Swedish operating room nurses' preventive interventions to reduce bacterial growth and surgical site infections, and to increase comfort in patients undergoing surgery
To

My family
Swedish operating room nurses' preventive interventions to reduce bacterial growth and surgical site infections, and to increase comfort in patients undergoing surgery
Cover image: Camilla Wistrand

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Abstract

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Surgical site infection is a major postoperative complication that causes patient suffering and is costly for society. The general aim of this thesis was to test and describe interventions performed by operating room (OR) nurses to prevent bacterial growth in surgical patients, with the intent to prevent surgical site infections (SSIs) whilst increase patients comfort.

In studies I and II, 220 pacemaker patients were tested to compare preheated skin disinfection with room-temperature skin disinfection regarding bacterial growth, skin temperature and patient experience. Preheated skin disinfection was not less effective compared to room-temperature skin disinfection in reducing bacterial growth after skin disinfection and there were no differences regarding SSIs three month postoperatively. Preheated skin disinfection reduces skin heat loss and was perceived as more pleasant compared to room-temperature skin disinfection.

In study III, 12 OR nurses were examined regarding bacterial growth on their hands and at the sterile glove cuff end after surgical hand disinfection and again after wearing sterile surgical gloves during surgery. They were compared with a control group of 13 non-health care workers. OR nurses’ hands had higher amounts of bacterial growth at two of three culture sites after surgical hand disinfection compared with the control group, and the bacterial growth increased in both groups with time during surgery. There seems to be a risk of bacterial growth at the glove cuff end during surgery, involving the same type of bacteria as isolated from the hands.

In study IV, 890 OR nurses answered an online questionnaire describing OR nurses interventions guided by national guidelines to reduce SSIs, such as preparation of the patient skin, patient temperature, and OR materials used. The proportion of the OR nurses who complied with the national guidelines preventive interventions was high: skin disinfection solution (93.5%), drapes (97.4%) and gowns (83.8%), and double gloves (73%). However, when guidelines were lacking the interventions differed.

Keywords: skin disinfection, patient experience, skin temperature, intra-operative, surgical site infection, bacterial growth, recolonization.

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<td>Bacteria isolated from cultures</td>
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<tr>
<td>C</td>
<td>Celsius</td>
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<tr>
<td>CI</td>
<td>Confidence interval</td>
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<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention (USA)</td>
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<td>CDS</td>
<td>Cold Discomfort Scale</td>
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<tr>
<td>CFU</td>
<td>Colony-forming units</td>
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<tr>
<td>Commensal bacteria</td>
<td>Symbiotic relationship between two populations without harm to each other</td>
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<tr>
<td>CoNS</td>
<td>Coagulase-negative staphylococci</td>
</tr>
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<td>Contamination</td>
<td>Bacterial contamination of otherwise sterile area</td>
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<td>CRT</td>
<td>Cardiac resynchronization therapy</td>
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<tr>
<td>DDD</td>
<td>Dual chamber rate adaptive pacemaker</td>
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<td>HCW</td>
<td>Health care worker</td>
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<td>HLR</td>
<td>Heart and lung resuscitation</td>
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<td>ICD</td>
<td>Implantable cardioverter–defibrillator</td>
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<tr>
<td>IQR</td>
<td>Interquartile range</td>
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<tr>
<td>IR</td>
<td>Infrared</td>
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<tr>
<td>NICE</td>
<td>National Institute for Health and Care Excellence (UK)</td>
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<tr>
<td>NRS</td>
<td>Numerical rating scale</td>
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<td>OR</td>
<td>Operating room</td>
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<tr>
<td>Recolonization</td>
<td>Bacterial regrowth after skin disinfection</td>
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<tr>
<td>RCT</td>
<td>Randomized controlled trial</td>
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<tr>
<td>Resident bacteria</td>
<td>Bacteria living in a specific area of the body</td>
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<tr>
<td>SSI</td>
<td>Surgical site infection</td>
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<tr>
<td>Transient bacteria</td>
<td>Bacteria temporarily living on the skin surface</td>
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<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
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<tr>
<td>VVI</td>
<td>Single ventricular rate adaptive pacemaker</td>
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List of original papers

