ (n=42 participants) 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% vs 70% alcohol, 50% vs 90% alcohol and 70% vs 90% alcohol and no significant differences in SSI incidence were reported (RR not estimable - no events in either group, RR 0.26 [0.01 to 5.89] and RR 0.36 [0.02 to 8.05] respectively.

Aqueous iodine vs iodine in alcohol

One quasi-RCT 76 (n=220 participants) found little difference between aqueous iodine to iodine in alcohol. (EL 1-) Patients' skin disinfected with 10% povidone-iodine solution which was then applied to wound edges was compared to disinfection with 2% iodine in 70% alcohol and then application of iodine tincture to wound edges. No significant difference in SSI incidence between the two groups was found (RR 1.21 [0.73 to 2.00]).

Surgical site infection: full guideline DRAFT (April 2008)

Comparison:					
	02 Antiseptic 1 vs antiseptic 2				
Outcome:	04 lodine 1 vs lodine 2 - Aqueous iodin	e vs iodine in alcohol			
Study	Treatment	Control	RR (fixed)	Weight	RR (fixed)
or sub-category	n/N	n/N	95% CI	%	95% CI
Nothuis Subtotal (95% Cl)		23/118 118		100.00	1.21 [0.73, 2.00]
Kothuis	24/102	23/118		100.00	1.21 [0.73, 2.00]
	Treatment), 23 (Control)		10 10 10 10 10 10 10 10 10 10 10 10 10 1		
	neity: not applicable				
· · · · · · · · · · · · · · · · · · ·	fect: Z = 0.73 (P = 0.47)				

Favours treatment Favours contro

Alcohol vs iodine in alcohol

Two studies ⁶⁹ (preliminary and definitive) made four comparisons of alcohol vs 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 vs 2% iodine in 50% alcohol, 70% alcohol vs 2% iodine in 70% alcohol, 70% alcohol vs 2% iodine in 90% alcohol and no significant differences in SSI incidence were reported (RR 1.96 [0.10 to 38.71], RR 1.41 [0.07 to 27.63] and RR 0.58 [0.06 to 5.88] respectively).

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

Study	Treatment	Control		RR (fixed)	Weight	RR (fixed)
or sub-category	n/N	n/N		95% CI	×	95% CI
01 1 min scrub with 70% alcoho	I vs 1 min scrub with 2% io	line in 50% alcohol				
Alexander prelim	2/45	0/17	•		→ 100.00	1.96 [0.10, 38.79]
Subtotal (95% Cl)	45	17			100.00	1.96 [0.10, 38.79]
Fotal events: 2 (Treatment), 0 (C	ontrol)			23-29-332		
Fest for heterogeneity: not appli	cable					
Fest for overall effect: Z = 0.44	(P = 0.66)					
02 1 min scrub with 70% alcoho	l vs 1 min scrub with 2% io	line in 70% alcohol				
Alexander prelim	2/45	0/12	+		→ 100.00	1.41 [0.07, 27.63]
Subtotal (95% Cl)	45	12		د کرک کے د	100.00	1.41 [0.07, 27.63]
Fotal events: 2 (Treatment), 0 (C	Control)					
Fest for heterogeneity: not appli	cable					
fest for overall effect: Z = 0.23	(P = 0.82)					
03 1 min scrub with 70% alcoho	l vs 1 min scrub with 2% io	line in 90% alcohol				
Alexander definitive	3/147	5/164			75.28	0.67 [0.16, 2.75]
Alexander prelim	2/45	1/13	+	-	24.72	0.58 [0.06, 5.88]
Subtotal (95% Cl)	192	177			100.00	0.65 [0.19, 2.17]
fotal events: 5 (Treatment), 6 (C	Control)					
Test for heterogeneity: Chi ² = 0.1	01, df = 1 (P = 0.92), l ² = 0%					
Fest for overall effect: Z = 0.71	(P = 0.48)					

Iodophor film vs Iodine/Iodophor scrub and paint

Two RCTs identified from the Cochrane review ⁷⁷ examined the effects of an iodophor-in-alcohol, film forming, water insoluble antiseptic compared to an aqueous iodophor scrub and paint. (EL 1+)

Heterogeneity prevented pooling of results ($I^2 = 71.2\%$) and no 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).

Review: Comparison: Outcome:	antiseptics 02 Antiseptic 1 vs antiseptic 2 05 Iodine 1 vs Iodine 2 - Iodine film vs iod	ine scrub and paint			
Study or sub-categor	Treatment v n/N	Control n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
01 One-step iod	lophor/alcohol water insoluble film vs Povid	lone-iodine five minute s	crub then paint		
Roberts	10/104	9/96		56.19	1.03 [0.44, 2.42]
Segal	1/49	7/45	+	43.81	0.13 [0.02, 1.03]
			0.1 0.2 0.5 1 2	5 10	
			Favours treatment Favours con	trol	

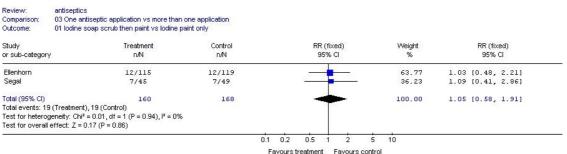
One antiseptic application vs more than one application

Two studies compared single and multiple applications of povidone iodine.

One trial 78 compared a single application of PI paint versus a 5 minute scrub with PI followed by PI paint; both solutions were aqueous. (EL 1+)

One trial ⁷⁹ compared a single application of PI paint versus a 5 minute scrub with PI soap followed by aqueous PI paint, and was designed as an equivalence study. (EL 1+)

The meta-analysis 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].



Tavou's reament. Tavou's control

Is there a difference in preoperative skin antiseptics used for adults and neonates (especially premature)?

Overview of evidence

No papers solely examining the effects of preoperative skin antiseptic agents in neonates and children were found

Evidence statement

There is no evidence to determine differences in use or difference in the effects of preoperative skin antiseptics in neonates, infants and children, compared to adults.

Is the use of preoperative skin antiseptics clinically and cost-effective in reducing the rate of surgical site infection (bearing in mind patient subgroups based on age/surgical site)? Is there a difference in preoperative skin antiseptics used for adults and neonates (especially premature)?

Health economics overview of evidence

No evidence was found that met the inclusion criteria for the HE analysis.

Surgical site infection: full guideline DRAFT (April 2008)

Table 1 Costs of chlorhexidin	ne and PI (BNF September 20	J07)	
Solution	Quantity	Cost	
Chlorhexidine 0.05%	1000mL	£0.77	
Povidone-Iodine			
Antiseptic paint 10%	8mL	£0.93	
Alcoholic solution 10%	500mL	£1.83	
Antiseptic solution 10%	500mL	£1.68	
Skin cleanser solution 4%	250mL	£1.97	
Surgical Scrub 7.5%	500mL	£1.70	

Table 1Costs of chlorhexidine and PI (BNF September 2007)

Health economics evidence statement

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

Evidence statement

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 PI paint. (EL 1+)

There is insufficient evidence from one underpowered RCT to establish if 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 if 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 if 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 to 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 aqueous solution of povidone-iodine (EL 1+)

No evidence was found on the use of skin antiseptics in neonates.

GDG interpretation

Only one study addressed whether <u>any</u> 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.

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

Although there are concerns about toxicity from skin antiseptics in neonates, no evidence was found.

GDG Recommendations

In adults the skin at the surgical site should be prepared immediately prior to the skin incision using an antiseptic preparation (aqueous or alcohol based) - povidone iodine or chlorhexidine are most suitable.

In neonates local practices for the use of skin preparation should be followed.

Appropriate care should be taken to ensure drying and avoid pooling when alcohol based preparations are used if diathermy is to be undertaken.

6.7 Diathermy

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 which 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 if the use of diathermy to make an incision causes more SSIs.

Overview of evidence

Eight RCTs were identified.

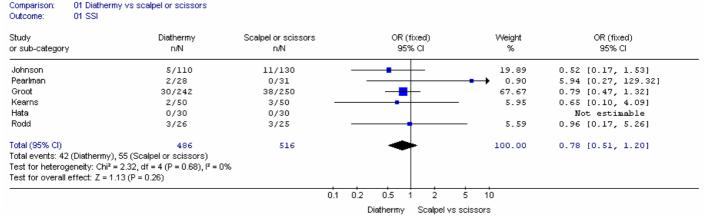
In total, eight trials ⁸⁰⁻⁸⁷ (n=1122 patients) were included with patients undergoing surgery for abdominal or thoracic operations, radial artery harvesting, cholecystectomy, mastectomy for breast cancer and gastrectomy for gastric cancer. No study specified that children were included.

Incisions were made with different types of cutting instruments and were grouped as scalpel, scissors, diathermy (cautery unit, electrocautery, electrosurgery, diathermy scissors, electrocautery scalpel, monopolar electrosurgery), laser (Carbon Dioxide and Nd:Yag) and ultrasonic scalpel (ultracision harmonic shears)

Diathermy vs scalpel or scissors

Six RCTs ⁸⁰⁻⁸⁵ (1002 participants) compared the effect on SSI rate of incision made with diathermy or scalpel/scissors. (EL 1+)

Meta analysis showed that there was no statistically significant difference between the use of diathermy compared to scalpel or scissors for incisions (fixed OR = 0.78 [95%CI 0.51 to 1.20]).



Diathermy vs Laser

methods of incision

Review:

Two trials (n=78 participants) examined the comparative effect on SSI incidence following incision made with diathermy or laser^{84;86}. Both trials involved patients undergoing cholecystectomy, however, 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 significance (fixed OR = 0.10 [95% CI 0.01 to 1.10])⁸⁶. (EL 1+) The other trial showed no difference in SSIs with the use of diathermy compared to laser (fixed OR = 2.15 [95% CI 0.10 to 25.9])⁸⁴. (EL 1+)

Surgical site infection: full guideline DRAFT (April 2008)

page 57 of 165

Heterogeneity prevented pooling of results (I2 = 67.4%).

Review: Comparison: Outcome:	methods of incision 02 Diathermy vs Laser 01 SSI				
Study	Diathermy	Laser	OR (fixed)	Weight	OR (fixed)
or sub-category	n/N	n/N	95% Cl	%	95% Cl
Pearlman	2/28	1/29		→ 16.08	2.15 [0.18, 25.19]
Steger	1/11	5/10		83.92	0.10 [0.01, 1.10]
			0.1 0.2 0.5 1 2 Diathermy Laser	5 10	

Diathermy vs ultrasonic scalpel

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

One study reported no SSIs in either treatment group ⁸¹ (EL 1+) and the other showed no significant difference in SSI incidence between groups (fixed OR = $3.35 [95\% \text{ CI } 0.32 \text{ to } 35.36])^{87}$. (EL 1+)

Review:	methods of incision
Comparison:	 03 Diathermy vs uttrasonic scalpe
Outcome:	01 SSI

Study or sub-category	Diathermy n/N	Ultrasonic scalpel n/N				R (fi: 95%	(ed) Cl			Weight %	OR (fixed) 95% Cl
Tsimonyiannis Hata	3/20 0/30	1/20 0/30						-		→ 100.00	3.35 [0.32, 35.36] Not estimable
		0).1	0.2	0.5	1		2	5	10	
				0	liatherm	Y	Ultra	sonic :	scalp	el	

Evidence statements

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

There is insufficient evidence to suggest whether the use of diathermy compared to 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

GDG Recommendation

Diathermy as a method of surgical incision should not be used as a method to reduce SSI.

If diathermy is to be used, care should be taken when using inflammable skin preparations.

If an alcoholic skin preparation has been used then the operative area should be dried, and any pooled skin preparation removed, before the use of diathermy.

6.8 Maintaining patient homeostasis

During surgery, particularly with a general anaesthetic, patient homeostasis has to be maintained by the operative team. All tissues heal most effectively in optimal conditions of oxygenation, perfusion and normothermia. Does maintenance of oxygenation and perfusion, normothermia and blood glucose influence the rate of SSI?

6.8.1 Oxygenation

Is patient perioxygenation 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 which 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 surgical site infection.

Overview of the evidence

Five RCTs were identified.

Perioperative high oxygen concentration vs Perioperative low oxygen concentration

Four RCTs (n=989 adults)^{88 89 90 91} compared the effect of the administration of high concentrations of oxygen during surgery and following surgery on the incidence of surgical site infection. (EL 1+) The participants were adults booked for elective surgery. Incidence of surgical site infection was the primary outcome measured in all studies, although definitions varied among studies.

Two of the studies ⁸⁸ (n=500 adults) ⁸⁹ (n=291 adults) found a statistical significance favouring the administration of high concentrations of O2 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]). Another of the studies ⁹⁰ (n=160 adults) found a statistical significance favouring the low oxygen concentrations group (OR=2.63 [95%CI 1.11to 6.20]), Figure 2. The smaller study ⁹¹ (n=38 adults) found no statistically significant difference between the two groups (OR=0.63 [95%CI 0.09 to 4.26]).

Analysis of these four RCTs presented significant heterogeneity ($I^2=74.5\%$) attributable to one of the studies 90 . Therefore the data from the other three RCTs ^{88 89 91} were pooled in a meta-analysis (I2=0%) that showed a statistically significant difference favouring the administration of high concentrations of oxygen (OR=0.50 [95%CI 0.32 to 77]), Figure 1. OXYGENATION

Study or sub-category	high [O2] n/N	Standard [O2] n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Greif	13/250	28/250	— — —	44.58	0.43 [0.22, 0.86]
Belda	22/148	35/143		50.91	0.54 [0.30, 0.97]
Mayzler	2/19	3/19	•	4.51	0.63 [0.09, 4.26]
Total (95% CI) Total events: 37 (high [O2]), 66 Test for heterogeneity: Chi² = (Test for overall effect: Z = 3.1)	0.28, df = 2 (P = 0.87), I ² = 0	412	•	100.00	0.50 [0.32, 0.77]

Figure 1

Review

	ri-operative high oxygen concentra rgical site infection	ation vs. Peri-operative low (ygen concentration		
Study or sub-category	high [O2] n/N	Standard [O2] n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Pryor	20/80	9/80		100.00	2.63 [1.11, 6.20]
Total (95% Cl) Total events: 20 (high [Test for heterogeneity: Test for overall effect:	not applicable	80	-	100.00	2.63 [1.11, 6.20]

Figure 2

Postoperative supplemental oxygenation vs Standard treatment

A single RCT ⁹² (n=24 participaths) compared the effects of postoperative oxygenation administered in the recovery room versus the standard postoperative treatment, where no oxygenation was provided, on the Surgical site infection: full guideline DRAFT (April 2008) page 59 of 165

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 significant difference was found between the two groups.

Evidence statement

There is evidence to suggest that higher inspired oxygen concentrations in the perioperative period reduces surgical site infection rates, when compared to 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 FiO_2 of 80% oxygen can be achieved in the recovery room. It is normal practice to ensure that oxygenation in the recovery room is optimal (sufficient to provide a greater than 95% haemoglobin saturation) and that giving an FiO_2 of more than 40% may not offer any further benefit. Patients with COPD might well be put at a disadvantage by a FiO2 of over 40%.

The physiological mechanisms underlying the use of a FiO_2 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 (see below) 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.

GDG Recommendation

Oxygen should be administered to ensure a haemoglobin saturation of greater than 95% during major surgery and in the recovery period.

Research Recommendation

Further research is needed both to investigate the value of supplemented oxygenation in the recovery room and to understand the mechanisms associated with the prevention of SSI.

6.8.2 Perfusion

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

Introduction

Patients should be presented in the anaesthetic room, prior to general anaesthetic in particular, with optimal hydration. The purpose of the review was to determine the clinical effectiveness of perioperative perfusion and hydration for the prevention of surgical site infection.

Overview of the evidence

A single RCT was identified.

Supplemental perioperative fluid management vs Standard perioperative fluid management

The RCT ⁹³ (n=256 participants) looked at the effects of perioperative administration of supplemental IV fluids on surgical site infection rates and wound healing. (EL 1+) The study included adults undergoing open elective colon resection. Incidence of surgical site infection was the primary outcome measure (other outcomes were the ASEPSIS score for wound healing assessment, ICU admissions and length of hospitalization). No statistically significant difference was found among the two groups (OR=0.73 [95%CI 0.32 to 1.68]), Figure 1.

Comparison:	arison: 01 Supplemental perioperative fluid management vs. Standard perioperative fluid management								
Study or sub-category	supplemental fluids n/N	standard fluids n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl				
Kabon	11/129	14/124		100.00	0.73 [0.32, 1.68]				
Test for heteroge	129 supplemental fluids), 14 (standard fluids) neity: not applicable ffect: Z = 0.73 (P = 0.46)	124	-	100.00	0.73 [0.32, 1.68]				
			0.1 0.2 0.5 1 2 Favours treatment Favours cr	5 10					

Figure 1

Evidence statement

There is insufficient evidence to suggest that supplemental perioperative IV fluids reduce surgical site infection rates compared with standard perioperative fluid management. EL 1+

GDG interpretation

The GDG recognise 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.

GDG Recommendation

It is essential that a patient's physiological condition is maintained during surgery and this includes adequate perfusion.

6.8.3 **Perioperative warming**

What is the clinical effectiveness of perioperative warming to reduce surgical site infection?

Introduction

There is convincing physiological evidence that avoiding hypothermia, particularly after general anaesthesia, leads to avoidance of many postoperative complications, including infectious complications and SSI. The purpose of the review was to determine the clinical effectiveness for perioperative warming therapy for the prevention of surgical site infection.

Overview of the evidence

Two RCTs were identified.

Intraoperative normothermia vs standard intraoperative care

An RCT ⁹⁴ (n=200 participants) compared the effect of the intraoperative use of systemic warming therapy with the standard intraoperative care (that did not include warming therapy) for the prevention of SSI. (EL 1+) Patients were undergoing elective colorectal surgery for cancer and IBD. Incidence of surgical site infection was the primary outcome. The trial found a statistically significant reduction of SSI in the group that received the warming therapy (RR=0.31 [95%CI 0.13 to 0.74]), Figure 1.

