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Surgical site infection: Evidence Update

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Surgical site infection

Evidence Update June 2013

A summary of selected new evidence relevant to NICE clinical guideline 74 'Prevention and treatment of surgical site infection' (2008)

Evidence Update 43



Evidence Updates provide a summary of selected new evidence published since the literature search was last conducted for the accredited guidance they relate to. They reduce the need for individuals, managers and commissioners to search for new evidence. Evidence Updates highlight key points from the new evidence and provide a commentary describing its strengths and weaknesses. They also indicate whether the new evidence may have a potential impact on current guidance. For contextual information, this Evidence Update should be read in conjunction with the relevant clinical guideline, available from the NICE Evidence Services topic page for [infection control](#).

Evidence Updates do not replace current accredited guidance and do not provide formal practice recommendations.

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Introduction

This Evidence Update identifies new evidence that is relevant to, and may have a potential impact on, the following reference guidance:

- ¹  **[Surgical site infection. NICE clinical guideline 74 \(2008\).](#)**

A search was conducted for new evidence from 13 April 2011 to 8 January 2013. A total of 1639 pieces of evidence were initially identified. Following removal of duplicates and a series of automated and manual sifts, 26 items were selected for the Evidence Update (see Appendix A for details of the evidence search and selection process). An [Evidence Update Advisory Group](#), comprising topic experts, reviewed the prioritised evidence and provided a commentary.

Although the process of updating NICE guidance is distinct from the process of an Evidence Update, the relevant NICE guidance development centres have been made aware of the new evidence, which will be considered when guidance is reviewed.

Other relevant information

The Evidence Update makes reference to surgical site infection criteria as defined by the US Centers for Disease Control and Prevention:

- Mangram AJ, Horan TC, Pearson ML et al. (1999) [Guideline for prevention of surgical site infection \(CDC\)](#). *Infection Control and Hospital Epidemiology* 20: 247–78

Feedback

If you have any comments you would like to make on this Evidence Update, please email contactus@evidence.nhs.uk

¹ NICE-accredited guidance is denoted by the Accreditation Mark 

Key points

The following table summarises what the Evidence Update Advisory Group (EUAG) decided were the key points for this Evidence Update. It also indicates the EUAG's opinion on whether the new evidence may have a potential impact on the current guidance listed in the introduction. For further details of the evidence behind these key points, please see the full commentaries.

The section headings used in the table below are taken from the guidance.

Evidence Updates do not replace current accredited guidance and do not provide formal practice recommendations.

Key point	Potential impact on guidance	
	Yes	No
<p>Preoperative phase</p> <ul style="list-style-type: none"> • The benefits of preoperative bathing or showering with antiseptics in preventing surgical site infection appear to be uncertain. Evidence for the most effective type of antiseptic wash also appears to be inconclusive, and further research is needed. • Evidence for preoperative hair removal in reducing surgical site infection rates is insufficient. If hair removal is necessary, then clipping may be associated with a reduced rate of infection. • Evidence for the effect of surgical teams wearing or removing finger rings and nail polish on surgical site infection rates is lacking. • Preoperative antibiotic prophylaxis plus antiseptic skin preparation may reduce surgical site infection risk after cardiac device implantation surgery (compared with no or postoperative antibiotics). • Antibiotic prophylaxis appears to reduce surgical site infection rates in elective open hernia repairs that use a mesh implant, but not in repairs performed without mesh. • Antibiotic prophylaxis in breast cancer surgery without reconstruction may reduce the risk of surgical site infection (although this does not take into account other issues such as the potential for drug reactions and increased bacterial antimicrobial resistance). • Evidence suggests that administering antibiotics after, rather than before, tourniquet inflation may be associated with a reduced rate of surgical site infection, but further research is needed. 		<ul style="list-style-type: none"> ✓ ✓ ✓ ✓ ✓ ✓ ✓
<p>Intraoperative phase</p> <ul style="list-style-type: none"> • Evidence for the effect of surgical masks on surgical site infection rates is insufficient and more research is needed. • The most effective antiseptic for skin preparation before surgical incision remains uncertain. • Abdominal incision with diathermy appears to have no advantage over using a scalpel in reducing surgical site infection rates, but more research is needed. 		<ul style="list-style-type: none"> ✓ ✓ ✓

Key point	Potential impact on guidance	
	Yes	No
<ul style="list-style-type: none"> • Perioperative oxygen supplementation does not appear to reduce surgical site infection rates, but more research is needed to investigate subgroups of patients for whom supplemented oxygen could be beneficial. • Haemodynamic goal-directed therapy (titration of fluid and inotropic drugs to reach normal or supraoptimal physiological endpoints such as cardiac output and oxygen delivery) appears to reduce surgical site infection rates. • Limited evidence suggests that a gentamicin-impregnated sponge may reduce rates of deep sternal wound infection after cardiac surgery via median sternotomy. • No particular dressing type emerges as the most effective in reducing risk of surgical site infection, although silver nylon dressings may be more effective than gauze. Further research to establish efficacy among modern dressing types is needed. • Risk of surgical site infection appears to be no different when leg wounds are closed with staples or with sutures after vein harvesting for coronary artery bypass grafting. • Antimicrobial-coated sutures may reduce surgical site infection risk versus uncoated sutures, although this effect may be specific to particular types of surgery (such as abdominal procedures). • Laparoscopy appears to be associated with lower rates of surgical site infection than open surgery among some subgroups; namely, obese patients, and those undergoing colorectal surgery. • Wound-edge protection devices may reduce surgical site infection rates after open abdominal surgery, but further research is needed. 	✓*	<ul style="list-style-type: none"> ✓ ✓ ✓ ✓ ✓ ✓ ✓
<p>Postoperative phase</p> <ul style="list-style-type: none"> • Negative pressure wound therapy appears to reduce surgical site infection rates after invasive treatment of lower limb trauma, but may be less effective in other patient groups such as those with multiple comorbidities. Further research is needed. 		<ul style="list-style-type: none"> ✓

* Evidence Updates are intended to increase awareness of new evidence and do not change the recommended practice as set out in current guidance. Decisions on how the new evidence may impact guidance will not be possible until the guidance is reviewed by NICE following its published processes and methods. For further details of this evidence in the context of current guidance, please see the full commentary.

1 Commentary on new evidence

These commentaries analyse the key references identified specifically for the Evidence Update. The commentaries focus on the 'key references' (those identified through the search process and prioritised by the EUAG for inclusion in the Evidence Update), which are identified in bold text. Supporting references provide context or additional information to the commentary. Section headings are taken from the guidance.

Glossary of terms

The following terms are used to classify surgical wounds:

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

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

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

1.1 [Information for patients and carers](#)

No new key evidence was found for this section.

1.2 [Preoperative phase](#)

Preoperative showering

[NICE CG74](#) recommends that patients should be advised to shower or have a bath (or be helped to have a shower, bath or bed bath) using soap, either the day before, or on the day of, surgery. Three reviews have recently assessed preoperative showering with antiseptics.

A Cochrane review by [Webster and Osborne \(2012\)](#) evaluated randomised controlled trials (RCTs) comparing preoperative showering or bathing with any antiseptic, before any type of surgery in any setting, to reduce surgical site infection. A total of 7 RCTs (n=10,157) were identified, all of which examined chlorhexidine.

For the primary outcome of surgical site infection (as defined by individual trial authors), preoperative showering or bathing with chlorhexidine was found to be no more effective than:

- placebo (relative risk [RR]=0.91, 95% CI 0.80 to 1.04, p=0.17; 4 RCTs, n=7791)
- soap (RR=1.02, 95% CI 0.57 to 1.84; 3 RCTs, n=1443)
- or no washing (RR=0.82, 95% CI 0.26 to 2.62; 3 RCTs, n=1142).

Limitations of the evidence included that only 1 of the identified studies was published within the last 20 years, during which time practices may have changed.

A systematic review by [Jakobsson et al. \(2011\)](#) examined the effects of the number of antiseptic showers, and type of antiseptic, on surgical site infection. Randomised and non-randomised clinical trials of preoperative disinfection showers in any healthcare setting, examining outcomes of surgical site infection or level of skin bacteria, were included. Trials of disinfection of hands or materials were excluded. A total of 10 studies (n=7351) were

identified, which examined the effect of 1 shower (2 studies), 2 showers (5 studies), or 3 or more showers (3 studies). Most trials compared chlorhexidine with soap or placebo but differences between studies prevented meta-analysis.