This thesis is based on the following original papers, which will be referred to by their Roman numerals:


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Preface

When I began to work as an operating room (OR) nurse, I struggled to keep myself and my surroundings as sterile as possible. It is demanding to maintain a high hygiene standard, especially when bacteria are invisible to the human eye. One of the responsibilities of OR nurses is to provide the best possible care for the patient to prevent suffering and complications. The patient is surrounded with a surgical team, each with their own perspective of what constitutes the best possible outcome for the patient. My perspective and/or work involve many preventive interventions to reduce surgical site infections (SSIs) in the patient. Of these many preventive interventions, one is preparing the skin of the patient. The skin of the patient is routinely disinfected directly prior to surgery. It was when I first performed the skin disinfection on a patient who was awake that I realized that the skin disinfection process felt uncomfortably cold for the patient. The question “why don’t we preheat the solution?” was the starting point for this dissertation, and immediately thereafter, “is it as effective and safe for the patient?”
Background

Patient safety
Patient safety, threatened by health care-associated infections, is of international concern. With emerging antibiotic resistance, it is important to find safe preventive interventions for the patients undergoing surgery. Compliance with several interventions is needed to provide optimal care and safety for the patient. The evidence-based national guidelines for health care can be found in the online Handbook for Healthcare. SSI is a patient injury which should be prevented, and a report from the Swedish Association of local Authorities and Regions showed that among nosocomial infections, the third most common infection was SSIs. Swedish law regarding patient safety (2010:659) states that health care workers (HCWs) should lead and control the activity in such a way that good care is sustained and should also provide needed interventions to prevent patient injury. There are many strategies to prevent SSIs at the operating departments, such as following care bundles, which provide for correct administration of, for example, antibiotics, and for correct hair removal, preservation of normothermia, and correct skin disinfection. Moreover, the Handbook for Healthcare guides the HCW to use the right strategies and interventions to minimize bacterial contamination in the surgical patient during surgery, such as employing basic hygiene procedures, controlled OR ventilation, sterile material, and preoperative skin preparation of patients and of hands of the HCWs.

OR nurses
Internationally, there are differences concerning which profession is responsible for preparing the patient with respect to hygienic procedures such as skin disinfection at the OR. It may be nurses with different educational levels, or it may be the surgeon. In Sweden, it is the OR nurse who prepares the patient for the surgical procedure at the OR. This does not include any part of the patient anaesthesia, which is performed by the team of anaesthesiologists and nurse anaesthetists. In Sweden, OR nurses have a minimum of four years of education, comprising three years to achieve a nursing degree, which includes a bachelor’s degree, followed by one year of postgraduate education at an advanced level directed towards OR care. OR nurses’ procedures are designed to provide a secure environment for the patient, which includes ensuring a hygienic, aseptic...
environment; preparing the patient skin; draping; maintaining body temperature; caring for the instruments; and fulfilling assistance and circulation roles (i.e. non-sterile person assisting the sterile surgical team).\(^{10, 11}\)

**Surgical site infection**

SSIs are the third most common among hospital-acquired infections in Sweden, which is in concordance with data from the United Kingdom\(^7, 12\). The probability of acquiring an SSI in general is approximately 10\%, with variations depending on surgical specialties and registration.\(^{13, 14}\) Surgical wounds are classified by different sources of expected contamination. The four-graded classification is class I, clean; class II, clean–contaminated; class III, contaminated; and class IV, dirty–infected.\(^{15}\) The classification is often associated with the proportion of SSIs.\(^{14, 16}\) Cardiac device implantation is classified as clean surgery, and the incidence of SSI is approximately 1\%,\(^{17, 18}\) and according to the Swedish pacemaker registry for 2015, about 0.6\%.\(^{19}\) It is difficult to assess additional costs for SSIs. Depending on the location of the SSI, a severe SSI might be one that occurs after open heart surgery, where a deep sternal infection can double or even triple the usual cost of treatment.\(^{20-22}\) For example, the additional mean cost for treatment of a deep sternal infection in Örebro (Sweden) in 2006 was calculated to be approximately 130,000 SEK (14,481 EUR).\(^{23}\)