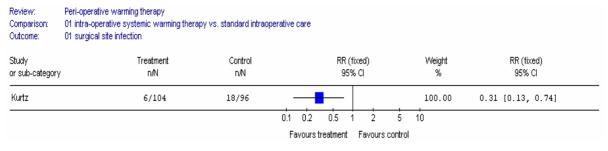


Figure 1

Preoperative warming therapy vs standard preoperative care

An RCT ⁹⁵ (n=421 participants) examined the effect of preoperative local and systemic warming therapy against the standard preoperative care (that did not include warming therapy) in the incidence of SSI. Surgery performed included hernia repair, varicose vein and breast cancer. The main outcome was surgical site infection. The trial found a statistically significant reduction of SSI in the group that received the local warming intervention when compared to the standard care (RR=0.24 [95%CI 0.09 to 0.66]), Figure 2, as well as in the group that received the systemic warming therapy when compared to the standard care (RR=0.39 [95%CI 0.16 to 0.91]), Figure 3.

Review: Comparison: Outcome:	Peri-operative warming therapy 02 pre-operative local warming therapy vs 01 surgical site infection	standard pre-operati	ve care		
Study or sub-category	rreatment v n/N	Control n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Melling	5/138	19/139		100.00	0.27 [0.10, 0.69]
			Favours treatment Favours contr	ol	
	Figure 2				
Review: Comparison: Outcome:	Peri-operative warning therapy 03 pre-operative local warning therapy vs 01 surgical site infection	standard pre-operati	ve care		
Study or sub-category	Treatment	Control n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Melling	8/139	19/139		100.00	0.42 [0.19, 0.93]
			0.1 0.2 0.5 1 2 5 Favours treatment Favours contr	10 ol	

Figure 3

No statistical significance was found in the incidence of SSI when comparing the local warming intervention against the systemic warming intervention (RR=0.62 [95%CI 0.20 to 1.93]), Figure 4.

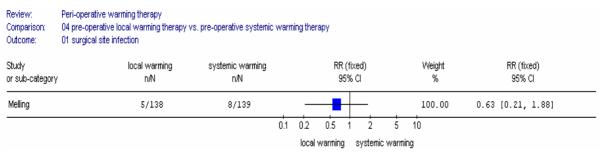


Figure 4

Is perioperative patient warming cost effective? If so, then which is the most effective intra / immediate postoperative method?

Health economics overview of evidence

Four studies were included in the cost-effectiveness review 96 97 98 99.

Forced air warming vs routine thermal care

Three economic evaluations ^{96 97 98} compared active warming using forced air to conventional treatment of hypothermia. It was found, given the clinical evidence, that pre- and intraoperative warming prevented SSIs when compared with routine thermal care, forced air warming is likely to be highly cost-effective.

Forced air warming vs radiant warming

One economic evaluation ⁹⁹ compared two different practices of maintaining patients' core body temperatures; forced air warming and radiant warming. The authors found, that although the costs of radiant warming were higher at first, after around 170 operations the two warming devices were found to have the same costs, with radiant warming requiring no further ongoing costs and consuming around half the energy of the forced air warming devices.

Health economics evidence statement

There is evidence that preoperative and intraoperative warming using forced air warming generates overall cost savings when compared to routine thermal care (e.g. use of warmed mattresses and blankets), due to reductions in the cost of the operation and the recovery time from the anaesthetic. Therefore, given the clinical evidence that these techniques prevent SSIs compared with routine care, preoperative and intraoperative warming using forced air warming is likely to be highly cost effective (*see Appendix G*).

Evidence statement

There is evidence to suggest that local or systemic preoperative warming therapy reduces SSI incidence compared with no preoperative warming therapy. [EL 1+]

There is evidence to show that intraoperative warming therapy to maintain patient's normothermia during colorectal surgery reduces surgical site infection rates compared with standard operative care.[EL 1+] There is insufficient evidence to show a difference in SSI rates between preoperative local warming and preoperative systemic warming therapy. [EL 1+]

GDG interpretation

There is evidence that perioperative patient warming to maintain normothermia reduces the risk of SSI. Nevertheless, the GDG is aware that certain types of surgery such as cardiac and neuro-surgery require hypothermic techniques. The implications of changes in body temperature on the incidence of SSI are unknown in these groups of patients. Although the evidence relates to specific types of general surgery, the GDG believe that the findings are generalisable.

GDG Recommendation

Perioperative patient warming should be undertaken to reduce SSI unless contraindicated in specific circumstances.

6.8.4 Perioperative blood glucose control

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 which 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 surgical site infection.

Overview of the evidence

Two RCTs were identified ¹⁰⁰ ¹⁰¹.

Postoperative intensive blood glucose control vs. Postoperative standard blood glucose control

An RCT ¹⁰⁰ (n=61 participants) included adult patients of a general surgical ICU requiring treatment for hyperglycaemia. The trial examined the effects of postoperative tight glycaemic control (BG<120mg/dL) on surgical site infection rates. Incidence of surgical site infection was reported as one of the outcomes (other outcomes were serum glucose values and other types of nosocomial infections). The study reported a statistically significant reduction of SSI in the group that received the more rigorous blood glucose control (approx. from histogram provided by the authors, OR=0.15 [95%CI 0.03 to 0.77]). EL 1-

Another RCT ¹⁰¹ (n=78 participants) compared the effect of intensive blood glucose control (glycaemia between 80 and 120 mg/dL) and insulin therapy against conventional intensive blood glucose control (glycaemia maintained under 220mg/dL) and insulin therapy. 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 out of 40 SSI in the Intensive BGC group against 2 out of 38 SSI in the standard BGC group, OR 0.46 [95%CI 0.04, 5.31), Figure 1. EL 1-

Review: Comparison: Outcome:	Glycaemic Control 01 tight blood glucose control vs. standard 01 SSI	d blood glucose control				
Study or sub-category	tight BG control n/N	Standard BGC n/N	,	iixed) 6 Cl	Weight %	OR (fixed) 95% Cl
Bilotta	1/40	2/38	↓		100.00	0.46 [0.04, 5.31]
			0.1 0.2 0.5 Favours treatment	1 2 5 Favours cont		

Figure 1

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 is well recognised 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 post op range.

There are two underpowered RCTs only one of which shows a significant risk for raised blood glucose and SSI.

GDG Recommendations

Treatment to reduce raised blood glucose postoperatively, with the aim of reducing SSI should not be undertaken in patients who do not have diabetes, to prevent SSIs.

Overall, it is essential that optimal physiological homeostasis is maintained during surgery and this includes adequate perfusion, oxygenation and temperature control.

Research Recommendation

Research should be undertaken into the possible benefits of improved glucose control postoperatively, with adequately powered RCTs in a broad range of surgical procedures.

6.9 Intracavity lavage and wound irrigation

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

Introduction

Cavity and wound irrigation during a surgical procedure have been advocated to reduce the risk of SSI. The purpose of this review was to determine their effectiveness.

Overview of evidence

Twenty RCTs were identified.

Wound Irrigation

Five studies (n=4021 participants) were included in the review of wound irrigation ¹⁰² ¹⁰³ ¹⁰⁴ ¹⁰⁵ ¹⁰⁶. Patients were undergoing surgery for acute appendicitis, general abdominal surgery and general surgery. Two studies specified including included children and adults ¹⁰³ ¹⁰⁴.

Saline vs Antibiotic wound irrigation

Three RCTs (n=2423 participants) were included in this comparison. (all EL 1+) Heterogeneity prevented meta analysis (I2 = 66.6%). None of the studies found a significant difference in wound infection rates following irrigation with saline or with antibiotic.

One trial 102 (n=249 participants) reported no 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 ¹⁰⁴ ¹⁰⁵ also reported no significant differences in SSI incidence between the saline groups and groups receiving tinadazole (OR 0.38 [95% CI 0.13 to 1.08]) and DAB solution (OR 0.91 [95%CI 0.57 to 1.45]) respectively.

Review: Comparison: Outcome:	Lavage and wound irrigation 01 Wound irrigation 01 Saline vs Antibiotic - Wound infection				
Study or sub-category	Saline n/N	Antibiotic n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Farnell Eklund Al-Shehri	36/836 5/253 7/132	39/828 13/257 1/117		73.32 24.72	0.91 [0.57, 1.45] 0.38 [0.13, 1.08] 6.50 [0.79, 53.61]
			0.1 0.2 0.5 1 2 5		

Saline vs Antiseptic

One study ¹⁰⁶ (500 participants) examined the effect of saline compared to povidone-iodine irrigation on the incidence of wound infection. Participants were undergoing general surgery. There were 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]). (EL = 1+)

Comparison: 01 V	age and wound irrigation Vound irrigation Saline vs Antiseptic - wound infection						
Study or sub-category	Saline n/N	Antiseptic n/N		OR (fix 95%		Weight %	OR (fixed) 95% Cl
Sindelar	39/258	7/242				→ 100.00	5.98 [2.62, 13.65]
Total (95% CI) Total events: 39 (Salin Test for heterogeneity Test for overall effect		242				100.00	5.98 [2.62, 13.65]
			0.1 0		2 5 Eavours antise	10	

Irrigation (with antibiotic or saline) vs no irrigation

One study ¹⁰⁴ (n=1979 participants) with three relevant treatment arms permitted comparison of the relative effect of irrigation (with antibiotic or saline via subcutaneous catheter, which comprised two of the three

Surgical site infection: full guideline DRAFT (April 2008)

study arms) compared to no irrigation (subcutaneous catheter only). No significant difference in wound infection rate was found (OR 0.81 [95% CI 0.55 to 1.18]). (EL 1+)

Comparison: 01 Wound	d wound irrigation rrigation h (antibiotic or saline) vs No Irr	igation			
Study or sub-category	Irrigation n/N	No irrigation n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Farnell	75/1664	45/815		100.00	0.81 [0.55, 1.18]
Total (95% Cl) Total events: 75 (Irrigation), 4 Test for heterogeneity: not a Test for overall effect: Z = 1	pplicable	815	•	100.00	0.81 (0.55, 1.18)
			0.1 0.2 0.5 1 2 Favours irrigation Favoursno	5 10	

Wound syringe pressure irrigation with saline vs no irrigation

One study 103 (n=283 participants) 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. 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]). (EL 1+)

Comparison: 01 Woun	and wound irrigation id irrigation id syringe pressure irrigation vs no) irrigation			
Study or sub-category	Pressure irrigation n/N	No irrigation n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Cervantes-Sanchez	11/127	39/156	—	100.00	0.28 [0.14, 0.58]
Total (95% Cl) Total events: 11 (Pressure Test for heterogeneity: no Test for overall effect: Z =		156		100.00	0.28 [0.14, 0.58]
			0.1 0.2 0.5 1 2	5 10	
			Favours pressure irr Favours n	n irrig	

Intracavity lavage

Fourteen studies (n=2065 participants) were included in this review of intracavity lavage ¹⁰⁷⁻¹²⁰. Patients were undergoing surgery for perforated appendicitis and/or peritonitis, general surgery, colorectal surgery, biliary operation, rectal resection, protectomy, caesarean, abdominal surgery, intestinal surgery, surgery with a likelihood of bacterial contamination of the peritoneum. Two studies specified including children and adults ^{108 114} and three studies only included children ^{112 116 120}.

Intraoperative ^{107 110 112 115 116 117 118 119 120} and post operative ^{108 111} lavage was performed in eleven studies. One study ¹¹⁴ did not specify the timing of lavage.

Two studies were of both wound irrigation and cavity lavage (antibiotic vs saline ¹¹³ and compared to IV antibiotics alone with antibiotics given IV plus via lavage ¹⁰⁹).

Antibiotic lavage vs saline lavage

Four studies ¹¹⁰ ¹¹⁴ ¹¹⁶ ¹¹⁷ (360 participants) were included in a meta-analysis of the comparison antibiotic lavage against saline lavage. (all EL 1+)

Antibiotics used were cefotetan, cephalothin, chloramphenicol and kanamycin respectively. Individual study results and the pooled estimate (OR 0,90 [95% CI 0.54 to 1.49]) showed no difference in SSI incidence between antibiotic lavage and saline lavage usage.

Review: Comparison: Outcome:	Lavage and wound irrigation 02 Intracavity lavage 01 Antibiotic lavage vs saline lavage				
Study	Antibiotic	Saline	OR (fixed)	Weight	OR (fixed)
or sub-category	/ n/N	n/N	95% CI	%	95% CI
Rambo	11/44	13/50		28.84	0.95 [0.37, 2.40]
Sherman	5/36	6/43		14.88	0.99 [0.28, 3.57]
Schein	5/29	5/29		13.07	1.00 [0.26, 3.91]
Grieg	15/64	18/65		43.21	0.80 [0.36, 1.77]
Total (95% CI)	173	187		100.00	0.90 [0.54, 1.49]
Total events: 36	6 (Antibiotic), 42 (Saline)		-		
Test for heterog	geneity: Chi ² = 0.14, df = 3 (P = 0.99), l ² = 0%				
Test for overall	effect: Z = 0.42 (P = 0.68)				
			0.1 0.2 0.5 1 2 5	; 10	
			Favours antibiotic - Favours salin		

One study ¹¹⁸ 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 in patients undergoing intestinal surgery.

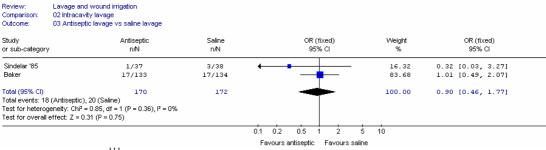
A significant difference in wound infection incidence was found that favoured tetracycline lavage (OR 0.29 [95%CI 0.13 to 0.65]). (EL 1+)

Review: Comparison: Outcome:	Lavage and wound irrigation 02 Intracavity lavage 02 Antibiotic lavage vs Saline lavage - wo	unds			
Study or sub-category	Tetracycline n/N	Saline n/N	OR (fixed) 95% Cl	VVeight %	OR (fixed) 95% Cl
Silverman	10/95	24/83	_	100.00	0.29 [0.13, 0.65]
Test for heterog	95 (Tetracycline), 24 (Saline) eneity: not applicable effect: Z = 3.01 (P = 0.003)	83	-	100.00	0.29 [0.13, 0.65]
			0.1 0.2 0.5 1 2 5 Favours tetracycline Favours salin		

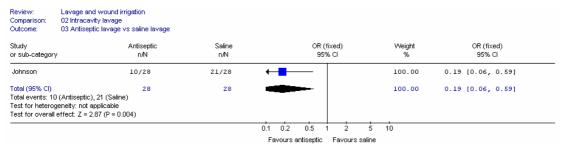
Antiseptic lavage vs saline lavage

Two RCTs of intraoperative lavage ^{107;119} and one of postoperative lavage ¹¹¹ were included. (all EL 1+). The antiseptics used in the intraoperative studies were taurolidine and 10% povidone iodine solution respectively. The postoperative lavage study also used povidone iodine solution.

A meta-analysis of the intraoperative lavage papers showed no difference in SSI incidence when either antiseptic or saline was used for intracavity lavage (OR 0.90 [95% CI 0.46 to 1.77]).

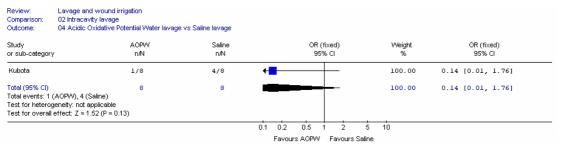


One trial ¹¹¹ which included 56 patients undergoing rectal excision for cancer, showed that postoperative lavage of the perineal space with povidone iodine resulted in statistically significantly fewer wound infections than when saline was used (OR 0.19 [95% CI 0.06 to 0.59]). (EL 1+)



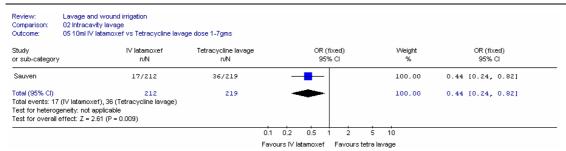
AOPW lavage vs saline lavage

One underpowered study of children with appendicitis and peritonitis compared the effects of Acidic Oxidative Potential Water lavage with saline lavage ¹¹². (EL 1-) No significant difference in wound infection rates was identified (OR 0.14 [95% CI 0.01 to 1.76]).



IV antibiotic 1 vs Lavage Antibiotic 2

One study ¹¹⁵ (n=431 participants) undergoing abdominal surgery compared the effects of 1g 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 to 7 gms.



Drain vs Lavage

One study ¹²⁰ of 53 children with perforated appendix found no statistically significant difference in SSI incidence between the insertion of peritoneal drains alone compared to lavage with saline (OR 4.50 [95%CI 0.82 to 24.83]). (EL 1+)

Review: Comparison: Outcome:	Lavage and wound irriga 02 Intracavity lavage 06 Drain vs aggressive s										
Study or sub-category		Drain n/N	Saline lavage n/N				R (fixe 15% C			Weight %	OR (fixed) 95% Cl
Toki		6/24	2/29				_			→ 100.00	4.50 [0.82, 24.83]
Test for heterog	Drain), 2 (Saline lavage) jeneity: not applicable effect: Z = 1.73 (P = 0.08)	24	29							100.00	4.50 [0.82, 24.83]
				0.1	0.2	0.5	1	2	5	10	
					Favo	urs drair	n F	avours	saline	lavag	

Saline lavage vs no lavage

Another small study ¹⁰⁸ of 83 patients with perforated appendicitis and peritonitis found significantly fewer SSIs in the groups randomised to no use of closed saline postoperative peritoneal lavage (CPPL) against closed CPPL (OR 6.30 [95%CI 1.27 to 31.27]). (EL 1-)

Review: Comparison: Outcome:	Lavage and wound irrigation 02 Intracavity lavage 07 Closed saline postoperative peri	toneal lavage (CPPL) vs no	PPL		
Study or sub-category	Saline CPPL n/N	No CPPL n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Buanes	9/39	2/44		→ 100.00	6.30 [1.27, 31.27]
Test for heterog	39 Saline CPPL), 2 (No CPPL) eneity: not applicable effect: Z = 2.25 (P = 0.02)	44	0.1 0.2 0.5 1 2 Favours saline CPPL Favou	5 10 urs no CPPL	6.30 [1.27, 31.27]

IV antibiotic vs Lavage and Irrigation antibiotic vs Lavage and Irrigation and IV antibiotic One study with three treatment arms ¹⁰⁹ found no significant differences in wound infection incidence amongst any comparisons of IV antibiotic vs Lavage and Irrigation antibiotic vs Lavage and Irrigation and IV antibiotic. (EL 1+) The antibiotic used was cefamandole.