The authors stated that no definitive conclusion could be made about the optimal number of preoperative showers, but noted that in 8 of the studies, chlorhexidine led to a reduction in skin bacterial levels. However, skin bacteria do not necessarily correlate with surgical site infection risk. Limitations of most studies included that the number of showers was of secondary interest and the showering process was not explicitly described. Additionally, of the included studies, only 4 were assessed as being high quality evidence, 4 involved 60 or fewer participants, and only 1 was published within the last 20 years during which time practices may have changed.

A systematic review by [Kamel et al. \(2012\)](#) also evaluated preoperative antiseptics for preventing surgical site infections. Randomised and non-randomised studies of 3 types of skin antiseptic (iodophors, alcohol, or chlorhexidine) used before thoracic, cardiac, plastic, orthopaedic, neurological, abdominal, or pelvic surgery were included. A total of 20 studies (n=9520) were identified, examining: one antiseptic versus another (9 studies), antiseptic showers (7 studies), iodophor incise drapes (3 studies), and antiseptic versus soap, alcohol or saline (2 studies). Heterogeneity between studies prevented meta-analysis.

The authors stated that based on results from 3 RCTs and 4 cohort studies (n=2512), preoperative showering appeared to reduce skin bacterial levels, but that the effect on surgical site infection was inconclusive. They also stated that conclusions about the most effective antiseptic could not be made.

Limitations of the evidence included that:

- formulation, strength and application of antiseptics were inconsistent among studies
- the included studies were of mixed quality and randomisation was often poorly reported
- a wide range of procedures were included limiting conclusions about specific patient groups.

Taken together, these studies indicate that the benefits of preoperative bathing or showering with antiseptics in preventing surgical site infection appear to be uncertain. Evidence for the most effective type of antiseptic wash also appears to be inconclusive. These data are unlikely to affect recommendations in [NICE CG74](#) to have a shower or bath with soap before surgery. Further robust evidence is needed from large trials to compare no showering versus single or multiple showers, including comparisons of soap versus a range of antiseptics.

Key references

[Jakobsson J, Perlkvist A, Wann-Hansson C \(2011\) Searching for evidence regarding using preoperative disinfection showers to prevent surgical site infections: a systematic review. Worldviews on Evidence-Based Nursing 8: 143–52](#)

[Kamel C, McGahan L, Polisena J et al. \(2012\) Preoperative skin antiseptic preparations for preventing surgical site infections: a systematic review. Infection Control & Hospital Epidemiology 33: 608–17](#)

[Webster J, Osborne S \(2012\) Preoperative bathing or showering with skin antiseptics to prevent surgical site infection. Cochrane Database of Systematic Reviews issue 9: CD004985](#)

Hair removal

[NICE CG74](#) states: do not use hair removal routinely to reduce the risk of surgical site infection, and do not use razors for hair removal, because they increase the risk of surgical site infection. If hair has to be removed, use electric clippers with a single-use head on the day of surgery.

A Cochrane review by [Tanner et al. \(2011\)](#) investigated preoperative hair removal to reduce surgical site infection. RCTs and quasi-RCTs examining a primary outcome of hair removal

versus no hair removal, and secondary outcomes of different methods, settings, and timings of hair removal before surgery, were included. A total of 14 trials (n=3838) were identified.

For the primary outcome, a comparison of shaving (of either body or scalp hair) versus no hair removal found no significant difference in rates of surgical site infection between groups (RR=1.75, 95% CI 0.93 to 3.28, p=0.084; 4 RCTs, n=575). A non-significant difference in infection rate was also seen with clipping scalp hair versus no hair removal (RR=1.00, 95% CI 0.06 to 15.65, p=1.0; 1 RCT, n=130). When shaving was compared with clipping (of either body or scalp hair), significantly more surgical site infections were seen with shaving (RR=2.03, 95% CI 1.14 to 3.61, p=0.017; 3 RCTs, n=1343).

Limitations of the evidence included that:

- some comparisons were underpowered
- the methodological quality and reporting for most of the included trials was described as poor
- none of the trials used standardised definitions of surgical site infection
- only 2 of the 14 trials were published within the last 20 years, during which time practices may have changed.

The authors concluded that evidence for preoperative hair removal in reducing surgical site infection rate is insufficient. If hair removal is necessary, then clipping may be associated with a reduced rate of infection. This is consistent with current recommendations in [NICE CG74](#).

Key reference

Tanner J, Norrie P, Melen K (2011) [Preoperative hair removal to reduce surgical site infection](#). Cochrane Database of Systematic Reviews issue 11: CD004122

Hand jewellery, artificial nails and nail polish

[NICE CG74](#) recommends that the operating team should remove hand jewellery, artificial nails and nail polish before operations.

A Cochrane review by [Arrowsmith and Taylor \(2012\)](#) examined the effects of wearing or removing nail polish and finger rings among surgical scrub teams on postoperative surgical site infection. No trials were found for the primary outcome of infection rate. A single RCT (n=102) was identified evaluating a secondary outcome of whether nail polish, worn by scrub nurses, affected the number of bacterial colony forming units on hands after scrubbing before surgery (only the dominant hand was tested). No significant differences in the number of bacteria on hands before or after scrubbing were seen between nurses with either unpolished nails, recently applied nail polish (less than 2 days old), or old nail polish (more than 4 days old).

Limitations of the evidence included that only 1 small trial, examining a secondary outcome, was identified (which the authors stated was underpowered to detect clinically important differences). The authors concluded that there is a lack of evidence for the effect of surgical teams wearing or removing finger rings and nail polish on surgical site infection rates. Evidence of the impact of nail polish on skin bacterial levels is also insufficient; therefore these data are unlikely to affect [NICE CG74](#).

Key reference

Arrowsmith VA, Taylor R (2012) [Removal of nail polish and finger rings to prevent surgical infection](#). Cochrane Database of Systematic Reviews issue 5: CD003325

Antibiotic prophylaxis

[NICE CG74](#) recommends giving antibiotic prophylaxis to patients before:

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

Antibiotic prophylaxis should not be used routinely for clean non-prosthetic uncomplicated surgery.

Antibiotics in cardiac device implantation surgery

A systematic review and meta-analysis by [Darouiche et al. \(2012\)](#) investigated the use of prophylactic antibiotics and antiseptics to prevent surgical site infection after implantation of an electronic cardiac device. RCTs of perioperative antiseptics and antibiotics (local or systemic), alone or combined, during initial or repeat implantation of pacemakers or cardioverter-defibrillators, were included. A total of 15 studies (n=3970) were identified. The primary outcome of surgical site infection included septicaemia, septic shock, infective or bacterial endocarditis, valve infection, and cellulitis.

A significant reduction in the incidence of surgical site infection was seen after systemic antibiotics plus skin antiseptics 1 hour before surgery, versus either no antibiotics (RR=0.13, 95% CI 0.05 to 0.36, p<0.00001; 6 RCTs, n=1766), or postoperative antibiotics (RR=0.14, 95% CI 0.03 to 0.60, p=0.008; 1 RCT, n=100).

Limitations of the evidence included that:

- the quality of most studies was assessed as poor to moderate
- only 5 studies used the criteria for surgical site infection as set out by the US Centers for Disease Control and Prevention
- various antibiotics were used across the trials (with some used in isolation and some in combination) therefore conclusions about specific antibiotics could not be made
- the wide inclusion criteria of antibiotics and antiseptics in any combination made it difficult to draw conclusions about either antimicrobial technique.

The evidence suggests that preoperative antibiotic prophylaxis plus antiseptic skin preparation may reduce surgical site infection risk after cardiac device implantation surgery (compared with no or postoperative antibiotics). This is consistent with recommendations in [NICE CG74](#) for antibiotic prophylaxis in clean surgery using an implant.