To produce an accurate description of SSIs, it is crucial to use consistent criteria for diagnosis of SSIs, and today the definition of SSI most frequently referred to in the literature is that of the U.S. Centers for Disease Control (CDC).\(^{15}\) The CDC’s criteria for SSIs are divided into three main classifications, such as superficial incisional SSI, deep incisional SSI, and organ/space SSI. A common criterion is that the SSI occur within 30 days, or within one year, if an implant is in place.\(^{15}\)

Many SSIs are caused by the commensal skin flora, such as coagulase-negative staphylococci (CoNS),\(^{24-26}\) which are the microorganisms that are the most difficult to reduce by skin disinfection; hence, they inhabit the lower level of the skin such as in the hair follicles and sebaceous glands.\(^{13, 27}\) These microorganisms are often slow growing and are often seen in SSIs when foreign materials are implanted or when the patient has a depressed immune defence. If the skin or wound is contaminated by virulent *Staphylococcus aureus*, then all individuals are at risk of acquiring an SSI.\(^{4, 13, 18, 28}\) Other risk factors for SSIs are surgical technique and patient characteristics. Moreover, the type of surgical procedure influences the
risk for SSI, depending on the use of diathermy, and on drainage, foreign material, surgical classification, and haematoma. During anaesthesia, the timing is crucial regarding antibiotic administration and maintaining patient body temperature. The patient may have risk factors such as diabetes, obesity, high age, malnutrition, smoking, eczema, and so forth.15

**The human skin flora**

The skin is an organ that among other things protects the tissue and organs inside the body from the outside environment. Bacteria inhabiting the skin are involved in protecting and maintaining a healthy skin barrier.29 Bacteria found on the human skin are divided into two groups, transient and resident bacteria. The resident bacteria are present permanently, while the transient bacteria more frequently move between humans. The microorganisms that are transient are more easily removed than the resident ones, which always are present in the host. Under normal circumstances, the transient bacteria are unable to persist on the skin for a longer time due to competition from the resident bacteria.29 The most abundant microorganisms on the human skin are mainly CoNS, *Corynebacterium*, and *Propionibacterium acnes*.30, 31 Bacteria can be found at different levels of the skin. Many colonize the skin surface, but bacteria also inhabit deeper layers of the skin, in hair follicles and sebaceous glands.30, 32 The density of microorganisms is higher on sebaceous-rich and moist skin sites, and the total number of aerobic bacteria found on the skin can vary from $10^2$ cells/cm² at the arm site to $10^7$ cells/cm² at the arm pit.33, 34 Anaerobic bacteria are mostly present at sebaceous-rich areas and nearly absent at other more dry areas such as legs and arms.33 The body site that holds the highest microbial density is the axilla, followed by the cranium, sole of foot, forehead, upper back, subclavia, lumbar area, arm, lower back, chest, deltoid area, leg, palm, abdomen, and dorsum of foot.35 Skin with eczema or other diseases has been shown to be heavily colonized with *S. aureus*.36 Looking at the healthy skin flora, there are some differences between genders and individuals. Men tend to have higher counts of microorganisms compared with women.35, 37, 38 Men shed colony-forming units (CFU/m³) up to seven times more compared to women.39 Individuals within each gender also differ, but the flora of the same individuals appears to be constant.31, 38, 40
Bacteria
The human skin is predominately colonized by *Staphylococcus*, *Corynebacterium*, and *Propionibacterium*. The most common microorganisms that cause SSIs in cardiac patients are *S. aureus*, CoNS, and Gram-negative bacteria. Different factors will determine whether particular bacteria will cause an infection, such as how, and how much, bacteria come in contact with the host, and the virulence of the specific bacteria. The virulence of the bacteria is defined by the ability to cause an infection even in low numbers. These two factors together with the host defences are important when calculating the risk of acquiring SSIs. The risk of acquiring an SSI is higher with a large contamination by virulent bacteria together with an immune-compromised host. Some bacteria can multiply every 20 minutes, such that in a favourable environment one bacterium can multiply up to as many as 32,768 after five hours, while others only divide once a day.