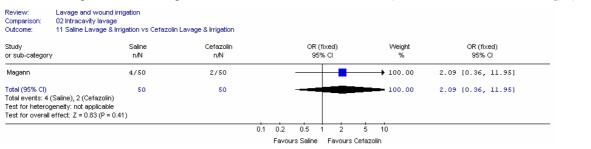
IV cefamandole vs Lavage and Irrigation cefamandole (OR 0.23 [95%CI 0.01 to 5.95]).

IV cefamandole vs Lavage and Irrigation and IV cefamandole (OR 0.23 [95%CI 0.01 to 5.95]).

Lavage and Irrigation and IV cefamandole vs Lavage and Irrigation cefamandole (OR 1.00 [95% CI 0.06 to 11.95]).

Lavage and Irrigation Saline vs Lavage and Irrigation AB

One RCT of women undergoing caesarean section found no difference in wound infection rate following lavage and wound irrigation with either saline or cefazolin¹¹³ (OR 2.09 95%CI 0.36 to 11.95]). (EL 1+)



Surgical site infection: full guideline DRAFT (April 2008)

Evidence statements

Wound irrigation

There is some evidence of no difference in SSI incidence after intraoperative subcutaneous wound irrigation using antibiotics or saline.

There is evidence from one study of decreased SSI incidence following intraoperative subcutaneous wound irrigation using povidone iodine compared to saline.

There is evidence from one study of no difference in SSI incidence following use of subcutaneous wound irrigation compared to the use of a drain but with no irrigation.

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.

Intracavity lavage

There is evidence of no difference in SSI incidence after antibiotic compared with saline lavage.

There is evidence from one study that the incidence of SSI is decreased when tetracycline lavage is compared with saline lavage.

There is evidence of no difference in SSIs incidence when either antiseptic or saline is used for intraoperative intracavity lavage.

There is evidence from one small study of fewer wound infections when povidone iodine was used for postoperative lavage of the perineal space compared with saline.

There is some evidence from one small study that there is no significant difference in wound infection rates between usage of AOPW compared with saline for lavage.

There is some evidence of no difference in SSI incidence following the use of drains alone compared with saline lavage.

There is some evidence from one small study that there is a significant increase in wound infection rates using saline CPPL compared with no CPPL.

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.

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.

GDG interpretation

There is some evidence from research that is up to 20 to 30 years old that intraoperative subcutaneous wound irrigation with povidine iodine or 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 possibly obsolete.

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

There is no evidence that intra-cavity 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 povidine iodine reduces SSI.

Although wound irrigation with povidone iodine may reduce SSI it has probably been increasingly considered that it is unnecessary with the advent of rational effective antibiotic prophylaxis.

Similarly routine tetracycline cavity lavage to reduce the risk of SSI should not be used.

Current practice has improved to make these approaches of wound and cavity lavage possibly obsolete.

GDG Recommendations

Wound irrigation during surgery should not be undertaken to reduce SSI.

Surgical site infection: full guideline DRAFT (April 2008)

Routine intracavity lavage during surgery to prevent SSIs should not be used.

Research Recommendation

Irrigation with modern antiseptics, and saline under pressure with or without added antiseptics, should be repeated in a broader range of surgery, particularly as there is an increase in resistance that requires less reliance on antibiotics.

6.10 Antiseptics and antimicrobials prior to wound closure

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 practiced as a method of intraoperative decontamination after 'contaminated' and 'dirty' surgical procedures, or operations which involve the insertion of a prosthetic 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 redisinfection before wound closure vs no skin iodine redisinfection

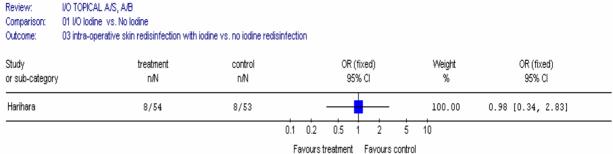
One multicentre RCT ¹²¹ (n=1340 participants) looked at the effect of skin iodine redisinfection, with and without the use of incisional drapes, just before wound closure in the prevention of surgical site infection. (EL 1+) Participants were women undergoing caesarean sections. The trial found a lower rate of SSI in the groups receiving the iodine application but there was no statistical significance in the results OR 0.69 (95%CI [0.45 to 1.07]) and OR 0.77 (95%CI [0.47 to 1.25]) Figure 1.

Comparison: Outcome:	01 I/O lodine vs. No I 03 intra-operative ski	odine	n iodine vs. no iodine redisinfi	ection		
Study or sub-category		treatment n/N	control n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Cordtz (with dra	pes)	41/325	58/337		57.25	0.69 [0.45, 1.07]
Cordtz (no drap	es)	31/324	43/354		42.75	0.77 [0.47, 1.25]

Favours treatment Favours control

Figure 1

One RCT ¹²² (n=107 participants) investigated the effect of povidone-iodine applied to the surgical site before closure in the incidence of surgical site infection. (EL 1-) Patients were undergoing gastric and colorectal surgery. The main outcome reported was surgical site infection. The study found no statistically significance difference between the groups OR 0.98[95%CI 0.34 to 12.83]; Figure 2.



Surgical site infection: full guideline DRAFT (April 2008)

page 70 of 165

Figure 2

Povidone iodine spray application before wound closure vs no iodine spray application

Three RCTs (n=855 participants) examined the effect of povidone iodine spray – a PI dry powder ¹²³ ¹²⁴ and a PI solution ¹²⁵ - 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 (I2=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 3.

Comparison:	01 intra-operative topical iodine application vs. no lodine application
Outcome:	01 surgical site infection

Study or sub-category	Treatment n/N	Control n/N	OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
01 surgical site infection					
Gray	7/71	20/82	_	26.19	0.34 [0.13, 0.86]
Walsh	28/308	40/319		55.91	0.70 [0.42, 1.16]
Sherlock	6/39	13/36	_	17.90	0.32 [0.11, 0.97]
Subtotal (95% CI)	418	437	◆	100.00	0.54 [0.36, 0.81]
Total events: 41 (Treatment),	73 (Control)		-		
Test for heterogeneity: Chi2 =	2.78, df = 2 (P = 0.25), I ² = 28.0%				
Test for overall effect: Z = 2.9	17 (P = 0.003)				
Total (95% CI)	418	437	•	100.00	0.54 [0.36, 0.81]
Total events: 41 (Treatment),	73 (Control)		-		•
Test for heterogeneity: Chi2 =	2.78, df = 2 (P = 0.25), I ² = 28.0%				
Test for overall effect: Z = 2.9	17 (P = 0.003)				
			0.1 0.2 0.5 1 2	5 10	
			Favours treatment Favours co	ntrol	

Figure 3

Topical iodine application in dirty surgery vs 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 ¹²⁴ and dirty abdominal surgery ¹²⁵. Pooling the data together was inappropriate due to high heterogeneity (I²=65%). Both trials found that the application of iodine to the wound favoured the prevention of SSI. This finding was statistically significant for the bigger RCT ¹²⁴, OR 0.17 [95%CI 0.06 to 0.50]), Figure 4.

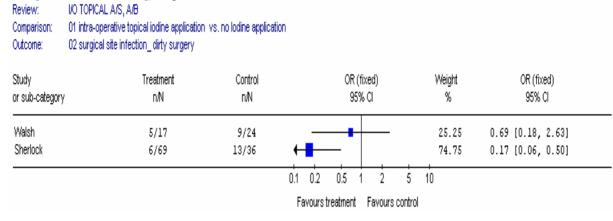


Figure 4

Intraoperative topical antibiotics before wound closure

Three RCTs were identified.

Intraoperative gentamicin implant before wound closure vs no topical gentamicin implant

Two RCTs ¹²⁶ ¹²⁷ (n=2492 participants) investigated whether an implant of gentamicin-collagen applied underneath the sternum before wound closure 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. A

Surgical site infection: full guideline DRAFT (April 2008)

statistically significant difference was found favouring the group treated with the gentamicin implant when two studies were combined in a meta-analysis (OR 0.49 [95%CI 0.34 to 0.68]), (I2=0%); Figure 5.

2 intra-operative topical antibiotics					
Treatment n/N	Control n/N			Weight %	OR (fixed) 95% Cl
11/272	16/270	-+	_	15.51	0.67 [0.30, 1.47]
42/983	87/967	+		84.49	0.45 [0.31, 0.66]
1255	1237	•		100.00	0.49 [0.34, 0.68]
reatment), 103 (Control)		•			
eity: Chi ² = 0.78, df = 1 (P = 0.38), l ² = 0%					
ect: Z = 4.16 (P < 0.0001)					
		0.1 0.2 0.5	2	5 10	
		Four we treatment	Fououro o	ostrol	
	n№ 11/272 42/983	2 intra-operative topical antibiotics 1 surgical site infection Treatment Control n/N n/N 11/272 16/270 42/983 87/967 1255 1237 reatment), 103 (Control) eity: Chi ² = 0.78, df = 1 (P = 0.38), l ² = 0%	2 intra-operative topical antibiotics 1 surgical site infection Treatment Control OR (1 n/N n/N 959 11/272 16/270 42/983 87/967 1255 1237 ◆ reatment), 103 (Control) etty: Chi ² = 0.78, df = 1 (P = 0.38), I ² = 0% ect: Z = 4.16 (P < 0.0001)	2 intra-operative topical antibiotics 1 surgical site infection Treatment Control OR (fixed) n/N n/N 95% Cl 11/272 16/270 42/983 87/967 1255 1237 ← 1255 1237 ← reatment), 103 (Control) etty: Chi ² = 0.78, df = 1 (P = 0.38), I ² = 0% ect: Z = 4.16 (P < 0.0001) 0.1 0.2 0.5 1 2	2 intra-operative topical antibiotics 1 surgical site infection Treatment Control OR (fixed) Weight n/N 95% Cl % 11/272 16/270 42/983 87/967 15. 51 84. 49 1255 1237 reatment), 103 (Control) etty: Chi ² = 0.78, df = 1 (P = 0.38), I ² = 0% ect: Z = 4.16 (P < 0.0001) 0.1 0.2 0.5 1 2 5 10

Figure 5

Intraoperative cefotaxime before wound closure in contaminated surgery vs no topical cefotaxime before wound closure

A single RCT ¹²⁸ (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 surgical site infection 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.

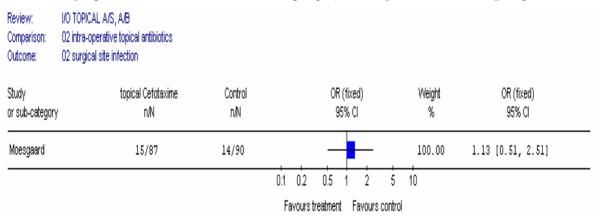


Figure 6

Evidence statements

There is limited evidence that topical povidone iodine spray onto the superficial wound layers prior to incision closure can reduce the incidence of SSI. EL 1+

There is no evidence that re-disinfection of the skin, adjacent to the wound, with iodine in alcoholic solution prior to incisional closure reduces 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 no evidence that the addition of topical cefotaxime to systemic antibiotic prophylaxis reduces the SSI rate 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 appendicitis in adults (both classified as contaminated surgery), prior to incisional closure, reduces the incidence of SSI. Although this interpretation is based on three papers which are underpowered, show some heterogeneity and do not reflect current clinical practice, the GDG consider this to be of clinical relevance based on the meta-analysis. However re-disinfection of the skin using alcoholic iodine solution adjacent to the wound has no effect.

As povidine 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.

The insertion of a collagen gentamicin 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.

The instillation of cefotaxime into wounds prior to closure appears to have no effect on SSI incidence after surgery for peritonitis.

GDG Recommendations

Single-use povidone iodine spray into the incision, prior to closure, should be considered in elective colorectal surgery and surgery for perforated gangrenous appendicitis in adults.

Collagen gentamicin implants into the sternal wound should be considered after cardiac surgery.

The use of intraoperative skin re-disinfection or topical cefotaxime is not recommended.

Research recommendations

The use of povidone iodine spray and other antiseptic products applied to the wound prior to closure should be researched in elective, clean non-prosthetic surgery, particularly as there is an increase in resistance that requires less reliance on antibiotics.

The use of other antiseptic products applied to the wound to reduce SSI should be considered.

Further research should be undertaken into the use of collagen implants with antibiotics or antiseptics.

6.11 Closure methods

Which type of suture is clinically effective as a closure method?

Introduction:

The role that suture materials and methods play in surgical site infections is still not well understood. It is thought that silk and catgut, which are currently abandoned from 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 surgical site infections.

Overview of evidence:

Overview of evidence:

One systematic review and 47 RCTs were identified.

Characteristics of clinical studies included in the review

All studies included adults except for four129-132) that were exclusively in children. In three studies wounds rather than patients were randomised 133-135.

There was a range of types of surgery from minor operations (e.g. to remove benign skin lesions from the back) to major operations (e.g. for extensive cancer). Some operations were classified as 'clean', others

'clean/contaminated', 'contaminated' or 'dirty' (e.g. where abdominal trauma such as a gunshot wound had perforated bowel). All studies were of parallel group design except two that were of split body design ^{136;137} and one that randomised the upper and lower parts of the wound ¹³⁸. The tissue adhesive studies excluded surgical procedures on high tension sites such as the elbow and knee.

Eight studies included in the review had three or more relevant comparison arms ^{133;139-143 135}.

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 if this had been accounted for in two of the analyses134;135.

The method of randomisation was reported in 19 studies and was classified as adequate 133;136;137;144-146

130;140;141;147-150 Osther 1995 143;151-154. The rest did not state the method of randomisation or were unclear.

Allocation concealment was reported in 12 studies and was assessed as being adequate or partially adequate 130-133;141;143;145-147;152;154-157;157;158

There was an attempt at blinding the outcome assessor in 14 studies 156 130;131;136;140;143;148;151;157-161. In 10 studies 129;132;135;137;138;141;144;155;162;163 the outcome assessors were not blinded, and in the rest blinding was not stated.

There were no withdrawals in 9 studies 129;139;144;147;149;150;164-166. One study had more than 20% loss to follow up 141 (22-32% across groups). Only two studies 144;154 stated they carried out intention to treat analyses. Comparability of the groups at study entry was usually demonstrated.

Ten studies 133;146 138 130;132;140;141;149;152;157 reported an a-priori sample size power calculation.

The following comparisons were examined:

A Closure of the skin

- 1. Suture material 1 compared with suture material 2
- 2. Suturing technique 1 compared with suture technique 2
- 3. Non-suture compared with suture closure material
- 4. Non-suture closure material 1 compared with non-suture closure material 2
- 5. Primary skin closure compared with delayed skin closure
- B Closure of internal layers
 - 6. Suture material 1 compared with suture material 2
 - 7. Suturing technique 1 compared with suture technique 2
 - 8. Suture type 1 compared with suture type 2 (e.g. mesh/suture)
 - 9. Other comparisons

A) Closure of the skin

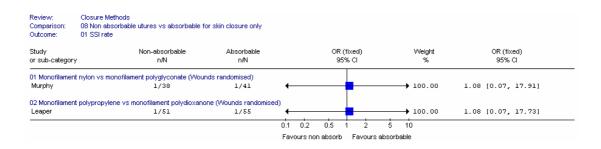
Suture material 1 compared with suture material 2

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 ¹⁶⁷ (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 two weeks post-operatively and bacteriological confirmation of infection was required

In one RCT 134 (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 polydioxonone (n=55).)

The incidence of SSI was low, confidence intervals were wide and neither result was statistically significant.



Triclosan coated vs traditional coated polyglactin 910 sutures:

One study 129 (n=135) included paediatric patients undergoing general surgery in a trial comparing the effects of triclosan coated vs traditional coated polyglactin 910 sutures on SSI incidence. EL 1- There were two infections in the triclosan coated sutures group (n=91) and none in the traditional coated sutures group (n=44). This difference was not significant (OR 2.49 [95% CI 0.12 to 52.89]).

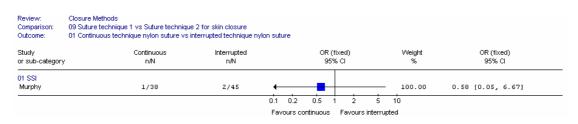
Review: Comparison: Outcome:	Closure Methods 02 Suture 1 vs Suture 2 for skin closure 01 Triclosan coated polyglactin 910 suture vs	traditional coated poly	glactin 910 suture
Study or sub-category	Triclosan coated n/N	Traditional coated n/N	OR (fixed) Weight OR (fixed) 95% Cl % 95% Cl
Ford	2/91	0/44	→ 100.00 2.49 [0.12, 52.89]
			0.1 0.2 0.5 1 2 5 10 Favours triclosan Favours traditional

Suturing technique 1 compared with suture technique 2

It is 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 135 (n=60) of patients undergoing clean orthopaedic procedures, randomised wounds to continuous polyamide (n=38 wounds) or interrupted polyamide suture techniques (n=45 wounds) for closure of the skin. EL 1- There was one infection found in the continuous suture technique group and two in the interrupted suture group. The confidence interval was too wide to draw conclusions from this study (OR 0.58 [95% CI 0.05 to 6.67]).



Bilayer technique compared with buried vertical mattress sutures:

One study161 (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. EL = 1-. Both arms appeared to use the same suture material .This difference was not significant (OR: 1.53 [95%CI 0.24 to 9.59]).