Key reference

[Darouiche R, Mosier M, Voigt J \(2012\) Antibiotics and antiseptics to prevent infection in cardiac rhythm management device implantation surgery. Pacing and Clinical Electrophysiology 35: 1348–60](#)

Antibiotics in hernia repair

A Cochrane review by [Sanchez-Manuel et al. \(2012\)](#) assessed the effect of antibiotic prophylaxis on surgical site infection rates after hernia repair. RCTs of antibiotic prophylaxis among adult patients undergoing elective open inguinal or femoral hernia repair, with either herniorrhaphy (non-mesh repair) or hernioplasty (mesh repair) were included. Trials of laparoscopic repair, and those using antiseptic prophylaxis, were excluded. A total of 17 RCTs (n=7843) were identified. The primary outcome was surgical site infection as defined by individual trial authors.

Overall, surgical site infection rate was significantly lower with antibiotic prophylaxis than control (3.1% versus 4.5% respectively; OR=0.64, 95% CI 0.50 to 0.82, p=0.00042; 17 RCTs, n=7843). Subgroup analysis indicated that infection rates after herniorrhaphy were not significantly different between the antibiotic and control groups (3.5% versus 4.9% respectively; OR=0.71, 95% CI 0.51 to 1.00, p=0.052; 6 RCTs, n=4269). However, after

hernioplasty, infection rates were significantly lower with antibiotics than control (2.4% versus 4.2% respectively; OR=0.56, 95% CI 0.38 to 0.81, p=0.0023; 11 RCTs, n=3574).

Limitations of the evidence included that:

- although most studies used treatments relevant to modern practice, some of the older studies involved antibiotics that may now be considered inappropriate (such as ampicillin)
- a wide variety of antibiotics were used across the trials, so no conclusions about efficacy of particular antibiotics could be made
- adverse events or bacterial resistance after using antibiotics were not considered by the review
- laparoscopic procedures were not included so the conclusions relate only to open surgery.

The evidence suggests that antibiotic prophylaxis appears to reduce surgical site infection rates in elective open hernia repairs that use a mesh implant, but not in repairs performed without mesh. This is consistent with recommendations in [NICE CG74](#) to use antibiotic prophylaxis in clean surgery involving an implant.

Key reference

Sanchez-Manuel FJ, Lozano-García J, Seco-Gil JL (2012) [Antibiotic prophylaxis for hernia repair](#). Cochrane Database of Systematic Reviews issue 2: CD003769

Antibiotics in breast cancer surgery

Two studies recently assessed antibiotic prophylaxis to prevent surgical site infection after breast cancer surgery.

A Cochrane review by [Bunn et al. \(2012\)](#) examined RCTs and controlled trials of patients undergoing breast cancer surgery (with or without immediate reconstruction) that compared preoperative or perioperative antibiotic prophylaxis with none or placebo. A total of 7 studies (n=1945) were identified, none of which included reconstructive surgery.

For the primary outcome of surgical site infection, a significantly reduced incidence of infection was seen with prophylactic antibiotics compared with no antibiotics or placebo (RR=0.72, 95% CI 0.53 to 0.97, p=0.031; 7 studies, n=1945).

Limitations of the evidence included that: no trials involved reconstructive surgery so results only apply to procedures without reconstruction; and various antibiotics were used across the trials therefore conclusions about specific antibiotics could not be made.

A double-blind RCT (n=254) in the Philippines by [Cabaluna et al. \(2013\)](#) also investigated antibiotic prophylaxis in breast cancer surgery. Patients were randomised to placebo or to active treatment (1 g intravenous cefazolin² in 10 ml sterile water 30 minutes before incision), and all patients received preoperative povidone-iodine antiseptic skin preparation. After surgery, all patients had a drain fitted, their incisions closed with staples or Vicryl sutures, and sterile dressings applied. Wounds were assessed on the day after surgery, before discharge, then weekly for 4 weeks at a breast care centre.

The trial included women with breast cancer (Eastern Cooperative Oncology Group score 0–1, clinical stage I to IIIC), undergoing elective modified radical mastectomy at a single tertiary hospital. Exclusion criteria were: recurrent breast cancer; previous radiotherapy; diabetes mellitus or severe malnutrition; corticosteroid therapy; simultaneous breast reconstruction or bilateral oophorectomy; antibiotic treatment within 1 week before surgery; allergy to cephalosporins; and existing local infection. Surgical site infection was defined according to the US Centers for Disease Control and Prevention criteria.

² Cefazolin did not have UK marketing authorisation for perioperative prophylaxis at the time of publication of this Evidence Update.

For the primary outcome of surgical site infection within 30 days, there was no difference in infection rate between the placebo group (19/127; 15.0%) and the antibiotic group (17/127; 13.4%; $p=0.719$). The authors then added the results of their trial to the meta-analysis from the Cochrane review by Bunn et al. (2012) discussed above. The overall significance of the meta-analysis did not change, which still favoured antibiotics. However, the authors performed a further meta-analysis combining the results of their RCT with a subset of studies from the Cochrane review that principally considered mastectomy (including wide local excision). The effect of antibiotic prophylaxis on infections was no longer significant for this patient group (RR=0.84, 95% CI 0.61 to 1.17, $p = 0.31$; 5 studies, $n=1050$).

Limitations of the evidence included that:

- 40 different surgeons with a wide range of experience carried out the procedures, which increased the potential for inter-operator variability (however, this could improve the generalisability of results outside of the trial)
- the amount of postoperative infection was at the higher end of reported rates, suggesting that other variables may have influenced outcomes
- postoperative care of drains by patients was not assessed, which may have affected infection rates.

Taken together, the evidence suggests that antibiotic prophylaxis in breast cancer surgery without reconstruction may reduce the risk of surgical site infection. However, other issues such as cost, and the potential for drug reactions and increased bacterial antimicrobial resistance, are also important considerations. The potential for adverse outcomes with overuse of antibiotics means that this evidence is unlikely to affect recommendations [NICE CG74](#) not to use antibiotics in clean non-prosthetic surgery.

Key references

Bunn F, Jones DJ, Bell-Syer S (2012) [Prophylactic antibiotics to prevent surgical site infection after breast cancer surgery](#). Cochrane Database of Systematic Reviews issue 1: CD005360

Cabaluna ND, Uy GB, Galicia RM et al. (2013) [A randomized, double-blinded placebo-controlled clinical trial of the routine use of preoperative antibiotic prophylaxis in modified radical mastectomy](#). World Journal of Surgery 37: 59–66

Antibiotics in tourniquet surgery

[NICE CG74](#) recommends that when antibiotic prophylaxis is needed, a single dose of antibiotic intravenously on starting anaesthesia should be considered. However, prophylaxis should be given earlier for operations in which a tourniquet is used.

An RCT ($n=106$) in Nigeria by [Akinyoola et al. \(2011\)](#) investigated the effect of administering antibiotics before and after tourniquet application on surgical site infection. Consecutive patients at a single hospital, who were undergoing clean, elective orthopaedic surgery on the lower limb involving a tourniquet, were included. Patients (matched for age, sex, and operation type) were randomised to intravenous cefuroxime administered either 5 minutes before limb exsanguination and tourniquet inflation, or 1 minute after tourniquet inflation (followed in all cases by 3 postoperative antibiotic doses, 8 hours apart). All patients received general anaesthesia (except 2 who were given spinal anaesthesia), and had the tourniquet applied to their thigh.

Most procedures (72%) were open reduction and internal fixation of fractures (with the remainder being mainly soft tissue releases). There was no significant difference in the types of procedure carried out between the groups ($p=0.332$). Patients were followed up for at least 12 months, and surgical site infection (defined as spontaneous pus drainage after suture removal or in association with overt wound dehiscence) was determined by the 2 operating surgeons. Visual analogue scoring of the wound was also performed independently by a

senior registrar in another unit for 28 days after surgery, although it was not clear whether this was used to inform diagnosis of infection.

Significantly fewer surgical site infections were seen in the group who received antibiotics after tourniquet inflation (2/52; 3.9%) than among those who were given antibiotics before inflation (8/54; 14.8%; $p=0.031$).

Limitations of the evidence included that:

- the surgeons performing the operations were also involved in diagnosing wound infection, which may have been a source of bias
- some soft tissue operations were included that would not routinely involve antibiotic prophylaxis under NICE guidance
- no data about the timing of tourniquet release were provided, which may also have been a factor in the outcomes seen.

The evidence suggests that administering antibiotics after, rather than before, tourniquet inflation may be associated with a reduced rate of surgical site infection. This is opposite to the practice currently recommended in [NICE CG74](#), but limitations of the evidence mean that further research in larger trials is needed to confirm findings. This evidence is therefore unlikely to affect current guidance.