Staphylococci
The genus *Staphylococcus* consists of more than 40 different species and about 20 subspecies. The distribution of *Staphylococcus* on the human skin consists mainly of *S. epidermidis* and *S. hominis*, followed by *S. haemolyticus*, *S. capitis*, and *S. aureus*. The distribution of staphylococci is somewhat different. *S. aureus* are mostly found in the nares. Microscopically, staphylococci resemble clusters of grapes and they are Gram-positive cocci. Species identification has been made by colony morphology, coagulase and DNase test, and other biochemical tests, predominantly API kits. Since the introduction of MALDI-TOF MS, this method has replaced all other routine methods at the clinical microbiological laboratories, since it provides a rapid, cheap, and reliable method for determination of staphylococci to species level. On agar plates *S. aureus* appear as yellow opaque colonies, compared with CoNS, which have white to grey colonies. Staphylococci are mainly divided into the two groups coagulase-positive and coagulase-negative staphylococci. This separation is of clinical interest because *S. aureus* (coagulase-positive) is one of the most important and virulent pathogens causing SSIs in humans. *S. aureus* is often a transient bacterium but may also be a resident bacterium that can colonize nares and axillae, and does so, comprising up to 30% of the population. It has been shown that the carriers of *S. aureus* who acquire bacteraemia, mostly is caused by endogenous strains. *S. aureus* causes, in addition to SSIs, a broad
spectrum of infection such as impetigo, endocarditis, scaled skin syndrome, urinary tract infections, toxic shock syndrome, and sepsis.48 *S. aureus* protects itself with different toxins and enzymes, together with the ability to form biofilm. *S. aureus* evades the host neutrophil and macrophage responses by using biofilm and avoiding destruction by phagocytosis.51, 52 *S. aureus* seem to be able to adhere and hide intracellularly, and thereby be protected from host defence mechanisms.47

Of the human resident staphylococci, the majority is *S. epidermidis*, which exists nearly everywhere on the human skin and is thought to be mutualistic for skin health and protective for colonization of pathogens.53 *S. epidermidis* binds to specific receptors that inhibit the adherence of the pathogenic *S. aureus*.54 *S. epidermidis* are particularly present at moist areas such as anterior nares, axillae, toe webs, and the inguinal area.46 An important virulence factor of CoNS is their ability to produce biofilm.55 Other less common *staphylococcus* is *Staphylococcus hominis* which is mostly found at the axillae, head, legs, and arms. *Staphylococcus capitis* are mostly found at the head and arms. *Staphylococcus warneri* that is only occasionally isolated from the skin.31

*Propionibacterium acnes*

*P. acnes* are gram-positive facultative anaerobic rods and are considered to be commensal bacteria and mutualistic bacteria. These bacteria are slow-growing bacteria that can be missed if they are not cultured for a longer time.56, 57 Cultured on agar plates, the colonies appears circular, with size 1 to 2 mm in diameter, glistening and opaque.56 *P. acnes* release protective fatty acids which inhibit the growth of the pathogenic *Streptococcus pyogenes*.41, 56, 58 *P. acnes* are mostly known for causing the skin disease acne vulgaris, but lately these resident bacteria have with improved diagnostics procedures been proven to be pathogen bacteria associated with foreign material or implanted medical devices such as pacemakers, shunts, etc.56, 57, 59-65 The major virulence factor of *P. acnes* is believed to be the biofilm formation that protects *P. acnes* from antibiotics and the host immune defence.56, 66