Non-suture closure material versus suture

Staples compared with skin sutures:

Eleven RCTs (total n=1353) were identified 137;138;142;144;154;155;160;162;163;167;168. Only one study 154 was believed to be at low risk of bias (EL=1+). Bias was possible or likely in the other ten RCTs (all EL=1-) due to poor reporting or uncertain methodology.

Patients were undergoing abdominal hysterectomy 155, CABG 138;142;162, surgery for Dupuytren's contracture 144, head and neck tumour surgery 168, elective abdominal and breast surgery 163, clean orthhopaedic procedures 167, abdominal surgery with a midline wound 160 and vascular procedures 137;154.

All trials assessed wound infection, One study 137 had within-patient randomisation and another 138 had within-wound (upper/lower) randomisation. No study found a statistically significant difference in SSI incidence rate following closure with staples or sutures.

Review: Comparison: Dutcome:	Closure Methods 03 Non-suture methods of closure 01 Staples vs sutures				
Study or sub-category	Staples v n/N	Sutures n/N	Peto OR 95% Cl	Weight %	Peto OR 95% Cl
01 Wound infec	tion - patients randomised				
Beresford	5/48	4/46		17.27	1.22 [0.31, 4.78]
Mullen	6/40	3/37		- 16.89	1.93 [0.49, 7.70]
Ranaboldo	1/22	1/26	←	→ 4.08	1.19 [0.07, 19.75]
Chughtai	4/81	4/81		16.08	1.00 [0.24, 4.12]
Grgic	0/25	0/25			Not estimable
Murphy	1/31	1/29	← ●	→ 4.13	0.93 [0.06, 15.32]
Eldrup	3/69	7/68	_	19.62	0.42 [0.12, 1.51]
Wolterbeck	3/86	7/84	_	19.89	0.42 [0.12, 1.50]
Bhatia	0/13	1/18	<	2.05	0.18 [0.00, 9.48]
02 Wound infec	tion - part of body or wound randomised				
Harvey	1/20	1/20	← +	2.27	1.00 [0.06, 16.58]
Johnson	58/242	50/242		97.73	1.21 [0.79, 1.85]

Two studies 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 167 (n=60) found one episode of dehiscence in each arm (n=31 with staples versus 29 with sutures). EL 1-

One trial 168 (n=50) reported no dehiscence in either group. EL 1-

Tissue adhesive compared with suture:

13 studies were identified

Five studies compared closure with butylcyanoacrylate adhesive to suture closure 132;146;151;158;169. Eight studies compared octylcyanoacrylate adhesive to suture closure 130;131;136;143;159 140;147;170

The studies were examined as two subgroups according to the particular cyanoacrylates adhesive used (butyl and 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 (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.^{130;132;140;146;147;151;159;169;170}.

Study or sub-category	Adhesive n/N	Suture n/N		eto OR 95% Cl	Weight %	Peto OR 95% Cl
)1 butylcyanoacrylate						
Dowson	6/61	8/58			59.93	0.69 [0.23, 2.08]
Keng	0/21	0/22				Not estimable
Ozturan	0/34	3/67	← ■	<u> </u>	12.64	0.21 [0.02, 2.41]
van den Ende	4/50	2/50			27.43	2.02 [0.39, 10.43]
2 Octylcyanoacrylate						
Gennari	0/69	0/64				Not estimable
Jallali	0/12	0/13				Not estimable
Maartense	5/48	3/50				1.79 [0.42, 7.56]
Ong	0/26	0/33				Not estimable
Sebesta	1/30	0/29			→ 11.87	7.15 [0.14, 360.38]

Four RCTs.^{132;146;151;169} (n=363) that compared butylcyanoacrylate adhesive closure to suture closure reported the incidence of SSI. Participants were undergoing surgery requiring groin incisions, rhinoplasty or septorhinoplasty, laparoscopic general surgery and herniotomy or orchidopexy respectively. One study only included children¹³².

Overall more SSIs were found in the sutures group (13/197) than in the adhesive group (10/166), although one underpowered study169 found no SSIs in either group. (EL 1-) No individual study reported a significant outcome. Pooling was inappropriate given the likelihood of bias in two studies 146;169(both EL 1-) and conflicting results in the remaining two studies132;151 (both EL 1+)

Five RCTs (n=374) compared octylcyanoacrylate adhesive closure to suture closure and reported the incidence of SSI ^{130;140;147;159;170}. In two studies participants were undergoing laparoscopic surgery}^{140;170} and in the remaining studies participants were undergoing breast surgery¹⁵⁹, herniotomy ¹³⁰ and laparoscopic cholecystectomy¹⁴⁷. One study only included children ¹³⁰.

There were very few infections overall - 6/185 in the adhesive group and 3/189 in the sutures group. Three studies found no infection in either treatment group^{130;159;170}. One RCT (n=98) reported 5/48 SSIs in the adhesive group compared to 3/50 in the sutures group ¹⁴⁰. EL 1+ A further RCT of laparoscopic wounds (n=59) found one infection in the adhesive group (n=30) only ¹⁷⁰. EL 1- Neither result was significant.

Outcome 2 - Wound dehiscence

Nine trials reported the rate of incisional dehiscence following closure with tissue adhesives or suture ¹⁴⁶

Comparison: 01 Tissu	Methods e Adhesives e Adhesives vs Sutures - Wound	dehiscence				
Study or sub-category	Adhesive n/N	Suture n/N		eto OR 5% Cl	Weight %	Peto OR 95% Cl
01 Butylcyanoacrylate						
Dowson	4/61	2/58			43.57	1.90 [0.37, 9.77]
Ozturan	0/34	0/67				Not estimable
Sinha	3/20	2/24		-	→ 34.13	1.91 [0.30, 12.12]
van den Ende	3/50	0/50			22.30	7.70 [0.78, 75.76]
)2 Octylcyanoacrylate						
Gennari	0/69	0/64				Not estimable
Greene	0/20	0/20				Not estimable
Ong	0/26	0/33				Not estimable
Shamiyeh	1/26	0/26			→ 100.00	7.39 [0.15, 372.38]
Toriumi	0/54	0/57				Not estimable
			0.1 0.2 0.5	1 2	5 10	
			Favours adhesiv	e Favours s	uture	

Four RCTs (n=364) that compared butylcyanoacrylate adhesive closure to suture closure reported the incidence of wound dehiscence146 132;151;158. Participants were undergoing laparoscopic general surgery, hand or wrist surgery, rhinoplasty or septorhinoplasty, and herniotomy or orchidopexy respectively. One study only included children 132.

Overall more wound dehiscence was found in the adhesive group (20/165) than in the sutures group (40/199), although one study reported no episodes of wound dehiscence in either group¹⁵¹. EL 1+

Three trials 132;146;158found greater incidence of wound dehiscence in the adhesive group, but these findings were statistically insignificant. In one trial 146, 4/61 occurrences of wound dehiscence were

reported in the adhesive group compared to 2/58 in the suture group. EL 1- Another study 158 found 3/20 occurrences of minor wound dehiscence (gaping of 1 to 2 mm) in the adhesive group compared to 2/24 in the suture group. EL 1+

One study¹³² (n=100) in which children who were undergoing herniotomy or orchidopexy were randomized to butylcyanoacrylate adhesive or suture closure found no wound dehiscence in the suture group (0/50) and 3/50 wounds dehiscent for more than half their length (average wound length (2.5cm) in the tissue adhesive group. (EL 1+)

Pooling of the three higher quality studies^{132;151;158}

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] I2=0%).

Five RCTs 130;136;143;159 131 (n=395) that compared octylcyanoacrylate adhesive closure to suture closure reported the incidence of wound dehiscence. Patients were undergoing breast surgery 159, blepharoplasty 136, herniotomy 130, varicose vein surgery 143 and surgery for face and neck skin lesions 131. One study included adults and children 131.

There was one report of wound dehiscence (n=195) in the octylcyanoacrylate tissue adhesive group and none in the sutures group (n=200). This finding from one study ¹⁴³ was not 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 ^{131;136;146}.

Pooling the remaining higher quality trials $^{130;132;143;151;158;159}$ 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 sutures group. (EL 1+) There was no significant difference in the incidence of wound dehiscence for the use of tissue adhesives compared to 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 versus adhesive tape:

Two studies compared the use of octylcyanoacrylate tissue adhesive to adhesive tape for skin closure¹⁴⁰ ¹⁴³.

Outcome 1 - SSI

One study140 (n=90) including participants undergoing elective laparoscopic surgery, compared the effect on SSI of using tissue adhesive or adhesive tape. No significant difference in SSI incidence was identified (OR = 2.33 [95% CI 0.43 to 12.67]). EL 1+

Review: Comparison: Outcome:	Closure Methods 01 Tissue Adhesives 03 Tissue adhesive vs adhesive tape - SS	rate				
Study or sub-category	Tissue adhesive n/N	Adhesive tape n/N		OR (fixed) 95% Cl	Weight %	OR (fixed) 95% Cl
Maartense	5/48	2/42			→ 100.00	2.33 [0.43, 12.67]
			0.1 0.2 0.4 Favours tissue		5 10	

Outcome 2 - Wound dehiscence

One trial ¹⁴³ (n=79) that included patients undergoing varicose vein surgery found no significant difference in wound dehiscence rate following skin closure with octylcyanoacrylate tissue adhesive compared to adhesive tape (OR=0.96 [95%CI: 0.06 to 16.23]). EL 1+

Timing of closure 1 compared with timing of closure 2

• Delayed closure compared with primary closure Surgical site infection: full guideline DRAFT (April 2008)

One RCT was identified

One trial 153 (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+

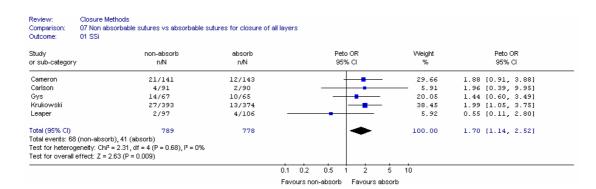
Significantly more SSIs were found in the group having their wounds primarily closed with staples (17/26) than in group whose wounds were randomised to delayed wound closure (8/22) (OR = 0.30 [95%CI 0.09 to 0.99]). This trial also reported wound dehiscence in 8/26 patients with primary wound closure compared with 3/22 patients in the delayed wound closure group (OR 0.36 (95%CI 0.08, 1.55).

B) Closure of Internal layers

Suture material 1 versus suture material 2

Non-absorbable suture material versus absorbable suture material: Five RCTs were identified

Five studies ^{145;148;156;171;172} 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).

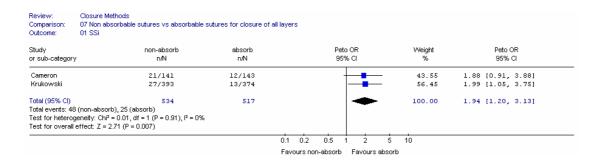


Outcome 1 - SSI

Two trials compared polyamide monofilament to polyglyconate monofilament ^{145;171}. One trial ¹⁴⁵(n=181) identified four infections in the group receiving polyamide sutures (4/91) and two in the polyglyconate sutures group (2/90). EL 1+ One trial ¹⁷¹ (n=132) found 14 infections in the polyamide suture group (14/67) and ten in the polyglyconate sutures group (10/65). 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^{148;156} compared polypropylene monofilament to polydioxanone monofilament. One trial ¹⁵⁶ (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 ¹⁴⁸ (n=767) found a statistically significant difference favouring 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+



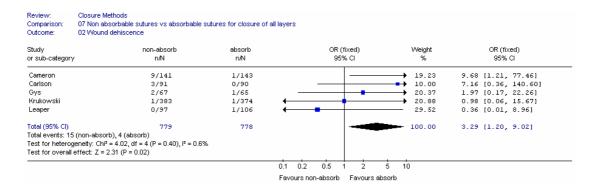
The pooled findings of these two trials demonstrated an overall significant effect favouring the use of absorbable polydioxanone sutures over polypropylene sutures for closure of all layers (Peto OR =1.94 [95%CI 1.20 to 3.13]).

One trial ¹⁷² (n=203) compared polyamide sutures to polydioxanone sutures. EL=1+ Two major SSIs were identified in the polyamide suture group (n=97) whilst 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 significant protective effect of using absorbable sutures was found compared to non-absorbable sutures in closure of all tissue layers (Peto OR = 1.70 [95% CI 1.14 to 2.52])

Outcome 2 - Wound dehiscence

Five trials ^{145;148;156;171;172} reported the incidence of wound dehiscence (burst abdomen) in the post-operative period.



One study ¹⁵⁶ found a 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-significant findings of the other trials, was very wide.

A meta-analysis of these five studies (non-absorbable sutures vs polydioxanone sutures) showed little heterogeneity ($I^2 = 0.6\%$) and significantly more wound infections occurring in the non-absorbable suture group (15/779) compared to the absorbable suture group (4/778) difference in the incidence of SSI between the groups (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.

Suture technique 1 compared with suture technique 2

Continuous versus interrupted:

Two relevant trials were identified ¹⁵⁰ and Gislason 1995. EL 1+

One trial (n=599) assessed the method of closing the internal tissue layers by mass closure with either continuous or interrupted polyglactin 910 sutures (Gislason 1995). EL=1+ Participants were undergoing major abdominal surgery. There were 17 SSIs in both of the continuous (n=163) and 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 significant (OR = 1.01 [95%CI 0.49 to 2.05]) and (OR = [95%CI 0.20 to 4.96]).

One trial ¹⁵⁰ (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 significant (OR = 1.27 [95%CI 0.70 to7.62]). No wound dehiscence was identified in either group.

Continuous loop compared with continuous mass closure:

One study 164 (n = 100) compared continuous loop with continuous mass closure with polypropylene sutures in patients undergoing laparotomy. EL=1+ There were 6/50 infections in the continuous loop group

compared to nine in the continuous mass closure group (n=50). This difference was not significant (OR = 0.62 [95%CI 0.20 to 1.90]).

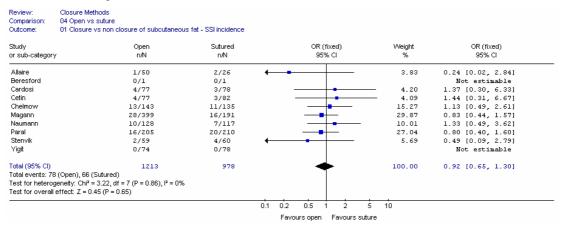
Continuous loop compared with continuous running suture:

One study ¹⁴⁹ (n=390) compared closure using continuous loop with a continuous running polydioxanone suture. EL 1+ There were 13 wound infections and 4 wounds that underwent dehiscence in the continuous running group (n=204) compared to 17 wound infections and 7 dehisced wounds in the continuous loop group (n=186). Neither of these differences was significant (OR = 0.68 [95%CI 0.32 to 1.43]) and (OR=0.51 [95%CI 0.15 to 1.78]).

Non closure compared with closure of subcutaneous tissue:

One systematic review ¹⁷³ that included five trials and four more recent trials ^{139;152;165;166} were identified to include in this comparison of closure compared with non-closure of the subcutaneous tissue. All EL 1+.

2189 participants undergoing caesarean section and procedures for CABG saphenectomy ¹⁶⁵, elective pelvic surgery ¹³⁹, elective abdominal surgery ¹⁵² and pilonidal sinus ¹⁶⁶ were included in a meta-analysis of these nine studies. All reported outcomes for SSI.



There was no heterogeneity and the pooled results demonstrated no significant difference in SSI incidence for the comparison (OR=0.92 [95% CI 0.65 to 1.30]).

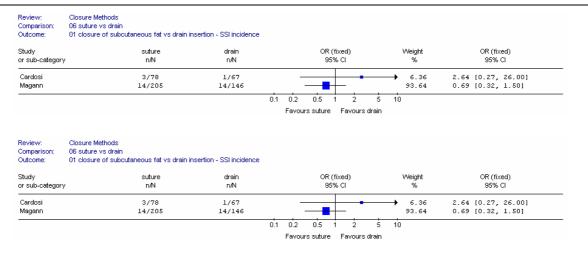
Non closure of subcutaneous fat compared with drain insertion: Two trials^{139;141} with three treatment arms were identified. EL 1+

This allowed comparison of no suturing of subcutaneous fat to 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 (48%); No significant difference in SSI rate was observed in either study (OR 0.69 (95%CI 0.32, 1.50)¹³⁹, 3.62 [95% CI 0.39 to 33.18]¹⁴¹). EL 1+

Review: Comparison: Outcome:	Closure Methods 05 non-closure of subcutaneous fat vs dra 01 non closure vs drain - SSI incidence	in insertion			
Study	non-closure	drain	OR (fixed)	Weight	OR (fixed)
or sub-category	n/N	n/N	95% Cl	%	95% Cl
Cardosi	4/77	1/67	-	→ 6.24	3.62 [0.39, 33.18]
Magann	14/205	14/146		93.76	0.69 [0.32, 1.50]
			0.1 0.2 0.5 1 2 5 Favours non-closure Favours drain	10	

Suture of subcutaneous fat compared with drain insertion: Data on SSI rates for suturing subcutaneous fat and drain groups can also be compared from the two studies (n=496 participants)^{139;141}.

EL 1+ Again results were conflicting and no significant difference in SSI rate was observed in either study.



Which type of suture is clinically and cost effective as a closure method?

Health economics overview of evidence

Six studies were included ¹⁷⁴ ¹⁴⁰ ¹⁴³ ¹⁷⁰ ¹⁷⁵ ¹⁷⁶.

The studies included material costs, costs for use of operating rooms and medical personal time. No costs for treating wound infection were included.

Two studies ¹⁴³ ¹⁴⁰ reported that adhesive tape was a faster and less costly closure method than tissue adhesive and sutures. To the same extent, tissue adhesives were found to be faster and less expensive than standard sutures in other three studies ¹⁷⁴ ¹⁷⁰ ¹⁷⁵. One single study ¹⁷⁶ that compared sutures to clips found the latter more costly when considering application, removal and dressings.

See Appendix H.

Health economics evidence statements

Tissue adhesive was consistently the most expensive for material costs. Adhesive tape was consistently the cheapest for material costs and also closure took the least time. Sutures required the greatest time for wound closure and also required a postoperative outpatient visit for removal.