Key reference

Akinyoola AL, Adegbehingbe OO, Odunsi A (2011) [Timing of antibiotic prophylaxis in tourniquet surgery](#). *Journal of Foot & Ankle Surgery* 50: 374–6

1.3 [Intraoperative phase](#)

Surgical face masks

Although [NICE CG74](#) recommends that the operating team should wear sterile gowns in the operating theatre during the operation, no recommendations are made specifically about the use of surgical face masks in preventing surgical site infection.

A Cochrane review by [Lipp and Edwards \(2012\)](#) examined whether face masks can prevent surgical site infection. RCTs and quasi-RCTs that compared infection rates with and without the use of disposable face masks, among surgical teams performing clean surgery, were included. A total of 3 trials ($n=2113$) were identified, but heterogeneity prevented meta-analysis.

For the primary outcome of effect on postoperative surgical wound infection (as defined by individual trial authors), no significant effect of wearing masks versus not wearing masks was seen in any of the 3 trials identified.

Limitations of the evidence included that:

- a wide range of types of surgery were included with no sub-analysis of specific types
- none of the studies measured compliance with correct mask wearing
- type of theatre ventilation used (such as conventional versus ultraclean) was not considered, which may have affected infection rates
- type of mask was specified in only 1 study
- the studies were published between 1986 and 2010, during which time mask design may have changed.

The authors concluded that evidence to assess the effect of surgical masks on surgical site infection rates was insufficient and more research is needed. Therefore, this evidence is unlikely to affect [NICE CG74](#). However, there are other reasons for wearing masks beside infection prevention, particularly as part of personal protective equipment for theatre staff. The

[full version of NICE CG74](#) noted that the issue of operating staff protection was beyond the scope of the guideline and is covered by health and safety regulations.

Key reference

Lipp A, Edwards P (2012) [Disposable surgical face masks for preventing surgical wound infection in clean surgery](#). Cochrane Database of Systematic Reviews issue 1: CD002929

Antiseptic skin preparation

[NICE CG74](#) recommends preparing the skin at the surgical site immediately before incision using an antiseptic (aqueous or alcohol-based) preparation: povidone-iodine or chlorhexidine are most suitable. Two reviews recently compared antiseptic skin preparations.

A Cochrane review by [Hadiati et al. \(2012\)](#) compared different types of preoperative skin preparation for preventing infection after caesarean section. Randomised, quasi-randomised, and cluster-randomised trials, evaluating any type of skin preparation of the incision area before elective or emergency caesarean section, were included. Studies of preoperative hand washing or bathing were excluded. A total of 5 trials (n=1462) were identified. Two trials compared incisional drapes with no drapes in women who had all received the same preoperative skin disinfection, and 3 trials compared different antiseptic preparations.

In women who had received skin preparation preoperatively (with either iodine or chlorhexidine, though these antiseptics were not compared directly), the use of drapes versus no drapes did not make a significant difference to the primary outcome of surgical site infection (RR=1.29, 95% CI 0.97 to 1.71, p=0.084; 2 trials, n=1294). There was also no significant difference in infection with parachlorometaxyleneol plus iodine versus iodine alone (RR=0.33, 95% CI 0.04 to 2.99, p=0.33; 1 trial, n=50). A single trial (n=79) comparing alcohol scrub plus iodophor drape versus iodophor scrub without drape reported no infections in either group.

Limitations of the evidence included the small number of trials identified, and the heterogeneity of disinfection methods which made pooling of data difficult. The authors concluded that there was insufficient evidence to determine the most effective type of skin preparation before caesarean section in preventing surgical site infection.

The systematic review by Kamel et al. (2012) (see 'Preoperative showering' in Section 1.2 for details) also examined antiseptic skin preparations. Based on mixed results from 5 RCTs, 2 cohort studies, and 2 case control-studies, the authors stated that conclusions about the most effective antiseptic could not be made. This review included an RCT (n=849) by [Darouiche et al. \(2010\)](#) that specifically compared chlorhexidine with povidone-iodine antiseptics before clean-contaminated surgery. The results indicated that an alcohol-based solution of chlorhexidine appeared to be superior for preventing surgical site infection. Evidence from this RCT was noted during [the decision whether to review NICE CG74](#) in 2011, but it was considered insufficient to warrant an update of the guideline at that time.

Taken together, current evidence suggests that the most effective antiseptic for skin preparation before surgical incision remains uncertain. These data are unlikely to affect recommendations in [NICE CG74](#) to use either povidone-iodine or chlorhexidine, though alcohol-based solutions may be more effective than aqueous solutions.

Key reference

Hadiati DR, Hakimi M, Nurdiati DS (2012) [Skin preparation for preventing infection following caesarean section](#). Cochrane Database of Systematic Reviews issue 9: CD007462

Supporting reference

Darouiche RO, Wall MJ Jr, Itani KM et al. (2010) [Chlorhexidine-alcohol versus povidone-iodine for surgical-site antiseptics](#). New England Journal of Medicine 362: 18–26

Diathermy

[NICE CG74](#) states: do not use diathermy for surgical incision to reduce the risk of surgical site infection.

A Cochrane review by [Charoenkwan et al. \(2012\)](#) investigated the effect of abdominal incision with either scalpel or electrodiathermy on overall wound complications. RCTs comparing rates of wound complications (incorporating several outcome measures, including infection) among patients undergoing major open abdominal surgery, regardless of incision orientation or surgical setting, were included. Quasi-RCTs were excluded. A total of 9 RCTs (n=1901) were identified.

From the studies reporting data for the primary outcome of overall wound complication rate, no difference was seen between patients whose abdominal incisions were made with diathermy or with a scalpel (RR=0.90, 95% CI 0.68 to 1.18, p=0.44; 7 RCTs, n=1559).

Limitations of the evidence included:

- incomplete reporting by most trials, and substantial heterogeneity among trials
- the use of a combined outcome of overall wound complications in the meta-analysis (although most of the RCTs contributing to it did examine wound infection as an outcome);
- only 174 instances of wound complication were recorded among the 1559 patients included in the meta-analysis, therefore the analysis may have been underpowered.

Evidence suggests that abdominal incision with diathermy appears to have no advantage over using a scalpel in reducing wound complications, but more research is needed. This is consistent with current recommendations in [NICE CG74](#) not to use diathermy for surgical incision to reduce surgical site infection risk.

Key reference

[Charoenkwan K, Chotirosniramit N, Rerkasem K \(2012\) Scalpel versus electrosurgery for abdominal incisions. Cochrane Database of Systematic Reviews issue 6: CD005987](#)

Maintaining patient homeostasis

Perioperative oxygen supplementation

[NICE CG74](#) recommends maintaining optimal oxygenation during surgery. In particular, patients should be given sufficient oxygen during major surgery and in the recovery period to ensure that a haemoglobin saturation of more than 95% is maintained. However, it does not make any recommendations about the use of perioperative high inspired oxygen therapy in preventing surgical site infection.

A systematic review and meta-analysis by [Togioka et al. \(2012\)](#) examined the role of perioperative oxygen supplementation in reducing surgical site infection. RCTs in adult populations comparing the perioperative use of supplemented compared with control oxygen concentrations were included. Studies of hyperbaric ventilation were excluded. A total of 7 RCTs (n=2728) were identified. In all 7 of the included trials, the supplemented oxygen group received 80% oxygen during surgery (plus at least 2 hours postoperatively), and the control groups were given either 30% or 35% oxygen.

No significant difference was seen in the primary outcome of surgical site infection rate (as defined by individual trial authors) between the supplemented oxygen and control groups (15.5% versus 17.5% respectively; odds ratio=0.85, 95% CI 0.52 to 1.38, p=0.51; 7 RCTs, n=2728). Several sensitivity analyses (excluding: the largest study; the lowest quality study; the study with an opposite result to other studies; and studies that included nitrous oxide, or that mandated either aggressive or conservative fluid management) did not alter the overall conclusion. However, 2 subgroup analyses did show a significant benefit of supplemented

oxygenation on surgical site infections. Namely, when studies of neuraxial anaesthesia were excluded (OR=0.66, 95% CI 0.46 to 0.93, p=0.02; 5 RCTs, n=1199); and when studies of colorectal surgery only were included (OR=0.48, 95% CI 0.32 to 0.71, p=0.0003; 4 RCTs, n=1039).

Limitations of the evidence included some heterogeneity among the included trials, for example with: antibiotic use, definition of surgical site infection, patient population, and duration of perioperative oxygen supplementation.

[NICE CG74](#) included a [research recommendation](#) about the value of supplemented oxygenation, and this review suggests that perioperative oxygen supplementation does not appear to reduce surgical site infection rate. The evidence is unlikely to affect the recommendation in [NICE CG74](#) to give sufficient oxygen to maintain a haemoglobin saturation of more than 95%. However, as indicated by the subanalyses in which neuraxial anaesthesia was excluded, and colorectal surgery only was included, there may be subgroups of patients for whom supplemented oxygenation could be beneficial. Further research to examine subgroups (incorporating appropriate monitoring of patient response in achieving optimal homeostasis) is needed.

Key reference

Togioka B, Galvagno S, Sumida S et al. (2012) [The role of perioperative high inspired oxygen therapy in reducing surgical site infection: a meta-analysis](#). *Anesthesia & Analgesia* 114: 334–42

Haemodynamic goal-directed therapy

[NICE CG74](#) recommends maintaining optimal oxygenation and adequate perfusion during surgery. It does not make any recommendations specifically about the use of haemodynamic goal-directed therapy (a haemodynamic treatment based on titration of fluid and inotropic drugs to reach normal or supraoptimal physiological endpoints such as cardiac output and oxygen delivery).

A systematic review and meta-analysis by [Dalfino et al. \(2011\)](#) assessed the effect of haemodynamic goal-directed therapy on surgical site infection rates. RCTs of goal-directed versus standard haemodynamic therapy in patients undergoing major surgery were included. Goal-directed therapy was defined as perioperative monitoring and manipulation of haemodynamic parameters to reach normal or supraoptimal values by fluid infusion alone or in combination with inotropic therapy within 8 hours after surgery.

Studies were excluded if:

- they involved mixed populations of critically ill, non-surgical, or postoperative patients with sepsis or organ failure
- they used late haemodynamic optimisation treatment
- there was no description of, or no difference in, optimisation strategies between groups
- therapy was titrated to the same goal in both groups, or not titrated to predefined endpoints.

One of the primary outcomes of the review was surgical site infection (either incisional and organ or space). A total of 26 RCTs (n=4188) were identified involving abdominal (21 trials), cardiac (3 trials) and orthopaedic (2 trials) surgery.

Goal-directed therapy appeared to significantly reduce surgical site infection rate compared with standard therapy (OR=0.58, 95% CI 0.46 to 0.74, p<0.0001; 18 RCTs, n=3550). Similarly significant effects were also seen in sensitivity analyses of: only trials at low risk of bias (14 RCTs; p<0.0001); only high-risk patients (13 RCTs; p=0.0001); and only studies using definitions of surgical site infection consistent with US Centers for Disease Control and Prevention criteria (8 RCTs; p=0.0001).

Limitations of the evidence included: heterogeneity among trials in the monitoring equipment used, the patients, the type and timing of interventions, and in the nature and level of targets; and that the type of control haemodynamic therapy used across the trials was not discussed in the review.

The evidence suggests that haemodynamic goal-directed therapy appears to reduce surgical site infection rates, which is broadly consistent with recommendations in [NICE CG74](#) to maintain optimal oxygenation and adequate perfusion during surgery.

It should also be noted that intraoperative fluid management is a [high impact innovation](#) (as set out by the Department of Health's 2011 report 'Innovation Health and Wealth, Accelerating Adoption and Diffusion in the NHS'), and is also a Commissioning for quality and innovation (CQUIN) [pre-qualification criterion for 2013/14](#).

Additional information about the review by Dalfino et al. (2011) is also available in an independent [critical appraisal report](#) produced for the Centre for Reviews and Dissemination's Database of Abstracts of Reviews of Effects.

Key reference

Dalfino L, Giglio MT, Puntillo F et al. (2011) [Haemodynamic goal-directed therapy and postoperative infections: earlier is better. A systematic review and meta-analysis](#). *Critical Care* 153: R154

Supporting reference

Centre for Reviews and Dissemination (2012) [Haemodynamic goal-directed therapy and postoperative infections: earlier is better. A systematic review and meta-analysis](#). Database of Abstracts of Reviews of Effects

Antiseptic and antimicrobial agents before wound closure

Although [NICE CG74](#) makes recommendations about the use of intraoperative topical skin disinfection to reduce the risk of surgical site infection, it does not make any recommendations about the use of antimicrobial implants before wound closure.

A double-blind RCT (n=720) in Germany by [Schimmer et al. \(2012\)](#) examined the use of a retrosternal gentamicin-collagen sponge in reducing wound complications after heart surgery. Patients aged 18 years or over at a single hospital, undergoing elective or emergency cardiac surgery via median sternotomy (first or resternotomy), and with no preoperative signs of thoracic inflammation, were included. Exclusion criteria were: existing osteitis, allergy to aminoglycoside antibiotics, immunosuppressive therapy, immunological disease, and pregnant or lactating women. Patients were randomised to implantation with a collagen sponge (placebo) or an identical sponge containing 2 mg gentamicin sulphate. The sponges were implanted retrosternally after preliminary placement of the sternal wiring, and the sternum was then wired and closed. The wound was sutured and then covered with a sterile dressing. All patients received intravenous cefuroxime 30 minutes before surgery and for up to 48 hours after. Patients were examined daily until discharged for signs of deep sternal wound infection (as defined by the US Centers for Disease Control and Prevention criteria).

For the primary outcome of deep sternal wound infection within 30 days, significantly fewer infections were seen after using the gentamicin sponge (2/353; 0.56%) than the placebo sponge (13/367; 3.52%; p=0.014). There was however no significant difference in the incidence of superficial sternal wound infection between the gentamicin (7/353; 1.98%) and placebo groups (11/367; 2.98%; p=0.47).

Limitations of the evidence included that:

- 80 patients were lost after randomisation (40 after revision surgery of bleeding, 20 after use of the wrong sponge, and 20 deaths)
- most patients (52.9%) underwent coronary artery bypass grafting but the type of vein used was not specified, which may have affected infection rates

- the trial did not examine the potential of the sponge as a source or promoter of infection, for example by including a 3rd arm with no sponge.

The evidence suggests that a gentamicin-impregnated sponge may reduce rates of deep sternal wound infection after cardiac surgery via median sternotomy, but limitations of the evidence mean that results are unlikely to affect [NICE CG74](#). The [full version of NICE CG74](#) made the following research recommendation: 'What is the cost effectiveness of collagen implants with antibiotics or antiseptics in the reduction in the incidence of surgical site infection?' This RCT did not examine cost effectiveness of the intervention.

Key reference

Schimmer C, Ozkur M, Sinha B et al. (2012) [Gentamicin-collagen sponge reduces sternal wound complications after heart surgery: a controlled, prospectively randomized, double-blind study](#). *Journal of Thoracic and Cardiovascular Surgery* 143: 194–200

Wound dressings

[NICE CG74](#) recommends covering surgical incisions with an appropriate interactive dressing at the end of the operation. However, it does not make any recommendations about specific types of dressing.

All dressings

A Cochrane review by [Dumville et al. \(2011\)](#) investigated wound dressings in the prevention of surgical site infections. RCTs that compared either different wound dressings, or dressing versus no dressing, in patients with postoperative wounds (of any contamination level) healing by primary intention, were included. Dressings must have been applied in the operating theatre. Trials of procedures involving graft sites, or in which patients had infected wounds at baseline, were excluded. A total of 16 RCTs (n=2578) were identified.

The authors stated that among the included trials, there was no evidence that covering wounds reduced the primary outcome of rate of surgical site infection (as defined by the US Centers for Disease Control and Prevention criteria, or individual trial authors), and that no particular wound dressing appeared to be better than any others, or than leaving the wound uncovered.

Limitations of the evidence included that:

- most modern dressings were compared only with basic wound contact dressings such as gauze or absorbent dressings, therefore performance versus other modern types was not clear
- many trials were small, and most studies were either assessed as poor quality, or could not be assessed because of incomplete reporting
- only 4 of the 16 studies were published within the last 10 years, during which time practices may have changed.