There was evidence that wound closure using tissue adhesives generated cost savings when compared to sutures for skin closure due to shorter time for wound closure and no need for a postoperative outpatient visit.

There was evidence that wound closure with adhesive tape generates cost savings when compared to tissue adhesives or sutures; adhesive tape was found to be faster to apply and less costly.

There was evidence that sutures were less expensive than clips.

Evidence statements

There insufficient evidence to determine if there is a difference between absorbable and non-absorbable monofilament sutures. EL 1-

For skin closure, there is insufficient evidence to determine if using triclosan coated or traditional, noncoated polyglactin 910 sutures has an effect on SSI. EL 1-

For skin closure, there is insufficient evidence to determine if 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 if there is a difference in the incidence of SSIs between bilayer and vertical mattress sutures. EL 1-

There is evidence of no difference in SSI incidence following use of staples or sutures for skin closure. EL 1+

There was insufficient evidence to determine whether there is a difference in SSI incidence following use of adhesives or sutures for skin closure. 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 with both adhesives. EL 1-

There is insufficient evidence to determine if there is a difference in rates of SSI or wound dehiscence between tissue adhesive and paper tape for skin closure. 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-

Closure of internal layers

Evidence statements

For closure of the abdominal wall, there is good evidence that there are statistically significantly fewer SSIs following the use of absorbable polydioxanone monofilament interrupted sutures compared with non-absorbable polypropylene monofilament interrupted sutures. 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 is wide. EL 1+

A meta -analysis of two studies suggested no significant difference in the rate 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 was insufficient evidence in a single study to determine if there is a difference in rates of infection between continuous loop and continuous mass closure for closure of internal soft tissue layers. 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 is wide.

There was insufficient evidence to decide if there was a difference in SSI rate between continuous loop and continuous running sutures for closure of internal soft tissue layers. EL 1+

There is evidence of no difference in effect on SSI rate after suturing the subcutaneous fat layer compared to its non-closure. EL 1+

There was insufficient evidence to show if there was a difference in SSI incidence between inserting a drain or not in the subcutaneous fat layer after abdominal/pelvic surgery. EL 1+

There was insufficient evidence to show if there is a difference in the rate of SSI between suturing or inserting a drain in the subcutaneous fat layer. EL 1+

GDG interpretation

The SSI definition used, how the assessments were made and the adequacy of the post-discharge surveillance varied between studies making the reviews difficult to interpret.

Clear relationships between suture materials and surgical dressings to prevention of SSI have not been proven, although the use of silk has been abandoned for closing skin.

There is insufficient evidence that the technique of skin closure (interrupted v continuous v subcuticular), or type of surgery (as examples head and neck v abdominal surgery) or the material used (sutures v tapes v clips v glue) directly influence the rate of SSI.

The cost of skin closure and removal of materials, if indicated, has a relationship to the method used.

In addition, the choice of technique or material used for skin closure may be influenced by surgical site, patient characteristics and the ease or speed inherent in the technique.

GDG Recommendation

In_general the choice of technique and material for skin closure should be guided by local protocol, costs and clinical needs.

Research recommendation

Further research on sutures should be conducted and based on multi-centred adequately powered, single intervention RCTs.

Closure of internal layers

Evidence statements

For closure of the abdominal wall, there is good evidence that there are statistically significantly fewer SSIs following the use of absorbable polydioxanone monofilament interrupted sutures compared with non-absorbable polypropylene monofilament interrupted sutures.

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.

A meta -analysis of two studies suggested no significant difference in the rate of SSI between continuous and interrupted sutures. However, one of the studies was probably confounded by the significant differential use of antibiotics.

There was insufficient evidence in a single study to determine if there is a difference in rates of infection between continuous loop and continuous mass closure for closure of internal soft tissue layers.

There was insufficient evidence to decide if there was a difference in SSI rate between continuous loop and continuous running sutures for closure of internal soft tissue layers.

There is evidence of no difference in effect on SSI rate after suturing the subcutaneous fat layer compared to its non-closure.

There was insufficient evidence to show if there was a difference in SSI incidence between inserting a drain or not in the subcutaneous fat layer after abdominal/pelvic surgery.

There was insufficient evidence to show if there is a difference in the rate of SSI between suturing or inserting a drain in the subcutaneous fat layer.

GDG interpretation

There is insufficient evidence to show that 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.

6.12 Wound dressings for SSI prevention

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 easy inspection of the wound postoperatively; absorb exudates; ease pain and provide protection for newly formed tissue (*see Appendix D*). 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

8 RCTs ^{177 178 179 180 181 182 183 184} were identified for inclusion.

Initial dressing versus no dressing

An RCT ¹⁷⁷ (n=207 participants) compared the use of a dry gauze dressing for five days against 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 surgical site infection. The study found no significant difference between the two groups; RR 0.78 (95%CI [0.49 to 1.26]), Figure 1.

Review: Comparison: Outcome:	Wound dressings for the prevention of SS 01 Dressing vs. no dressing 01 surgical site infection	3			
Study or sub-category	dressing n/N	vaseline ointment n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Phan	21/102	29/105	-	100.00	0.75 [0.46, 1.22]
			0.1 0.2 0.5 1 2 5 Favours dressing Favours vase	10 Hine	

Figure 1

Dressing1 vs dressing2

Hydrocolloid dressing vs absorbent dressing:

Two RCTs ¹⁷⁸ ¹⁷⁹ (n=670 participants) compared the use of hydrocolloid dressings against the use of dry absorbent dressings (comparator) for the prevention of SSI. (EL 1+) Participants were patients that had undergone cardiac surgery with a median sternotomy incision ¹⁷⁸ and elective vascular surgery ¹⁷⁹. Infection of the post-surgical wound was registered in the two studies; however, definition criteria used were different for both studies. None of the trials found a statistically significant difference between the two dressings groups regarding the incidence of wound infection: ¹⁷⁸ (RR 0.91(95%CI [0.30 to 2.78]); ¹⁷⁹ (RR 1.21 (95%CI [0.48 to 3.07]), Figure 2.

Review: Comparison: Outcome:	Wound dressings for the prevention of SSI 02 Hydrocolloid dressing vs. comparator 01 surgical site infection				
Study or sub-category	hydrocolloid n/N	comparator n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Wynne	6/267	6/243		46.58	0.91 [0.30, 2.78]
Vogt	9/70	7/66		53.42	1.21 [0.48, 3.07]
			0.1 0.2 0.5 1 2 4	5 10	
			Favours hydrocolloid Favours com	parator	

Figure 2

Hydroactive dressing vs absorbent dressing:

Two RCTs ¹⁷⁸ ¹⁸⁰ and a quasi-RCT ¹⁸¹ (n=1879 participants) compared the use of hydroactive dressings against the use of dry absorbent dressings (comparator) for the prevention of SSI. Participants were patients that had undergone sternotomy for cardiothoracic surgery ¹⁷⁸ ¹⁸¹ and orthopaedic surgery ¹⁸⁰. Surgical site infection was a primary outcome in all studies even if definition criteria varied among the studies.

The two RCTs 178 180 found a non statistically significant difference favouring the group receiving the absorbent dressing; 178 (RR 1.61 (95%CI [0.58 to 4.44]) and 180 (RR 1.25 (95%CI [0.35 to 4.52], EL 1+; Figure 3.

The quasi-RCT ¹⁸¹ found also a non statistically significant difference but it favoured the hydroactive dressing group (RR 0.78 (95%CI [0.41 to 1.50]), EL 1-, Figure 3.

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Review: Comparison: Outcome:	Wound dressings for the prevention of SSI 03 Hydroactive dressing vs. comparator 01 surgical site infection				
Study or sub-category	hydroactive v n/N	comparator n/N	RR (fixed) 95% Cl	Weight %	RR (fixed) 95% Cl
Wynne_Ha	9/227	6/243		19.64	1.61 [0.58, 4.44]
Cosker	5/100	4/100		13.55	1.25 [0.35, 4.52]
Segers	16/615	19/570		66.81	0.78 [0.41, 1.50]
			0.1 0.2 0.5 1 2 5	10	
			Favours hydroactive Favours comp	arator	

Figure 3

Hydroactive dressing vs hydrocolloid dressing:

An RCT ¹⁷⁸ (n=494 participants) looked at the use of hydroactive dressings against the use of hydrocolloid dressing in the incidence of SSI. (EL 1+) Participants were patients that had cardiothoracic surgery. The study reported SSI as main outcome. The difference found in SSI rates between the two groups under study was not statistically significant, (RR 0.56 (95%CI [0.20 to 1.59]), Figure 4.

Review:	Wound dressings for the prevention of SSI							
Comparison:	04 Hydrocolloid dressing vs. hydroactive dressing							
Outcome:	01 surgical site infection							
Study	hydrocolloid hydroactive	OR (fixed)	Vveight	OR (fixed)				
or sub-category	n/N n/N	95% Cl	%	95% Cl				
Wynne_hc/ha	6/267 9/227		100.00	0.56 [0.20, 1.59]				
		0.1 0.2 0.5 1 2 Favours hydrocolloid Favou	: 5 10 urshydroactive					

Figure 4

Polyurethane membrane dressing vs absorbent dressing:

Polyurethane membrane dressing vs hydroactive dressing:

One RCT ¹⁸⁰ (n=300 participants) investigated the effect of different types of dressing (polyurethane membrane dressing, hydroactive dressing and absorbent dressing) in the incidence of surgical site infection. (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 5; when comparing the polyurethane membrane dressing group against the hydroactive dressing group the difference favoured the latter but still, this was not statistically significant, (RR 1.25 [95%CI 0.35 to 4.52]); Figure 6.

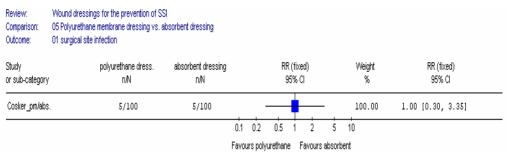


Figure 5

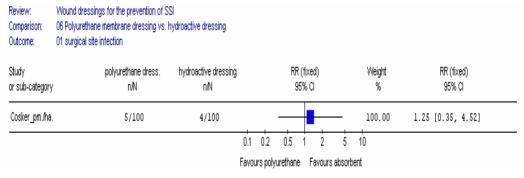


Figure 6

Absorbent dressing vs hydrocolloid dressing/ hydroactive dressing:

One RCT ¹⁸² (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 significance 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 7.

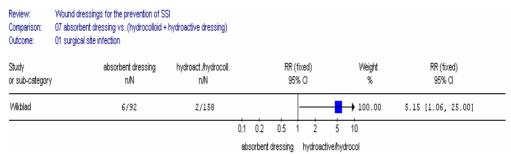


Figure 7

The RCT ¹⁸² reported several outcomes other that 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.

Duration1 of dressing in place vs duration2 of dressing in place

Wound covered for less than 12h vs wound covered for 48h:

One multicentre RCT ¹⁸³ (n=857 participants) investigated the effect on surgical site infection of removing the wound dressing (melolin and tape) and leaving it uncovered in the first 12 postoperative hours. This was compared against keeping the wound dry and covered for 48h postoperatively. (EL 1+) Participants were patients from a primary care setting that were undergoing minor skin excisions. The primary outcome was surgical site infection 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 8.

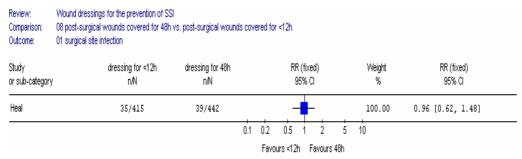


Figure 8

Wound covered for 24h vs wound covered until suture removal:

One quasi-RCT ¹⁸⁴ (n=1202 participants) examined the effect of leaving a post-surgical wound uncovered after the 24h following surgery on the incidence of SSI. Leaving the post-surgical wound exposed after the first day from the operation 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 surgical site infection. The study found no statistically difference between the two groups (RR 0.97 [95%CI 0.59 to 1.60]), Figure 9.

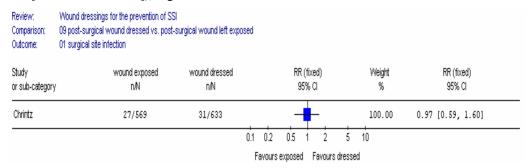


Figure 9

Health economics overview of evidence

The published evidence available identified ^{185 178 182 179} were costing analyses conducted in other countries that could not be used as evidence in a UK setting. A UK costing analysis was conducted (*see Appendix I*).

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 costminimisation 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 some evidence from one old RCT to show no difference in the incidence of SSI when comparing the use of a dry gauze dressing in the first five postoperative days against the use of a vaseline ointment. EL 1+

Dressing1 vs dressing2

Hydrocolloid dressing vs absorbent dressing There is evidence to suggest no difference in the use of hydrocolloid dressings when compared to the use of absorbent dressing for the prevention of SSI. EL 1+

Hydroactive dressing vs absorbent dressing

There is evidence to support that there is no difference between the use of hydroactive dressings and the use of absorbent dressing when considering the incidence of SSI. EL 1+

Hydroactive dressing vs hydrocolloid dressing There is evidence from a single RCT to suggest that the use of hydrocolloid dressings rather than the use of

hydroactive dressings makes no difference in the incidence of SSI. EL 1+

Polyurethane membrane dressing vs absorbent dressing

Polyurethane membrane dressing vs hydroactive dressing There is evidence from one poor quality study to suggest no difference (or to suggest some difference) in the incidence of SSI when comparing polyurethane membrane dressings with absorbent dressings or with hydroactive dressings. EL 1-

Surgical site infection: full guideline DRAFT (April 2008)

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Absorbent dressing vs hydrocolloid dressing/ hydroactive dressing

There is insufficient high quality evidence to suggest that there is a difference favouring the use of hydrocolloids or hydroactive dressings against the use of absorbent dressings. EL 1-

Duration1 of dressing in place vs duration2 of dressing in place

Wound covered for < 12h vs wound covered for 48h

There is evidence to suggest that there is no difference in the incidence of SSI when comparing the effect of keeping a wound uncovered after the first 12h following surgery with the effect of keeping the wound covered for 48h following surgery. EL 1+

Wound covered for 24h vs wound covered until suture removal

Insufficient high quality evidence suggests 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 24h following surgery in the prevention of SSI. EL 1-

GDG interpretation

Although there is no high quality evidence to support the use of a dressing in the immediate post operative period, 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 high quality 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.

GDG Recommendations

Surgical incisions should be covered with an appropriate interactive dressing in the immediate postoperative period.

Research recommendations

There should be further research on the benefit and cost effectiveness of different types of post-surgical interactive dressings.

7 **Postoperative phase**

7.1 Clean technique compared with aseptic non-touch techniques for dressing changes

Is there any clinical evidence to support the use of 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 micro-organisms on hands, surfaces or equipment from being introduced into the wound. When considering SSI incidence, it has to be asked if 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 ¹⁸⁶.

A small pilot RCT ¹⁸⁶ (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: mean difference: -3.80 cm3 (95%CI [-9.96 to 2.36]), Figure 1. However, the follow-up was only four days.

 Review:
 Dressing change techniques

 Comparison:
 01 clean dressing change technique vs. non-touch dressing change technique

 Outcome:
 01 wound healing wound volume reduction

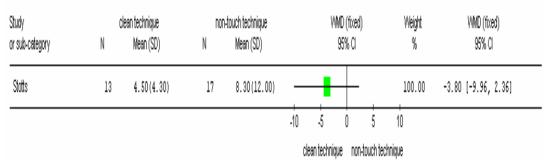


Figure 1

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

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.

GDG Recommendation:

'Aseptic' non-touch techniques should be used for removing or changing surgical wound dressings.

7.2 **Postoperative cleansing of the wound**

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 K*). As well as improving patient well-being, 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

One systematic review was identified

One well-conducted systematic review 187 (14RCTs) 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 cleansing with tap water with no cleansing were considered here.

In one quasi-RCT, patients (n=121 patients) who had undergone inguinal hernia and abdomino-perineal excision were allocated to either showering on the first post-operative 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 post-operatively.

In the other quasi-RCT, patients (n=82 patients) had undergone 'surgery with or without drains' and were allocated to either a showering (on 2nd 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). (OR $0.53\ 95\%$ CI [0.09 to 3.05]).

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 ¹⁸⁸.

An RCT ¹⁸⁸ 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 or chronic wounds. Since there was no difference in the incidence of wound infection among 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 BNF (September 2007) for Sodium Chloride solution (0.9%) as a skin cleanser was 95p for 1 litre.

Evidence statement

Two quasi-randomised studies showed no evidence of a difference in efficacy between cleansing agents for surgical wounds to prevent SSI. (EL 1+)

Surgical site infection: full guideline DRAFT (April 2008)

GDG interpretation

There appeared to be no obvious difference between cleansing solutions used for wound management in terms of the incidence of SSI.

The GDG consensus is 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.

GDG Recommendation:

If wound cleansing is indicated, sterile saline should be used.

Showering in the immediate postoperative period should not be undertaken specifically to reduce the rate of SSI.

When the surgical wound has separated or has been surgically opened to drain pus, then the use of tap water may be considered for wound cleansing.

7.3 Postoperative topical antimicrobials for prevention of SSI in surgical wounds healing by primary intention

What is the clinical effectiveness of topical antimicrobials to reduce surgical site infection?

Overview of evidence

One RCT was identified ¹⁸⁹.

A single RCT (n=92 participants) ¹⁸⁹ 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 surgical site infection. The antimicrobial used was a chloramphenicol ointment applied to the incisional site at the end of the procedure and at the 3rd day postoperatively. The trial found a non-statistically significant difference among the two groups (OR 0.43 [95%CI 0.12 to 1.54]), Figure 1.

Review: Comparison: Outcome:	post-operative topical antimicrobials in surg 03 post-operative topical antimicrobial for th 01 surgical site infection		by ! intention		
Study or sub-categor	chloramphenicol y n/N	Control n/N	OR (fixed) 95% Cl	VVeight %	OR (fixed) 95% Cl
Kamath	4/47	8/45		100.00	0.43 [0.12, 1.54]
			0.1 0.2 0.5 1 2 Favours treatment Favours co	5 10 ntrol	

Figure 1

Evidence statements

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.