The authors concluded that in the absence of clear evidence of benefit of any particular dressing type on surgical site infection risk, wound dressings should be chosen on the basis of cost and the properties of the dressing. This evidence is unlikely to affect [NICE CG74](#). Further research is needed, involving comparisons of modern wound dressings.

Key reference

Dumville JC, Walter CJ, Sharp CA et al. (2011) [Dressings for the prevention of surgical site infection](#). *Cochrane Database of Systematic Reviews* issue 7: CD003091

Silver nylon dressings

An RCT (n=110) in Florida, USA by [Krieger et al. \(2011\)](#) evaluated silver nylon dressings for preventing surgical site infection. Patients at a university-based tertiary referral centre, undergoing elective colorectal surgery with an anticipated abdominal incision length of at least 3 cm, were included. Exclusion criteria were: known allergy to silver; signs of abdominal wall infection; conditions preventing full skin closure during the operation; presence of abdominal mesh; pregnant or lactating women; and receipt of antibiotics within 1 week of surgery. Patients were randomised to a silver nylon or gauze dressing, which was applied in the operating room after surgery. All patients underwent a standard preoperative procedure including administration of antibiotics 30–60 minutes before surgery (ertapenem, or an alternative in people with penicillin allergy) but no mechanical bowel preparation (except for left colon or rectal surgery). Patients were followed up by appointment 7–10 days after surgery and by telephone after 30 days. Surgical site infection was determined by an unblinded physician from the surgical team using the US Centers for Disease Control and Prevention guidelines.

For the primary outcome of developing a surgical site infection, the total number of infections was lower with silver nylon dressings (7/55; 13%) than with gauze (18/54; 33%; p=0.011). A multivariate analysis excluded the possibility that other risk factors (such as diabetes, smoking or obesity) may have been predictors of infection.

Limitations of the evidence included that:

- the silver dressing was compared with gauze, therefore performance versus a modern dressing could not be gauged
- surgical site infection was diagnosed by an unblinded member of the operating team, which may have introduced bias
- although incision length was used to recruit patients, this was not measured for every patient.

The evidence suggests that silver nylon dressings appear to be more effective than gauze in preventing surgical site infections. Due to the limitations noted, this evidence is unlikely to affect [NICE CG74](#). Further research is needed to compare silver dressings with other modern wound dressings used in current practice.

Key reference

[Krieger BR, Davis DM, Sanchez JE et al. \(2011\) The use of silver nylon in preventing surgical site infections following colon and rectal surgery. *Diseases of the Colon & Rectum* 54: 1014–9](#)

Wound closure methods

[NICE CG74](#) does not make any recommendations about specific types of wound closure in preventing surgical site infection.

Staples versus sutures

A Cochrane review by [Biancari and Tiozzo \(2012\)](#) compared surgical site infection rates after the use of staples or sutures. RCTs comparing staples with any type of suture for wound closure after saphenous vein harvesting (excluding endoscopic vein harvest) for coronary artery bypass grafting, were included. Other methods of wound closure such as glue were excluded. A total of 4 studies were identified, but only 3 studies (148 wounds closed with staples, 175 closed with sutures) were included in the meta-analysis (the 4th study used staples to close one half of the wound, and sutures to close the other half, so was excluded).

No significant difference was seen in the primary outcome of surgical site infection rate (as defined by individual trial authors) between the use of staples (16/148; 10.8%) and sutures (14/174; 8%) for wound closure (RR=1.20, 95% CI 0.60 to 2.39, p=0.6).

Limitations of the evidence included that:

- only leg wounds after saphenous vein harvest were included, therefore results may not be transferable to other types of wound or surgery
- all studies were published in or before 2000 and newer products may now be in use
- the limited patient numbers may not be sufficient to detect clinically significant differences in infection rate
- the risk of bias in the included studies was reported to be high
- no data were provided about the experience of the surgeons performing the procedure and wound closure.

The authors concluded that there appears to be no evidence of a difference in the risk of surgical site infection when leg wounds are closed with staples or with sutures after vein harvesting for coronary artery bypass grafting. This evidence is therefore unlikely to affect [NICE CG74](#), but additional research focusing on other specific patient groups may be useful.

Key reference

[Biancari F, Tiozzo V \(2012\) Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery. Cochrane Database of Systematic Reviews issue 5: CD008057](#)

Antimicrobial sutures

Two systematic reviews recently investigated the effect of antimicrobial-coated sutures on surgical site infections.

A systematic review and meta-analysis by [Wang et al. \(2013\)](#) examined RCTs comparing sutures coated with triclosan (a broad-spectrum antiseptic agent) versus conventional uncoated sutures in preventing surgical site infections. A total of 17 RCTs (n=3720) were identified.

For the primary outcome of incidence of surgical site infection, from a fixed-effects model, triclosan-coated sutures appeared to significantly reduce infection rate versus uncoated sutures (RR=0.70, 95% CI 0.57 to 0.85, p<0.001; 17 RCTs, n=3720). Subanalyses by type of surgical procedure suggested that the effect was only significant with abdominal surgery (RR=0.69, 95% CI 0.50 to 0.97, p=0.03; 7 RCTs, n=1562), and not with breast (p=0.114; 3 RCTs, n=268) or cardiac surgery (p=0.18; 3 RCTs, n=933).

Limitations of the evidence included that:

- not all trials used diagnostic criteria for surgical site infection as set out by the US Centers for Disease Control and Prevention
- some trials used silk sutures as the comparator, which are not used in the UK
- only 3 trials were assessed as low risk of bias, with the remainder of uncertain or high risk of bias
- surgical site infection was not a primary end point in 3 trials
- there was heterogeneity among the trials in the type of patients and surgical procedures included.

A second systematic review and meta-analysis by [Edmiston et al. \(2013\)](#) also examined triclosan-coated sutures in preventing surgical site infections. A total of 13 RCTs (n=3568) were identified. Although the review by Edmiston et al. did not include all of the trials covered by the Wang et al. (2013) review, it did include 1 additional recent trial of colorectal surgery.

For the primary outcome of surgical site infection, meta-analysis of the 13 included trials showed a significant reduction in risk of infection with triclosan-coated versus uncoated sutures in both a fixed effects model (RR=0.73, 95% CI 0.59 to 0.91, p=0.005) and a random effects model (RR=0.69, 95% CI 0.53 to 0.92, p=0.011). The trial not included by the Wang et al. (2013) review indicated a significant effect of coated sutures among patients undergoing

colorectal surgery, consistent with the subgroup analysis by Wang et al. (2013) that reported a significant effect of coated sutures in reducing infection after abdominal surgery.

Limitations of the evidence included that:

- a comprehensive quality assessment of every trial included was not performed (scoring based on Oxford Centre for Evidence-based Medicine criteria indicated that 8 trials were level 1b evidence, and 5 trials were lower than level 1b)
- not all studies used diagnostic criteria for surgical site infection as set out by the US Centers for Disease Control and Prevention
- reporting of antimicrobial prophylaxis, and glycaemic and body temperature control, was inconsistent across trials
- patient risk factors were not addressed by the included trials.

Taken together, the evidence suggests that antimicrobial-coated sutures may reduce surgical site infection risk versus uncoated sutures, although this effect may be specific to particular types of surgery (such as abdominal procedures). This evidence may, therefore, have a potential impact on [NICE CG74](#), however details of any impact are outside the scope of the Evidence Update. Decisions on how the new evidence may impact guidance will not be possible until the guidance is reviewed by NICE following its published processes and methods.

A large RCT investigating the reduction of surgical site infection with triclosan-coated sutures in patients undergoing hip or knee replacement [is currently underway in the UK](#). This is consistent with the need for further data as set out in the [research recommendation in NICE CG74](#) about which closure methods reduce surgical site infection.

Key references

Edmiston CE, Daoud FC, Leaper DJ (2013) [Is there an evidence-based argument for embracing an antimicrobial \(triclosan\)-coated suture technology to reduce the risk for surgical-site infections?: A meta-analysis](#). *Surgery* 154: 89–100

Wang ZX, Jiang CP, Cao Y et al. (2013) [Systematic review and meta-analysis of triclosan-coated sutures for the prevention of surgical-site infection](#). *British Journal of Surgery* 100: 465–73

Minimally invasive surgery

[NICE CG74](#) does not make any recommendations about the use of minimally invasive surgery in preventing surgical site infection. Two systematic reviews recently examined the effect of laparoscopy on postoperative infections.

A systematic review and meta-analysis by [Shabanzadeh and Sorensen \(2012\)](#) investigated surgical site infection rate after laparoscopy in obese patients. RCTs and observational studies of obese patients (defined as body mass index of 30 or more, or an International Classification of Disease diagnosis of obesity or morbid obesity) comparing the effect of laparoscopic versus open surgery on surgical site infection were included. Infection was defined as the presence of pus, or a superficial, deep, or organ space infection (according to the US Centers for Disease Control and Prevention criteria) in the 30 days after surgery. A total of 8 RCTs (n=615) and 36 observational studies (n=58,755) were included. The RCTs were all of bariatric surgery (except 1 of appendicectomy), whereas the observational studies examined a wider range of procedures (cholecystectomy, appendicectomy, bariatric, hernia, colorectal, and general surgery).

Separate meta-analyses were performed of the RCTs and of the observational studies. A significantly lower rate of surgical site infection was seen after laparoscopy than open surgery in both of these analyses (RCTs: odds ratio=0.19, 95% CI 0.08 to 0.45, p=0.0002; observational studies: odds ratio=0.33, 95% CI 0.26 to 0.42, p=0.00001).

Limitations of the evidence included that:

- inconsistent (or unreported) definitions of surgical site infection were used across the studies
- none of the RCTs were set up to assess specifically the difference in surgical site infections between laparoscopic and open surgery (and may therefore have been underpowered)
- there were several issues among the observational studies, including different study designs, lack of adjustment for confounders, and inconsistent reporting of conversions to open surgery.

A systematic review by [Phatak et al. \(2012\)](#) examined different types of intervention (including laparoscopy) and their effects on surgical site infections after colorectal surgery. Systematic reviews from the Cochrane database evaluating interventions (other than antibiotics) to prevent surgical site infections after colorectal surgery were included. A total of 9 Cochrane reviews were identified, covering: anastomotic technique (2 reviews), mechanical bowel preparation, preoperative chlorhexidine bathing, early postoperative feeding, adhesive drapes, diverting ileostomy, use of drains, and laparoscopic versus open surgery. Bayesian meta-analysis was then used to re-analyse data from the Cochrane reviews. Bayesian methods can provide more detailed interpretation of the evidence base, such as the probability of a specific level of treatment effect after an intervention (for example, at least a 20% reduction in surgical site infections).

After standard meta-analysis, 2 of the interventions identified were shown to significantly reduce the risk of surgical site infections: laparoscopic colorectal surgery (RR=0.53, 95% CI 0.37 to 0.77, p=0.0007), and not using adhesive drapes (RR=0.81, 95% CI 0.67 to 0.98, p=0.03). However, from Bayesian analysis, only laparoscopy had a high probability (99%) of bringing about a greater than 20% reduction in surgical site infections.

Limitations of the evidence included that:

- surgical site infections were not the primary outcome of many trials included in the Cochrane reviews
- the Bayesian analyses only focused on 1 outcome (surgical site infections) and did not consider other potential benefits and harms
- only reviews from the Cochrane database were included
- despite the value of Bayesian analysis it cannot overcome methodological issues with the original trials.

Taken together, the evidence suggests that laparoscopy appears to be associated with lower rates of surgical site infection than open surgery among some subgroups; namely, obese patients, and those undergoing colorectal surgery. However, reduced rates of infection may not be a primary reason to undertake minimally invasive surgery. Other criteria and risk factors should also contribute to patient selection for laparoscopy. This evidence is therefore unlikely to affect [NICE CG74](#).

Key references

[Phatak UR, Pedroza C, Millas SG et al. \(2012\) Revisiting the effectiveness of interventions to decrease surgical site infections in colorectal surgery: a Bayesian perspective. Surgery 152: 202–11](#)

[Shabanzadeh DM, Sorensen LT \(2012\) Laparoscopic surgery compared with open surgery decreases surgical site infection in obese patients: a systematic review and meta-analysis. Annals of Surgery 256: 934–45](#)

Wound-edge protection devices

[NICE CG74](#) does not make any recommendations about the use of ‘wound edge protection devices’ (equipment used in abdominal surgery to protect the incision edges, comprising a semi-rigid plastic ring inserted into the incision with drapes attached to the circumference; also known as ‘wound guards’).

A systematic review and meta-analysis by [Gheorghe et al. \(2012\)](#) investigated the effect of wound guards on surgical site infections after open abdominal surgery. Controlled trials, prospective cohort studies, and case control studies of patients undergoing elective or emergency open abdominal surgery, comparing wound guards with control, were included. Any wound guard device in which incision edges were covered with an impervious plastic sheet was eligible. Exclusion criteria were studies examining other devices such as adhesive drapes (unless wound guards were also assessed), and those in which surgical site infections were defined only in terms of bacteria cultured or enumerated. A total of 12 studies (10 RCTs and 2 controlled trials; n=1933) were identified. Three of the trials involved generic abdominal surgery, 2 were of appendectomies, and the remainder mostly involved colorectal surgery.

The authors indicated that none of the included studies were of sufficient quality to be included in a formal meta-analysis. However, an exploratory meta-analysis using a random effects model suggested a potentially significant benefit of wound guards in reducing surgical site infection risk (RR=0.60, 95% CI 0.41 to 0.86, p=0.005).

Limitations of the evidence included that:

- the definition of surgical site infection varied considerably across the trials (only 2 used recognised definitions, with trial authors using their own definitions in the remainder)
- all of the included trials were assessed as being at medium or high risk of bias
- the type of wound guard used differed among studies, with the 3 most recent trials using a different device to earlier studies
- adjustment for risk-factors for surgical site infection was not widely performed, particularly in the older trials.

The authors concluded that wound-edge protection devices may reduce the surgical site infection rate after open abdominal surgery, but the current lack of high-quality studies means that more research is needed. This evidence is unlikely to affect [NICE CG74](#).

A large RCT investigating the effect of wound-edge protection devices on surgical site infection [is currently underway in the UK](#).

Key reference

[Gheorghe A, Calvert M, Pinkney TD et al. \(2012\) Systematic review of the clinical effectiveness of wound-edge protection devices in reducing surgical site infection in patients undergoing open abdominal surgery. Annals of Surgery 255: 1017–29](#)

1.4 [Postoperative phase](#)

Negative pressure wound therapy (NPWT)

[NICE CG74](#) does not make any recommendations about the use of NPWT in preventing surgical site infection. Two RCTs recently investigated the use of NPWT in different patient groups.

An RCT (n=81) in Washington DC, United States by [Masden et al. \(2012\)](#) examined the effect of NPWT on surgical site infection rates in patients with multiple comorbidities. Patients presenting to a single tertiary wound-healing centre (who were often referred after failed care of their wounds by other centres), for closure of abdominal or lower limb wounds, were included. Patients with adhesive tape allergies or any other potential for intolerance to NPWT,

and those with amputations distal to the forefoot (NPWT dressings are not easily applied to small irregular surfaces), were excluded. All wounds were initially closed with polypropylene sutures and staples, and wrapped in gauze. Patients were then randomised to either NPWT or to control (dry dressing with a non-adhesive silicone layer plus a silver layer). Wounds were examined by blinded researchers at 3 days, and then at the first and any subsequent outpatient visits; average follow-up was 113 days. Infection was defined as mild (erythema, inflammation) or severe (purulence, fever, leucocytosis).

For the primary outcome of wound infection, there was no significant difference between the NPWT group (3/44; 6.8%) and control group (5/37; 13.5%, $p=0.46$). Limitations of the evidence included the relatively small number of patients, and the use of a non-adhesive silicone dressing plus silver layer in the control group, which may not represent the type of dressing used in wider clinical practice.