GDG Recommendation

Topical antimicrobial agents, such as the antibiotic chloramphenicol applied as a paste, should not be used in the postoperative management of wounds to prevent SSI.

7.4 Dressing and antimicrobial impregnated dressings for the management of surgical wounds healing by secondary intention

Is it clinically effective the use of 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

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.

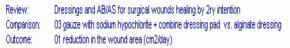
Overview of the evidence

Four RCTs were identified.

Four trials ¹⁹⁰ ¹⁹¹ ¹⁹² ¹⁹³ (n=226 participants) investigated the effect on wound healing when using different types of dressings, 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 between the studies.

Sodium hypochlorite soaked gauze + combine dressing pad vs combine dressing pad vs alginate dressing

One RCT (n=36) ¹⁹⁰ compared the use of a gauze soaked with sodium hypochlorite plus a combine dressing pad against the use of a combine dressing pad alone and against the use an alginate dressing. (EL 1-) The study included post-surgical abdominal wounds that presented 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 (Figure 1 and Figure 2). It found, however, that the wound size reduction appeared to be significantly greater when using the combine dressing pad against the use of the gauze rather than sodium hypochlorite + combine dressing (Figure 3 and Figure 4).



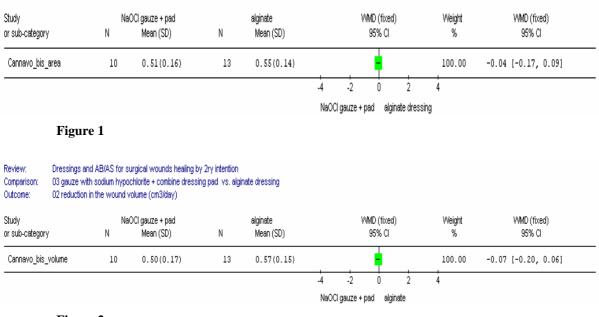
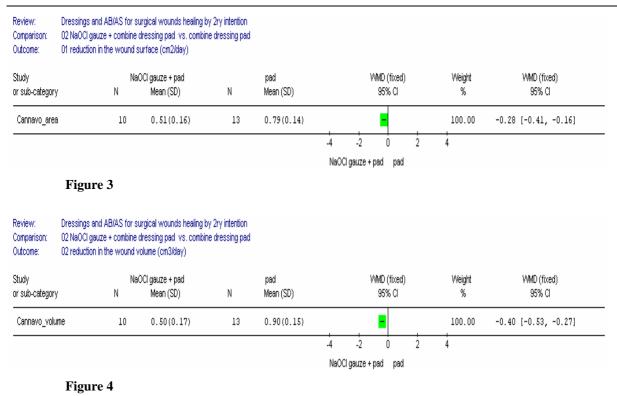


Figure 2

Surgical site infection: full guideline DRAFT (April 2008)

DRAFT FOR CONSULTATION



Silicone foam dressing compared with gauze soaked in mercuric antiseptic solution dressing One RCT (n=50 participants)¹⁹¹ examined the effect of using a silicone foam dressing compared with the use of a gauze soaked in a mercuric chloride solution in the management of 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. But, the trial did report a statistically significant difference in the 'time needed to a wound dry dressing' favouring the use of the foam dressing (60.3 days +/- 3.0 in the foam dressing group; 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 ¹⁹² (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 vs foam. (EL 1-) The study reported the wound size reduction and the number of wounds completely healed by the 4th 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 (n=34 participants) ¹⁹³ explored the use of alginate dressings for incised abscess cavities compared to saline-soaked gauze packs. (EL 1-) Wound healing was expressed as the proportion of patients with a completely healed wound after two weeks. It was found that the proportion of wounds healed was higher among the patients that received the saline-soaked gauze dressing. The result was not statistically significant (Figure 5).

DRAFT FOR CONSULTATION

Review:	Dressings and AB/AS for surgical wounds healing by 2ry intention							
Comparison:	08 gauze soaked with saline vs. calcium alginate dressing							
Outcome:	01 wound healing: proportion of complete healed wounds at week 2							
Study	saline-soked gauze alginate dressi	-	(fixed)	Weight	OR (fixed)			
or sub-category	n/N n/N		5% Cl	%	95% Cl			
Dawson	12/16 13/18			- 100.00	1.15 [0.25, 5.33]			
		0.1 0.2 0.5 saline-soaked gauze	1 2 alginate dres	5 10 ssing				

Figure 5

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 compared with 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 that there is any difference in the healing process of post-surgical open wounds in patients presenting with abscesses, when comparing moist cotton gauze with polyurethane foam with hydroactive particles dressings or gauze packing with saline or with 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 patients experience (for example pain).

A number of new dressings containing antimicrobials such as honey, silver and cadexomer iodine are now available and maybe 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 D*).

GDG Recommendation

Eusol and gauze, moist cotton gauze and mercuric antiseptic solutions should not be used in the management of surgical wounds healing by secondary intention.

Surgical wounds healing by secondary intention should be managed using an appropriate interactive dressing.

Healthcare professionals should refer to a tissue viability expert for advice on appropriate dressings for the management of surgical wounds healing by secondary intention.

Research recommendation

There is a need to evaluate the modern methods of chronic wound care in terms of management of SSI including alginates, foams and hydrocolloids and dressings containing antiseptics such as honey, cadexomer, iodine or silver.

7.5 Debridement

Is the use of debridement techniques clinically effective in the prevention and management of surgical site infection?

Introduction

The presence of dead (necrotic $-see \ glossary$) or damaged (slough $-see \ glossary$) 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 glossary).

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, due to other confounding factors such as the patient's co-morbidity, 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 different debridement techniques for the prevention and management of SSI was investigated.

Overview of evidence

Four RCTs were identified 194 195 196 197

Dextranomer compared with other dressings Three of the studies (n=110 participants)^{194 195 197} examined the effect of dextranomer (paste or beads) in the management of postoperative infected wounds. (EL 1-)

An RCT ¹⁹⁴ (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 to 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 ¹⁹⁷ (n=50 participants) compared dextranomer beads with a silicone foam 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 40.92+/-3.98 days and in the elastomer dressing group 36.96+/-3.18 days.

Another RCT (n=40)¹⁹⁵ compared the application of a dextranomer paste to the wound with the application of a gauze dressing soaked with polyvinylpirrolidone 10%. (EL 1-) The study included patients with postsurgically 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, necrotic tissue and presence of granulation tissue. None of the observed variables for the wound healing presented a statistically significant difference between the two groups; the only significant 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 vs dressing with saline

196 A small RCT (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 5.00+/-2.16 in the enzymatic dressing group and 13.45+/-6.77 in the dressing with saline group. There was not enough information provided to support the findings.

Evidence statement

There is insufficient evidence to decide if there is an effect on the healing of postoperative open and infected wounds healing when comparing dextranomer beads treatment with Eusol gauze dressing. (EL 1-)

Surgical site infection: full guideline DRAFT (April 2008)

The evidence from a small RCT which suggests that foam dressings favour the healing of postoperative open wounds when compared with dextranomer dressings is insufficient. (EL 1-)

There is insufficient evidence to suggest that there is an effect on the healing of postoperative infected wounds when comparing dextranomer paste with polyvinylpirrolidone 10%. (EL 1-)

The evidence from a small RCT suggesting that enzymatic dressings (streptokinase/ streptodornase) 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.

GDG Recommendation

Eusol and gauze, dextranomer and enzymatic treatments should not be used as debridement techniques in the management of SSI.

Research Recommendation

There is a need to evaluate the modern methods of debridement in surgical wounds healing by secondary intention.

Appendix A

Declarations of interest

GDG member	Interest						
David Evans	Member of the British Thoracic Society.						
	Member of the RCP Acute Medicine Task Force.						
	Wife was a Non-Executive Director of the Central Cornwall Primary Care Trust.						
Mark Farrington	Employed by the Health Protection Agency.						
	Provides occasional expert advice and commentary to various pharmaceutical companies, research organisations and healthcare equipment manufacturers. This has included 'Cambridg Healthcare and Biotech' on yet-to-be marketed antibiotics.						
	In the past, has performed research sponsored by laboratory/sampling equipment manufacturer and the National Blood Service.						
	Previously an Infection Control doctor at the BUPA Cambridge Lea Hospital, lecturing regularly to BUPA nursing staff nationally on infection control.						
	Has received educational travel grants to attend scientific meetings in the UK and abroad throughout career, from various pharmaceutical companies.						
Kate Gould	Sponsorship of travel to International Society of Heart and Lung Transplantation, and Interscience Conference on Antimicrobial Agents and Chemotherapy – Novartis.						
	Regional Microbiologist – HPA						
	DIPC and Consultant Microbiologist - Newcastle upon Tyne Hospitals NHS Foundation Trust						
	Sponsorship of travel to International Society for Heart and Lung Transplantation for other members of Laboratory team – Pfizer, Lederie, Astrazeneca						
David Leaper	Part-time medical advisor to Renovo who are in phase 3 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 US 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 Ethecon.						
	Clinical trials in conjunction with Ethicon, Hutchinson, and Arctic Bio. Trials involve sutures and wound care products.						
	Cardiff/Swansea group have financial support to undertake trial work.						
	New research group in Salisbury are in part funded by Convatec and financial support from Ethicon is pending, through a competitive grant from their Foundation, Tyco, Coloplast, Novartis and possibly Insense. Much of this work relates to topics in postoperative SSI care.						
	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 th 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.						

Appendix B

Clinical questions

- 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. Does mechanical bowel preparation reduce the rate of surgical site infection?
- 14. Does the removal of hand jewellery, artificial nails and nail polish reduce the incidence of surgical site infection?
- 15. What is the clinical effectiveness of parenteral or oral antibiotic prophylaxis for the prevention of surgical site infection compared to placebo or no antibiotic in patients undergoing surgery involving a skin incision?
- 16. For which types of surgery would prophylaxis by clinically and cost-effective? When should antibiotic prophylaxis be given pre/peri/post operatively?
- 17. What is the clinical hand decontamination strategy to use between subsequent surgeries?
- 18. What is the cost-effective hand decontamination strategy to use between subsequent surgeries?
- 19. Is the use of incise drapes clinically and cost-effective in reducing the incidence of surgical site infection?
- 20. Which incise drapes are clinically and cost-effective in reducing the incidence of surgical site infection?
- 21. Is the use of gowns clinically effective in reducing the incidence of surgical site infection?
- 22. Is the use of reusable or disposable surgical drapes and gowns related to surgical site infection?
- 23. Is there a difference between double vs single gloving affecting the incidence of surgical site infection?
- 24. Does the puncture rate of gloves correlate to the incidence of surgical site infection?
- 25. Is the use of preoperative skin antiseptics clinically effective in the prevention of surgical site infection?
- 26. Is there a difference in preoperative skin antiseptics used for adults and neonates (especially premature)?

- 27. Is the use of preoperative skin antiseptics clinically and cost-effective in reducing the rate of surgical site infection (bearing in mind patient subgroups based on age/surgical site)? Is there a difference in preoperative skin antiseptics used for adults and neonates (especially premature)?
- 28. Does use of diathermy for surgical incisions affect the rate of surgical site infection?
- 29. Is patient perioxygenation clinically effective for the prevention of surgical site infection?
- 30. What is the clinical effectiveness of perioperative perfusion and hydration for the prevention of surgical site infection?
- 31. What is the clinical effectiveness of perioperative warming to reduce surgical site infection?
- 32. Is perioperative patient warming cost effective? If so, then which is the most effective intro/immediate postoperative method?
- 33. What is the clinical effectiveness of strict blood glucose control to reduce surgical site infection?
- 34. Is intracavity lavage or wound irrigation clinically effective for the prevention of surgical site infection?
- 35. Is the application of intraoperative topical antiseptics/ antimicrobials before wound closure clinically effective in reducing surgical site infection rates?
- 36. Which type of suture is clinically effective as a closure method?
- 37. Which type of suture is clinically and cost effective as a closure method?
- 38. 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?
- 39. Is there any clinical evidence to support the use of 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?
- 40. 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?
- 41. 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?
- 42. What is the clinical effectiveness of topical antimicrobials to reduce surgical site infection?
- 43. Is it clinically effective the use of 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?
- 44. Is the use of debridement techniques clinically effective in the prevention and management of surgical site infection?

Appendix C

Definitions of surgical site infections

These definitions are those used by the Surgical Site Infection Surveillance Service in England. They are based on those published by CDC in 1992 and are classified as incisional (superficial or deep), or organ/space infection.

Superficial incisional infection

This is defined as a surgical site infection that occurs within 30 days of surgery and involves only the skin or subcutaneous tissue of the incision, and meets at least one of the following criteria:

Criterion 1: Purulent drainage from the superficial incision.

Criterion 2: The superficial incision yields organisms from the culture of aseptically aspirated fluid or tissue, or from a swab and pus cells are present.

Criterion 3: At least two of the following symptoms and signs are present:

- pain or tenderness
- · localised swelling
- redness
- heat

and

a. the superficial incision is deliberately opened by a surgeon to manage the infection, unless the incision is culture-negative

or

b. the clinician diagnoses a superficial incisional infection.

Note: Stitch abscesses: These are defined as minimal inflammation and discharge confined to the points of suture penetration, and localised infection around a stab wound. They are not classified as surgical site infections.

Deep incisional infection

This is defined as a surgical site infection involving the deep tissues (i.e. fascial and muscle layers) that occurs within 30 days of surgery if no implant is in place, or within a year if an implant is in place and the infection appears to be related to the surgical procedure, and meets at least one of the following criteria:

Criterion 1: Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

Criterion 2: The deep incision yields organisms from the culture of aseptically aspirated fluid or tissue, or from a swab and pus cells are present.

Criterion 3: A deep incision that spontaneously dehisces or is deliberately opened by a surgeon when the patient has a least one of the following symptoms or signs:

- fever (>38 °C)
- · localized pain or tenderness

unless the incision is culture-negative.

Criterion 4: An abscess or other evidence of infection involving the deep incision that is found by direct examination during re-operation, or by histopathological or radiological examination.

Criterion 5: Diagnosis of a deep incisional surgical site infection by an attending clinician

Note: An infection that involves both superficial and deep incision is classified as deep incisional surgical site infection

Surgical site infection: full guideline DRAFT (April 2008)

Organ/space infection

This is defined as a surgical site infection involving any part of the anatomy (i.e. organ/space), other than the incision, opened or manipulated during the surgical procedure, that occurs within 30 days of surgery if no implant is in place, or within one year if an implant is in place and the infection appears to be related to the surgical procedure, and meets at least one of the following criteria:

Criterion 1: Purulent drainage from a drain that is placed through a stab wound into the organ/space.

Criterion 2: The organ/space yields organisms from the culture of aseptically aspirated fluid or tissue, or from a swab and pus cells are present.

Criterion 3: An abscess or other evidence of infection involving the organ/space that is found by direct examination, during re-operation, or by histopathological or radiological examination.

Criterion 4: Diagnosis of an organ/space infection by an attending clinician

Note:

1. Occasionally, an organ/space infection drains through the incision. Such infection generally does not require re-operation and is considered to be a complication of the incision, and is therefore classified as a deep incisional infection.

2. Where doubt exists, refer to the Definitions of specific site of organ/space infection to determine if the organ/space infection meets the definition

The organ/space infection should be allocated to one of the specific sites in the following list:

- arterial or venous
- bone (osteomyelitis)
- endocardium (endocarditis)
- gastrointestinal tract

includes oesophagus, stomach, small and large bowel and rectum (excluding appendicitis and gastroenteritis.

• intra-abdominal

includes peritoneum, sub-phrenic or sub-diaphragmatic space, gall bladder, bile duct, liver (excluding hepatitis), spleen, pancreas, or other intra-abdominal tissue or area not specified elsewhere

- joint or bursa
- mediastinum (mediastinitis)
- myocardium or pericardium (myocarditis or pericarditis)
- other female reproductive tract

includes vagina, uterus, ovaries, or other deep pelvic tissue

• vaginal cuff.

Notes of application of definitions of surgical site infections

- 1. Clinicians diagnosis: these should be carefully evaluated before being accepted as meeting the definition of SSI.2. The prescription of antimicrobials would not be sufficient evidence of a clinician's diagnosis of SSI without confirmation that an SSI was the reason for treatment.
- 2. Micro-organisms from culture: the presence of pus cells is required to avoid the inclusion of positive cultures that reflect colonization rather than infection of the wound.

Specific sites of organ/space surgical site infection

Definitions of specific sites of organ/space surgical site infection are based on those used by the American National Nosocomial Infection Surveillance system.1

Arterial or venous infection

Arterial or venous infection, including arteriovenous graft, must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from arteries or veins removed during a surgical operation, and blood culture yielded no organisms or were not done.

Criterion 2: There is evidence of arterial or venous infection during a surgical operation or on histopathological examination.

Criterion 3: The patient has purulent drainage at the vascular site and blood cultures yielded no organisms or were not done.

Endocarditis

This includes endocarditis of a natural or prosthetic heart valve, and must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from valve or vegetation.

Criterion 2: The patient has two or more of the following signs or symptoms with no other recognised cause: fever (>38 °C), new or changing murmur, embolic phenomena, skin manifestations (i.e. petechiae, splinter haemorrhages, painful subcutaneous nodules), congestive heart failure, or cardiac conduction abnormality,* and at least one of the following:

- a. organisms cultured from two or more blood cultures
- b. organisms seen on Gram stain of valve, when blood cultures were negative or not done
- c. valvular vegetation seen during a surgical operation or autopsy
- d. positive antigen test on blood or urine (e.g. H. influenzae, S. pneumoniae, N. meningitidis, or Group B streptococci)
- e. evidence of new vegetation seen on echocardiogram

and if the diagnosis is made antemortem, the physician institutes appropriate antimicrobial therapy.