A second, multicentre RCT ($n=249$ patients, 263 fractures) in the United States by [Stannard et al. \(2012\)](#) investigated the effect of NPWT on infection rate after lower limb fracture. Patients from 4 centres with blunt, high-risk, high-energy trauma (tibial plateau, pilon, or calcaneus fracture) needing surgical stabilisation were included. Open fractures, or fractures operated on at least 16 days after injury (21 days for pilon fractures), were excluded. After open reduction and internal fixation of fractures, patients were then randomised to either NPWT or standard dressing. Dressings or NPWT were applied in the operating room, with dressings changed on day 2, then every 1 or 2 days. Patients were discharged once wound drainage was minimal. Primary outcome data for acute infection (during hospitalisation) and late infection were recorded. Infection was defined using a combination of clinical observation (presence of pus, erythema, fever, chills) and laboratory data.

Significantly more infections were seen in the standard dressings group (23/122; 19%) than the NPWT group (14/141; 10%; $p=0.049$), and risk of infection was greater with standard dressings (RR=1.9, 95% 1.03 to 3.55). The authors also noted that patients in the NPWT group were discharged 0.5 days earlier than those in the dressings group (although this was non-significant, $p=0.103$), which may suggest that costs of NPWT could be offset by reduced hospital stays.

Limitations of the evidence included that:

- length of follow-up was not clear
- 3 very different fracture types were examined, therefore results may not necessarily be extrapolated to individual types
- patients from 4 centres were included, which may have introduced heterogeneity of treatment and care
- trauma can be variable in terms of injury mechanism and the nature of fractures.

Taken together, the evidence suggests that NPWT appears to reduce the surgical site infection rate after invasive treatment of lower limb trauma, but may be less effective in other patient groups such as those with multiple comorbidities. Limitations with current data mean that more research is needed to confirm findings and to further examine the groups of patients who may benefit from NPWT, therefore this evidence is unlikely to affect [NICE CG74](#).

Key references

Masden D, Goldstein J, Endara M et al. (2012) [Negative pressure wound therapy for at-risk surgical closures in patients with multiple comorbidities: a prospective randomized controlled study](#). *Annals of Surgery* 255: 1043–7

Stannard JP, Volgas DA, McGwin G 3rd et al. (2012) [Incisional negative pressure wound therapy after high-risk lower extremity fractures](#). *Journal of Orthopaedic Trauma* 26: 37–42

2 New evidence uncertainties

During the development of the Evidence Update, the following evidence uncertainties were identified for the UK Database of Uncertainties about the Effects of Treatments (UK DUETs).

Preoperative phase

- [Preoperative bathing or showering with skin antiseptics to prevent surgical site infection](#)
- [Preoperative hair removal to reduce surgical site infection](#)
- [Removal of nail polish and finger rings to prevent surgical infection](#)
- [Local antibiotic and antiseptic prophylaxis in cardiac implantable electronic device implantation](#)
- [Antibiotic prophylaxis for hernia repair](#)
- [Prophylactic antibiotics to prevent surgical site infection after breast cancer surgery](#)

Intraoperative phase

- [Disposable surgical face masks for preventing surgical wound infection in clean surgery](#)
- [Skin preparation for preventing infection following caesarean section](#)
- [Scalpel versus electrosurgery for abdominal incisions](#)
- [Dressings for the prevention of surgical site infection](#)
- [Staples versus sutures for closing leg wounds after vein graft harvesting for coronary artery bypass surgery](#)
- [Wound edge protectors to reduce surgical site infection in open abdominal surgery](#)

Further evidence uncertainties for surgical site infection can be found in the [UK DUETs database](#) and in the [NICE research recommendations database](#).

UK DUETs was established to publish uncertainties about the effects of treatments that cannot currently be answered by referring to reliable up-to-date systematic reviews of existing research evidence.

Appendix A: Methodology

Scope

The scope of this Evidence Update is taken from the scope of the reference guidance:

- [Surgical site infection](#). NICE clinical guideline 74 (2008).

Searches

The literature was searched to identify studies and reviews relevant to the scope. Searches were conducted of the following databases, covering the dates 13 April 2011 (the end of the search period for [the latest review of the need to update NICE clinical guideline 74](#)) to 8 January 2013:

- CDSR (Cochrane Database of Systematic Reviews)
- CENTRAL (Cochrane Central Register of Controlled Trials)
- CINAHL (Cumulative Index to Nursing and Allied Health Literature)
- DARE (Database of Abstracts of Reviews of Effects)
- EMBASE (Excerpta Medica database)
- HTA (Health Technology Assessment) database
- MEDLINE (Medical Literature Analysis and Retrieval System Online)
- MEDLINE In-Process
- NHS EED (Economic Evaluation Database)

Table 1 provides details of the MEDLINE search strategy used (based on the search strategy for the reference guidance), which was adapted to search the other databases listed above. The search strategy was used in conjunction with validated Scottish Intercollegiate Guidelines Network [search filters for RCTs and systematic reviews](#).

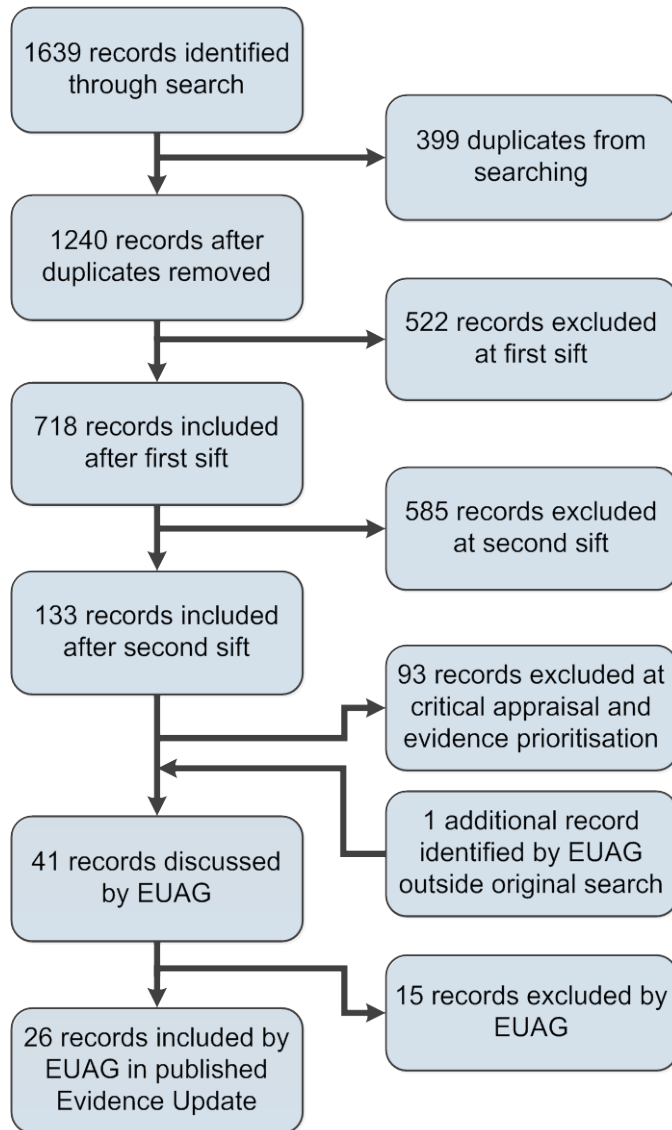
Additionally, 1 study (Edmiston et al. 2013) was identified outside of the literature search. Figure 1 provides details of the evidence selection process. The long list of evidence excluded after review by the Chair of the EUAG, and the full search strategies, are available on request from contactus@evidence.nhs.uk

There is more information about [how NICE Evidence Updates are developed](#) on the NICE Evidence Services website.

Table 1 MEDLINE search strategy (adapted for individual databases)

1	Surgical Wound Infection/	4	Wound Infection/
2	((surger\$ or surgical\$) adj3 (infect\$ or sepsis or septic\$ or dehiscen\$ or separat\$)).ti,ab.	5	(SSI or SSTI).ti,ab.
3	((wound? or incision\$) adj3 (infect\$ or sepsis or septic\$ or dehiscen\$ or separat\$)).ti,ab.	6	Surgical Wound Dehiscence/
		7	or/1-6

Figure 1 Flow chart of the evidence selection process



EUAG – Evidence Update Advisory Group

Appendix B: The Evidence Update Advisory Group and Evidence Update project team

Evidence Update Advisory Group

The Evidence Update Advisory Group is a group of topic experts who review the prioritised evidence obtained from the literature search and provide the commentary for the Evidence Update.

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