*For patients <1 year of age at least two of the following signs or symptoms with no other recognised cause: fever (>38 °C), hypothermia (<37 °C), apnoea, bradycardia, new or changing murmur, embolic phenomena, skin manifestations (i.e. petechiae, splinter haemorrhages, painful subcutaneous nodules), congestive heart failure, or cardiac conduction abnormality.

Gastrointestinal tract infection

This includes oesophagus, stomach, small and large bowel, and rectum (excluding gastroenteritis and appendicitis), and must meet at least one of the following criteria:

Criterion 1: There is an abscess or other evidence of infection seen during a surgical operation or on histopathological examination.

Criterion 2: Patient has at least two of the following signs or symptoms with no other recognised cause and compatible with infection of the organ or tissue involved: fever (>38° C), nausea, vomiting, abdominal pain, or tenderness, and at least one of the following:

- a. organisms cultured from drainage or tissue obtained during a surgical operation or endoscopy, or from a surgically placed drain
- b. organisms seen on Gram stain or multinucleated giant cells seen on microscopic examination of drainage or tissue obtained during a surgical operation or endoscopy or from a surgically placed drain
- c. organisms cultured from blood
- d. evidence of pathological findings on radiological examination
- e. evidence of pathological findings on endoscopic examination (e.g. Candida oesophagitis or proctitis).

Intra-abdominal infection

This includes gall bladder, bile ducts, liver (excluding viral hepatitis), spleen, pancreas, peritoneum, subphrenic or sub-diaphragmatic space, or other intra-abdominal tissue or area not specified elsewhere, and must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from purulent material from intra-abdominal space obtained during a surgical operation or needle aspiration.

Criterion 2: There is an abscess or other evidence of intra-abdominal infection during a surgical operation or on histopathological examination.

Criterion 3: The patient has at least two of the following signs or symptoms with no other recognised cause: fever (>38 °C), nausea, vomiting, abdominal pain, or jaundice, and at least one of the following:

- a. organisms cultured from drainage from surgically placed drain (e.g., closed suction drainage system, open drain, T-tube drain)
- b. organisms seen on Gram stain of drainage or tissue obtained during surgical operation or needle aspiration
- c. organisms cultured from blood and radiographic evidence of infection, e.g., abnormal findings on ultrasound, CT scan, magnetic resonance imaging (MRI), or radiolabelled scans (gallium, technetium, etc.) or on abdominal x-ray.

Joint or bursa infection

Joint or bursa infections must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from joint fluid or synovial biopsy.

Criterion 2: There is evidence of joint or bursa infection seen during a surgical operation or histopathological examination.

Criterion 3: The patient has at least two of the following signs or symptoms with no other recognised cause: joint pain, swelling, tenderness, heat, evidence of effusion or limitation of motion, and at least one of the following:

- a. rganisms and white blood cells seen on Gram stain of joint fluid
- b. positive antigen test on blood, urine, or joint fluid
- c. cellular profile and chemistry of joint fluid compatible with infection and not explained by an underlying rheumatological disorder
- d. radiographic evidence of infection, e.g., abnormal findings on x-ray, CT scan, magnetic resonance imaging (MRI), radiolabelled scan (gallium, technetium, etc.).

Mediastinitis

Mediastinitis must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from mediastinal tissue or fluid obtained during a surgical operation or needle aspiration.

Criterion 2: There is evidence of mediastinitis seen during a surgical operation or histopathological examination.

Criterion 3: The patient has at least one of the following signs or symptoms with no other recognised cause: fever (>38 °C), chest pain, or sternal instability,* and at least one of the following:

- a. purulent discharge from mediastinal area
- b. organisms cultured from blood or discharge from mediastinal area
- c. mediastinal widening on x-ray.

*For patients ≤ 1 year of age at least one of the following signs or symptoms with no other recognised cause: fever (>38 °C), hypothermia (<37° C), apnoea, bradycardia, or sternal instability.

Myocarditis or pericarditis

Myocarditis or pericarditis must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from pericardial tissue or fluid obtained by needle aspiration or during a surgical operation.

Criterion 2. The patient has at least two of the following signs or symptoms with no other recognised cause: fever (>38°C), chest pain, paradoxical pulse, or increased heart size,* and at least one of the following:

- a. abnormal ECG consistent with myocarditis or pericarditis
- b. positive antigen test on blood (e.g. H. influenzae, S. pneumoniae)
- c. evidence of myocarditis or pericarditis on histological examination of heart tissue
- d. fourfold rise in type-specific antibody with or without isolation of virus from pharynx or faeces
- e. pericardial effusion identified by echocardiogram, CT scan, magnetic resonance imaging (MRI), or angiography

*For patients ≤ 1 year of age at least two of the following signs or symptoms with no other recognised cause: fever (>38° C), hypothermia (<37° C), apnea, bradycardia, paradoxical pulse, or increased heart size

Osteomyelitis

Osteomyelitis must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from bone.

Criterion 2: There is evidence of osteomyelitis on direct examination of the bone during a surgical operation or histopathological examination.

Criterion 3: The patient has at least two of the following signs or symptoms with no other recognised cause: fever (>38°C), localised swelling, tenderness, heat, or drainage at suspected site of bone infection, and at least one of the following:

- a. organisms cultured from blood
- b. positive blood antigen test (e.g. H. influenzae, S. pneumoniae)
- c. radiographic evidence of infection, e.g., abnormal findings on x-ray, CT scan, magnetic resonance imaging (MRI), radiolabel scan (gallium, technetium, etc.).

Other infections of female reproductive tract

Other infections of the female reproductive tract including vagina, ovaries, uterus or other deep pelvic tissues (excluding endometritis or vaginal cuff infections), must meet at least one of the following criteria:

Criterion 1: Organisms are cultured from tissue or fluid from affected site.

Criterion 2: There is an abscess or other evidence of infection of affected site seen during a surgical operation or histopathological examination.

Criterion 3: The patient has two of the following signs or symptoms with no other recognised cause: fever (>38 °C), nausea, vomiting, pain, tenderness, or dysuria, and at least one of the following:

a. organisms cultured from blood

b. diagnosis by physician

Vaginal cuff

Vaginal cuff infection must meet at least one of the following criteria:

Criterion 1: Posthysterectomy patient has purulent drainage from the vaginal cuff.

Criterion 2: Posthysterectomy patient has an abscess at the vaginal cuff.

Criterion 3: Posthysterectomy patient has pathogens cultured from fluid or tissue obtained from the vaginal cuff.

Source: SSI Protocol Version 3.4 April 2004

Available: www.hpa.org.uk/infections/topics_az/hai/SSI_Protocol.pdf

CDC definitions from the HELICS (European network) SSI protocol

Case definitions of surgical site infections

In the HELICS collaboration surgical site infections will be defined according to the NNIS definitions, although in an earlier phase (HELICS I) a slightly different set of definitions was made. However, as most official networks adhere to the NNIS definitions, the largest degree of standardisation can be achieved by choosing the NNIS definitions. Some official networks may not be totally compliant to these definitions of surgical site infections to start with, but it is foreseen that setting these standards will lead to an increasing level of compliance.

Case definitions of surgical site infections:

SURGICAL SITE INFECTION

Surgical site infection: full guideline DRAFT (April 2008)

page 105 of 165

SUPERFICIAL. INCISIONAL.

Infection occurs within 30 days after the operation and infection involves only skin and subcutaneous tissue of the incision and at least one of the following

- 1. Purulent drainage with or without laboratory confirmation, from the superficial incision
- 2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
- 3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
- 4. Diagnosis of superficial incisional SSI made by a surgeon or attending physician.

DEEP INCISIONAL

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves deep soft tissue (e.g. fascia, muscle) of the incision and at least one of the following

- 1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
- 2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38° C), localized pain or tenderness, unless incision is culture-negative.
- 3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
- 4. Diagnosis of deep incisional SSI made by a surgeon or attending physician.

ORGAN/SPACE

Infection occurs within 30 days after the operation if no implant is left in place or within one year if implant is in place and the infection appears to be related to the operation and infection involves any part of the anatomy (e.g., organs and spaces) other than the incision which was opened or manipulated during an operation and at least one of the following

- 1. Puru drainage from a drain that is placed through a stab wound into the organ/space.
- 2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
- 3. An abscess or other evidence of infection invoMng the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
- 4. Diagnosis of organ/space SSI made by a surgeon or attending physician.

Appendix D

Wound dressings for SSI prevention

The majority of surgical wounds heal by *primary intention (see glossary)*. However, on some occasions it may not be advantageous to close the wound in this way, due 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)*. Also on occasions, a closed surgical wound may occasionally 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 degrees 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 post operative phase. These island dressings combine the advantages of transparent low adherent polyurethane film dressings, whilst also having the ability to absorb small amounts of excess exudate, aiding the normal debridement process in the wound (*debridement – see glossary*) 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:

(i). they allow postoperative inspection of the wound without disturbance of the dressing;

- (ii). they make the wound 'waterproof' to allow early showering or bathing whilst at the same time acting both as a barrier to possible external bacterial contamination and to prevent cross contamination to other patients;
- (iii). 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;
- (iv). they prevent any material from further contaminating the wound;
- (v). they maintain an optimal moist wound environment (Winter 1962), without causing maceration of the surrounding skin as the dressing material is permeable to moisture and gas;
- (vi). they prevent heat loss from the wound / maintain the optimal wound temperature
- (vi). they provide a cost effective approach to wound management as they reduce the number of dressings 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 e.g. analgesia may also be required.

Appendix E

Cost-effectiveness of hair removal

Five studies were included in the cost-effectiveness review ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷.

Using a series of case studies ¹⁵ in a descriptive pilot study undertaken in Belgium, compared the costeffectiveness 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.

Using what appeared to be a prospective cohort study undertaken in the USA; ¹⁶ compared preoperative hair removal with disposable razors, clipper and depilatory cream, as well as no hair removal.

Methodological quality of included health economic studies

It was difficult to assess from these studies which methods of hair removal (i.e. shaving, depilatory cream or clipping) were most cost-effective. In addition nearly all of these studies were undertaken more than 20 years ago. Three studies ¹³ ¹⁴ ¹⁶ had very limited cost analyses. ¹⁴ and ¹⁶ did not include the staff costs associated with hair removal which is important as the time spent by the health care professional removing hair from the patient will vary between the different preoperative hair removal interventions. ¹³ only included the costs of treating SSI in the analysis, and did not include the costs of preoperative hair removal.

Results

Two studies, ¹⁴ and ¹⁶, compared shaving 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 ^{14 15 16 17} compared shaving to depilatory cream. ¹⁴ found that the costs of consumables per 100 patients were approximately £14 for shaving and £22 for the depilatory cream. ¹⁵ 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). ¹⁶ found that use of the depilatory cream was more expensive than shaving (\$56.70 vs $11.40/m^2/1000$ 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. ¹⁷ found that the mean cost to prepare an area of $250cm^2$ (average hernia repair) cost £0.25 when using the depilatory cream compared to £0.80 when shaving, after taking into account the time of staff and the disposable equipment used.

Two studies ¹⁴ ¹⁶ examined depilatory cream with no preoperative hair removal. As these two studies only included the costs of preoperative hair removal, they found that cream was more costly than no hair removal.

Economic modelling

Data were used from a systematic review of the literature undertaken for the clinical review to derive the proportion of SSIs in each of the preoperative hair removal groups.

The identified papers reported that in some cases shaving cream could cause adverse skin reactions, and as such patients should be tested before full shaving by applying some cream on an inconspicuous part of the skin. In those patients where an adverse reaction to the cream was identified, it was assumed that hair removal using electric clippers would be used instead. From the literature the rate of adverse skin reactions to shaving cream was found to be 7.8%¹⁵.

Cost-utility analysis

Despite shaving with 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 1). As a result, when hair

DRAFT FOR CONSULTATION

removal using electric clippers was compared to no preparation, shaving cream, or shaving with razors, it was found to be dominant (i.e. it was both more effective and less costly).

Hair removal met	thoQALY	s Costs of 1	hairCosts of trea	tingTotal costs	(£) ICER (cost £ per QALY gained
	gained	removal	(£) SSI (£)		
Electric clipper	618.79	£2,516	£190,610	£193,126	
Cream	618.60	£2,250	£198,311	£200,561	Dominated by electric clipper
No preparation	617.86	£0	£227,699	£227,699	Dominated by electric clipper
Razors	615.35	£530	£328,355	£328,865	Dominated by electric clipper

Table 1QALYs gained and total costs for 1,000 patients undergoing surgery

Results of cost-utility analysis showed that hair removal with electric clippers was the most cost-effective method for preoperative hair removal. Not only was it found to be cost-effective, but 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 the model were in line with the results from other studies evaluating the costs of different hair removal methods, which did not recommend the use of razors for preoperative hair removal ¹³ ¹⁴ ¹⁵ ¹⁶ ¹⁷. As with other studies, although the use of razors was one of the cheapest interventions in terms of material costs ¹³ ¹⁵, 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.

Appendix F

Cost effectiveness of mupirocin nasal ointment to prevent surgical site infection caused by *S. aureus*

Literature review

Two were full economic analyses ^{24 25} were included.

A cost-effectiveness analysis conducted in the Netherlands ²⁴ compared mupirocin calcium ointment treatment with no preventative treatment in cardiothoracic surgery patients. This analysis was based on a study of 1,796 patients using a historical control. The analysis was conducted from the perspective of the health care system (only including costs to the health care system) with the timeframe for the analysis not stated. The outcome used was cost per SSI prevented. They reported that treating 1000 surgical patients with mupirocin would lead to a cost saving of \$747,969, \$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%), 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 ²⁵:

- 1. Screening patients for S.aureus colonization 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 gynaecologic surgery. The outcomes of the analysis were cost per infection avoided, and cost per life year saved. This analysis was based on one large RCT for mupirocin effectiveness in 3,864 surgical patients. The analysis was conducted from the perspective of society including patient expenses as well as the costs to the health care system. The timeframe 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 both published analyses were not conducted in the UK, a new model was developed for the purposes of this guideline.

The decision tree model

A simple decision analytic model was developed in Microsoft Excel® (see Figure 1) to assess the costeffectiveness 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 timeframe of one-year, meaning that no discounting of costs or benefits was undertaken.

The model compared the following three strategies:

- 1. No nasal decontamination
- 2. Treat all patients with mupirocin

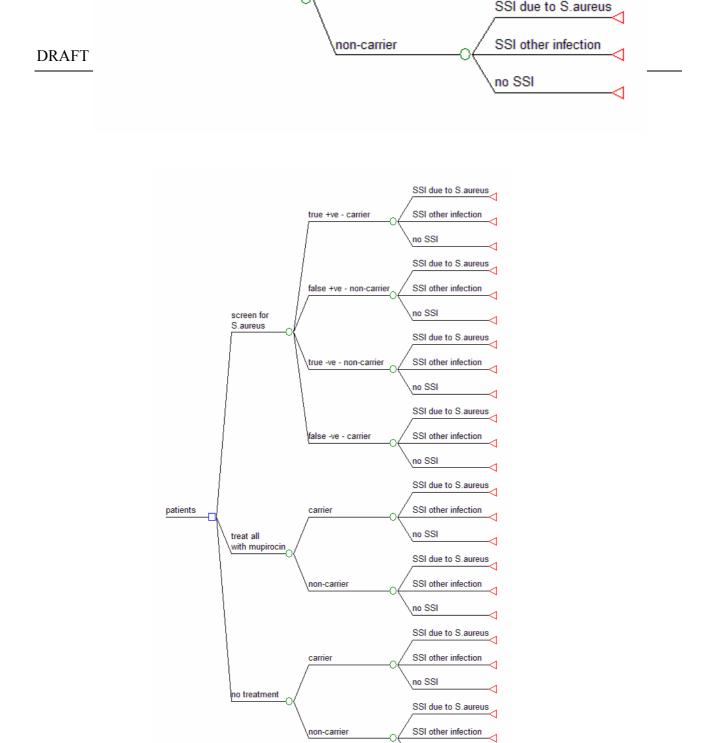


Figure 1 Decision tree of three treatment strategies

The analysis was based on a modelling exercise carried out in the US²⁵ 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 co-morbidities undergoing low-risk procedures. This model Young and Winston 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 surgical site infections 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 due to mupirocin use.

no SSI

The clinical evidence (see section 5.8) showed no statistically significant difference in the rate of SSI overall in all patients treated with mupirocin compared to 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 in S.aureus which would require a more complex model to be developed.

Surgical site infection: full guideline DRAFT (April 2008)

page 111 of 165

Model inputs

Table 1	Probabilities
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Variable	Value	Min	Ma x	Source	Notes
Prevalence of <i>S.aureus</i> nasal colonisation	0.23	0.19	0.5	Young (2006) 25	
Screening sensitivity	0.96	0.682	0.9 8	Ritchie (2007) 198	The base case for this model used the sensitivity and specificity for detecting MRSA, a conservative assumption.
Screening specificity	0.95	0.945	0.9 98	Ritchie (2007)	
Mortality with SSI	0.066	0.057	0.0 76	Coello (2005)	See Hair removal model from appendix E
Mortality without SSI	0.026	0.025	0.0 27	Coello (2005)	See Hair removal model from appendix E
No treatment – S.aureus c	arrier				
S.aureus infection	0.059			Perl (2002)	Beta distribution used for PSA
Other SSI	0.058			Perl (2002)	Beta distribution used for PSA
No treatment – Non carrie	er				
S.aureus infection	0.014			Perl (2002)	Beta distribution used for PSA
Other SSI	0.062			Perl (2002)	Beta distribution used for PSA
Mupirocin – S.aureus car	rier				
S.aureus infection	0.029			Perl (2002)	Beta distribution used for PSA
Other SSI	0.060			Perl (2002)	Beta distribution used for PSA
Mupirocin – Non carrier					
S.aureus infection	0.019			Perl (2002)	Beta distribution used for PSA
Other SSI	0.056			Perl (2002) 20	Beta distribution used for PSA

Table 2Utility

Outcome	Value	Min	Max	Source	Notes
Patients with SSI	0.57	0.51	0.64		See Hair removal model from appendix E
Patients with no SSI	0.64	0.57	0.71		See Hair removal model from appendix E
Dead	0				

Table 3 Costs

Resource item	Cost	Min	Max	Source	Notes
Real-time PCR swab	£5.18	£7.45	£19.4	GDG	Traditional culture nasal swab, 24-48hours,
			0		full cost plus overheads

DRAFT FOR CONSULTATION

Time to take swab	£2.55	£1.28	£3.83	Ritchie (2007) ¹⁹⁸	Costs associated with taking patient samples – staff nurse (grades D-G) spending approx. 5 mins providing info to patient, taking 2 swab samples and completing related administration such as labelling samples and sending them to the lab.
Hour of nurse time	£22.0 0	£16.5 0	£27.5 0	Curtis (2006) ¹⁹⁹	Nurse, day ward, cost per hour including qualifications
Nursing time mupirocin Application only	£9.17				Assuming 5 minutes per application for 5 days. Ritchie (2007) ¹⁹⁸
Mupirocin	£5.80	£2.90	£8.70	BNF 54	Bactroban Nasal (GSK) 3 g 0.2% mupirocin per patient
Bed day due to SSI	£307	£230	£383	Coello (2005) ²⁰⁰	
SSI treatment per patient	£3,48 6	£2,16 8	£5,23 5	Coello (2005) ²⁰⁰	Assuming 11.37 (min 9.43 days; max 13.66 days) additional hospital days to treat SSI

Results

As is shown in Table 4 and Table 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, 5 applications taking 25 minutes of a nurse's time (\pounds 9.17) plus the cost of the ointment (\pounds 5.80). The screening is also relatively low cost, \pounds 2.55 for the nurses time, and \pounds 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 4Cost per SSI prevented

Strategy	No of SSI	Cost
No nasal decontamination	85.36	£297,555
Screen for S.aureus and treat	81.42	£295,431
identified carriers		
Treat all patients with mupirocin	79.18	£290,963

Table 5	Cost per QALY	
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Strategy	QALY	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

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 6 shows the effect of assuming that mupirocin does not lead to any changes in SSI.

 Table 6
 Sensitivity analysis showing cost and QALY with no treatment effect

Strategy	QALY	Cost	
No nasal decontamination	615.59	£297,555	
Screen for S.aureus and treat	615.59	£309,179	
identified carriers			
Treat all patients with mupirocin	615.59	£312,522	

A sensitivity analysis with a lower SSI treatment cost is shown in Table 7 This is an important driver of the conclusions in the baseline analysis as it is this which causes treatment to be cost saving relative to no treatment.

Table 7Sensitivity analysis showing incremental cost per QALY with a lower SSI treatment cost (£2,168)

Strategy	QALY	Cost	Incremental QALY	Incremental	ICER
				cost	
No nasal decontamination	615.59	£185,093			
Screen for S.aureus and treat	615.95	£188,165	n/a	n/a	n/a
identified carriers			dominated	dominated	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 a SSI would have to fall to below £600 before the incremental cost-effectiveness ratio 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 multiway 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. This 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 which 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 whilst 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 on states with and without an SSI do not change. However, to reflect the importance of treatment costs of SSI to the model we've undertaken two Monte Carlo simulations, one with treatment costs for SSI at their baseline level (\pounds 3,486) and one with a lower treatment cost for SSI (\pounds 2,168).

Each Monte Carlo simulation consisted of 'running' the model 1,000 times. For each 'run' the strategy which 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 Figure 2 and Figure 3 respectively.

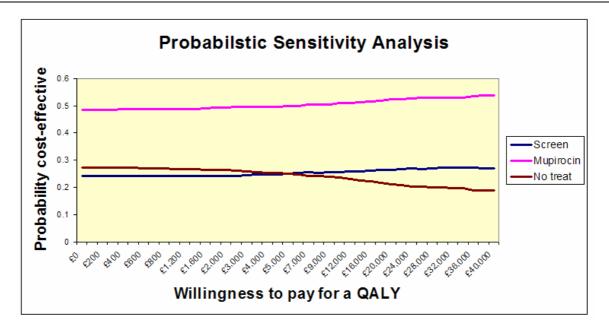


Figure 2 Cost effectiveness acceptability curve with the cost of treating SSI = £3,486

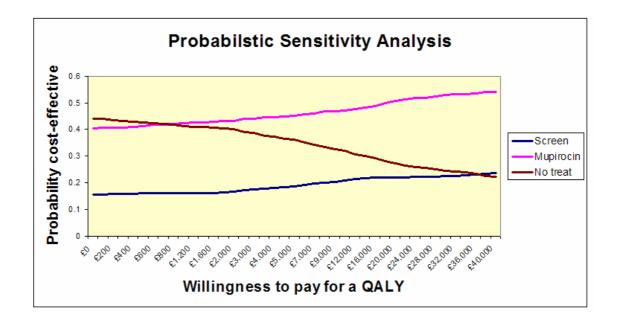


Figure 3 Cost effectiveness acceptability curve with the cost of treating $SSI = \pounds 2,168$

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 which assume that mupirocin does confer 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 that 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. Firstly, the cost-effectiveness of mupirocin is been driven by the point estimates derived from just one trial and

Surgical site infection: full guideline DRAFT (April 2008)

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 $\pm 20,000$ per QALY willingness to pay threshold.

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 which have not been incorporated into the model.

In the review of the clinical evidence (see 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. However, it should be noted that, in terms of all SSIs, the point estimates of these studies contradict each other. However, neither is statistically significant at the 5% level and therefore is consistent with no treatment effect, as the forest plot of the meta-analysis suggests.

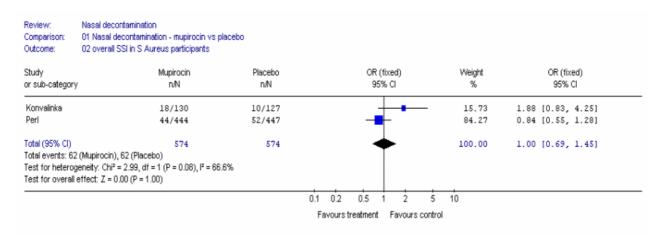


Figure 4 All infections in S.aureus carriers: mupirocin v placebo

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 our point estimates the effect size was closer to being statistically significant (though still not) in a comparison of S.aureus infections in S.aureus infections. Another of the potential harms of treating all patients mupirocin, in addition to the possible impact on antibiotic resistance is that it may increase the patient susceptibility to 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 G

Cost-effectiveness of perioperative warming

Four studies were included in the cost-effectiveness review 96 97 98 99

Three economic evaluations ^{96 97 98} compared active warming using forced air with conventional treatment of hypothermia. A further economic evaluation ⁹⁹ compared two different practices of maintaining patients' core body temperatures; forced air warming and radiant warming. However, there was no clinical evidence that compared forced air warming with radiant warming using SSI as an outcome measure.

Characteristics of included studies

In a randomised controlled study undertaken in patients undergoing abdominal surgery for cancer or inflammatory bowel disease in Germany, pre-induction and intraoperative warming using forced air warming in addition to conventional treatment of hypothermia was compared to conventional treatment for hypothermia alone ⁹⁶. The costing study, although including all the relevant costs of anaesthetic treatment, failed to include other costs accrued during the hospital stay (e.g. length of stay) in their analysis.

One study ⁹⁷ compared the costs and effects of actively warming patients intraoperatively using forced air warming to routine thermal care with warmed blankets in the USA. The study population comprised patients undergoing general endotracheal anaesthesia for an elective surgical procedure, who were at low risk of risk for perioperative complications. The methods used in the costing study undertaken were not clearly reported, making their results difficult to quantify and understand.

One study ⁹⁸ conducted a meta-analysis of 18 studies, including a total of 1,575 patients undergoing surgery with intraoperative normothermia in patients maintained. Mahoney & Odom (1999) included all relevant costs related to adverse outcomes and costs of treating hypothermia but did not include the costs of warming patients.

In a randomised controlled study undertaken in New Zealand, a study ⁹⁹ compared forced air warming and radiant warming for actively warming patients intraoperatively. The study population comprised female patients undergoing laparoscopic cholecystectomy. The cost results were not estimated using a detailed costing study, but by assuming a cost for each resource use component (i.e. blanket, blower unit and radiant warming). Therefore the cost results from this RCT undertaken in New Zealand need to be treated with caution.

Forced air warming vs routine thermal care

Three economic evaluations ^{96 97 98} compared active warming using forced air to conventional treatment of hypothermia.

One economic evaluation ⁹⁷ found that actively warmed patients required significantly less time to be discharged from anaesthetic recovery room than those receiving conventional treatment (94+/-42min vs 217+/-169, respectively; p<0.01). In terms of costs, the authors only included the costs of warming and those incurred during anaesthesia. The authors found that actively warmed patients incurred significantly lower mean costs than did those receiving conventional treatment (\pounds 408+/-105 vs \pounds 534 +/-250; p<0.05).

The second economic evaluation ⁹⁷ found that post-surgical emergence time, from completion of surgical dressing until extubation, was significantly reduced in patients who were actively warmed compared to those receiving routine thermal care (10+/-1min vs 14+/-1min; p<0.01). In terms of cost, the results showed that the use of forced air warming could incur an additional cost of \$15 per patient over routine thermal care, or generate savings of approximately \$30 per patient, depending on assumptions about the costing used.

The meta-analysis ⁹⁸ found that maintaining normothermia during an operation generated cost savings, when compared to mildly hypothermic patients, between \$2,495 and \$7,074 per patient, after including treatment

costs of operation, length of stay, and adverse effects such as infection or myocardial infarction, however, the costs of warming itself were not included.

Therefore, given the clinical evidence that pre- and intraoperative warming prevents SSIs when compared with routine thermal care, forced air warming is likely to be highly cost-effective.

Forced air warming vs radiant warming

One economic evaluation ⁹⁹ compared two different practices of maintaining patients' core body temperatures; forced air warming and radiant warming. The authors of this study found, that although the costs of radiant warming were higher at first, after around 170 operations the two warming devices were found to have the same costs, with radiant warming requiring no further ongoing costs and consuming around half the energy of the forced air warming devices.

Appendix H

Cost effectiveness of closure methods

Six studies were included in the economic review ¹⁷⁴ ¹⁴⁰ ¹⁷⁵ ¹⁴³ ¹⁷⁰ ¹⁷⁶.

Characteristics of included studies

The six studies ¹⁷⁴ ¹⁴⁰ ¹⁷⁵ ¹⁴³ ¹⁷⁰ ¹⁷⁶ included material costs, costs for use of operating rooms and medical personal time. No costs for treating wound infection were included.

¹⁷⁴ A study included a cost analysis alongside a clinical study conducted in Italy. Tissue adhesive (2-octylcyanoacrylate) was compared to standard sutures in breast surgery. No SSIs were reported for either closure method.

¹⁴⁰ Another study compared the closure of laparoscopic trocar wounds with tissue adhesive (octylcyanoacrylate), adhesive papertape or suture (poliglecaprone) in the Netherlands. The wound infection rate was highest in the octylcyanoacrylate group, but the difference between the groups was not significant. The costs of materials used and the costs for use an operating room and medical personnel were included. No costs for treatment of wound infections were included.

¹⁴³ A third study compared skin closure after phlebectomy with monofilament sutures, tape or tissue adhesive (octylcyanoacrylate) in Austria. No significant difference was found in the clinical outcomes.

¹⁷⁰ A forth study compared absorbable suture with tissue adhesive (octylcyanoacrylate) for closure of trocar sites in a US study. Wound complications rates were similar for the two groups.

¹⁷⁵ A fifth study was undertaken in the USA in patients undergoing elective laparoscopic surgery and compared octylcyanoacrylate adhesive with suturing, and was based on a quasi-randomised trial. No significant difference was found between wound infection rates in both groups.

¹⁷⁶ The last study compared clips to subcuticular vicryl sutures in patients with fracture neck of femur. This was a small, non-randomised, prospective study carried out in the UK[e3].

Findings

¹⁷⁴ The first study reported that the total mean costs were lower for tissue adhesives than for sutures for wound closure in breast surgery. The cost for tissue adhesive was higher than for standard sutures. Although the cost of postoperative visits increased the overall cost for sutures, compared to no visits for the tissue adhesives.

Adhesive paper tape was found to be significantly cheaper than the tissue adhesive (octylcyanoacrylate) and suture (poliglecaprone) in ¹⁴⁰. The material costs 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 secs and 33 secs vs 65secs, respectively).

Adhesive tape was found to be the lowest costing closure method in the ¹⁴³ analysis. It was the fastest method of wound closure (0.58 secs vs 0.64 secs for sutures and 1.14 secs for tissue adhesive). The material costs were also lowest for adhesive tape. ¹⁴³

¹⁷⁰ The study comparing absorbable suture with tissue adhesive, reported that the mean closure time for tissue adhesives was shorter than with sutures (3mins 42 secs compared to 14mins 5 secs). Although the costs of suture materials were much less than for the tissue adhesive (\$4.12 vs \$20.30). The operating room cost was high, \$35 per minute, and so tissue adhesives was the least expensive option.

¹⁷⁵ The study comparing octylcyanoacrylate adhesive with suturing reported that the median time to close the wound was less with tissue adhesive than sutures (2.5min vs 6 min suturing (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 to sutures.

 176 The study comparing clips with subcuticular vicryl sutures reported that dressing changes were needed less frequently in the suture group, on average 5 changes were needed compared to 3 for clips. 3 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, £5 compared to £18.10 for the clips. These costs included application, removal and dressings.

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Appendix I

Cost-analysis of wound dressings

The published evidence available were costing analyses conducted in other countries that could not be used as evidence in a UK setting. Therefore the GDG felt a UK costing analysis should be conducted. The dressings listed in the BNF were divided into categories. The main categories were 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).

The costs included the cost of the dressing (10 cm x 10 cm) (BNF September 2007) and a nurses time to change a dressing (PSSRU 2006). 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 (PSSRU 2006). For comparison 10cm by 10cm wound dressings were used or the next available size above (or 15g 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 change every 2 to 3 days
- Foam dressings changed every 3-4 days
- Hydrogel dressings changed every 1 to 2 days
- Hydrocolloid dressings changed every 3 to 4 days
- Vapour-permeable films and membranes changed every 5-7 days
- Wound contact materials changed every 4-7days
- Passive Dressings changed 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.

Results

A 10cm by 10cm dressing for a moderate to heavily exuding wound cost on average from £6.14 for a vaporpermeable dressing that needs to be changed every 5-7 days, to £83.84 for a passive dressing that needs to be changed 2 to 3 times per day.

Dressing type	frequency of change	Mean cost/week	Min. cost/week	Max. cost/week
alginate	2 - 3days	£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
Hydrofibre	2 - 3 days	£17.81	£17.81	£17.81
Vapour-permeable	5 - 7days	£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 1
 Costing analysis of a 10cm by 10cm dressing by dressing type for a moderate to heavily exuding wound

Surgical site infection: full guideline DRAFT (April 2008)

page 121 of 165

Dressing type	frequency of change	Mean cost/week	Min. cost per week	Max. cost per week
alginate	2 - 3days	£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
Hydrofibre	2 - 3 days	-	-	-
Vapour-permeable	5 - 7days	£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

Table 2Costing analysis of a 10cm by 20cm dressing by dressing type for a moderate to heavily exuding
wound (no hydrofibre dressings were available in this size or larger)

A further analysis was conducted for hydrocolloid dressings to compare products for different types of wound from lightly exuding to heavily exuding wounds.

Dressing type	frequency of change	Min. cost/week	lowest cost dressing
light to moderate	1 - 2 days	£16.30	Suprasorb H without adhesive border, thin
light to moderate - adhesive	1 - 2 days	£16.89	DuoDERM Extra Thin
Moderate to heavy	1 day	£24.50	Askina Biofilm Transparent
heavy	2 days	£35.96	CombiDERM
neuvy	2 days	200.00	
	- -		
	frequency of change	Max. cost/week	highest cost dressing
	frequency of		
Dressing type	frequency of change	Max. cost/week	highest cost dressing
Dressing type light to moderate	frequency of change 1 - 2 days	Max. cost/week £35.44	highest cost dressing Contreet® Hydrocolloid(Coloplast)

 Table 3
 Costing analysis of hydrocolloid dressings by type of wound

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 costminimisation analysis. There are many reasons for choosing a wound dressing depending on the surgery, type of wound, and characteristics of the patient.

Both the vapour-permeable dressings and 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). Although 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.

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Appendix J

General principles for hand hygiene (EPIC)

Hands of staff are the most common route by which micro-organisms 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. Whilst 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 micro-organisms acquired by touch are readily removed by soap and water, and by alcohol hand rubs or gels. Alcohol rapidly kills transient micro-organisms 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 micro-organisms such as *Clostridium difficile*. Their main advantage 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 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 micro-organisms 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 handrub is preferable unless hands are visibly soiled.

Hands should be washed with soap and water after several consecutive applications of alcohol handrub.

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 recommend 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 rubbed together towels.

Clinical staff should be aware of the potentially damaging effects of hands decontamination products and use emollient hand cream regularly to maintain the integrity of the skin.

Near-patient alcohol-based handrub should be made available in all healthcare facilities

Hand hygiene resources and individual practice should be audited at regular intervals and the results feedback to healthcare workers

Education and training in risk assessment, effective hand hygiene and glove use should form part of all healthcare workers annual updating

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Appendix K

Postoperative cleansing of the wound

Observations of current clinical practice would suggest that the majority of healthcare practitioners continue to use sterile normal saline for the cleansing of acute (e.g. surgical) wounds, whilst tap water is normally reserved for the cleansing of chronic wounds or for the initial cleansing of traumatic injuries whilst 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 (*see glossary*)]
- for the removal of 'mobile' slough
- · for the removal of foreign bodies including residues from other wound management products
- for the removal of wound crusts (generally these are made up of a combination of fibrin, dehydrated exudates and dressing residue most likely to be found at the wound edge)
- for the psychological well being 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 can not be said for tap water within the homes of patients.

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