**Biofilm**

Implanted foreign material is normally covered by non-pathogenic biofilm, usually consisting of plasma, fibrinogen, and collagen, which are employed in the normal functioning of the immune defence system. When a cardiac device such as a pacemaker is implanted, it poses a risk that the
contaminated with possibly bacteria present on the patient skin. This contamination may be the first step towards the formation of a multilayer biofilm incorporating bacteria, covering the implanted foreign surface. The pathogenesis of the bacteria, creating biofilm, is the ability to adhere to surfaces, both on tissue and foreign material. Biofilm consists mainly of a biochemical matrix of microbial cells and extracellular polymeric substances, mainly polysaccharides attached to the surface. The biofilm architecture consists of mushroom-shaped bacterial microcolonies, attached to each other. These microcolonies incorporate a myriad of channels that can deliver nutrients and oxygen to the bacteria inside. The matrix protects the bacteria from the hosts’ immune defences, such as antimicrobial peptides and neutrophil phagocytosis. Moreover, bacteria incorporated into the biofilm are protected from antibiotics by the specific physiology which reduces the antibiotics’ effect (decreased metabolism and aggressiveness), and by limiting the antibiotic ability to reach the bacteria inside the biofilm (reduced diffusion). Finally, when the biofilm is matured, it detaches colonies of bacteria to the surrounding tissue and the bloodstream. The reason for this action is still unclear, but theories are that the biofilm needs to dispatch colonies to maintain optimal thickness and function, or possibly to colonize elsewhere in the host body.

Preventing interventions for the patient undergoing surgery

Operating room environment and materials
To maintain the patient and sterile material free from bacteria from the air, the OR has a controlled ventilation system which cleans the air of bacteria, measured in CFU/m³. The quality of the air is dependent on the number of persons within the OR. The more persons within the OR, the higher the number of bacteria shed into the air. The air quality is also strongly dependent on the traffic in and out of the OR, which should be limited. To prevent cross-infection by exogenous transmission from persons present in the OR, all personnel should wear special work suits and caps, which reduces the spread of bacteria into the air, and these work suits should be laundered by the employer. Special clean air suits (single-use) reduce the spread of bacteria more effectively compared to more permeable material such as that found in reusable clothing. All sterile material that is handled by the sterile team is resterilized if it is reusable, and sterile materials for single use are disposed of. Draping materials should be for...
single use and cover the patient entirely, except for the surgical site. Drapes should be non-permeable for fluids and adhere to the patient body, approximately 10 cm into the disinfected area. Patients’ skin needs to dry completely for the drapes to adhere properly. All staff in the OR should wear caps and face masks (depending on local guidelines). Sterile gowns and gloves for single use should be used by all persons within the operating field. The use of surgical gloves is intended to prevent cross-infections between the patient and the surgical team. Double gloves are recommended. It has not yet been proven that use of double gloves reduces SSIs, but there are significantly fewer puncture holes in the inner glove compared to single glove perforations, and using indicator gloves makes it easier to detect puncture holes. The glove perforation sites are mostly found on the non-dominant hand, index finger, long finger, or ring finger. Studies performed on puncture holes in the surgical gloves often recommend a change of gloves, and some recommend glove changes after 90 minutes due to glove puncture rates and because bacterial counts increase with length of surgery. The use of double gloves increases the change of the outer gloves. Changing the outer glove before handling implant material has not been shown to reduce SSIs.

**Patient skin disinfection**

Skin disinfection is routine prior to surgical procedures. However, there is no consensus regarding which type of skin disinfectant is the most effective. In Sweden, the surgical skin disinfectant should preferably be chlorhexidine 5mg/ml in 70% ethanol and should be applied directly prior to surgery. It is thought that skin disinfection reduces SSIs due to the reduction of bacteria, but skin disinfection has not yet been proven to reduce SSIs. Skin disinfection does not make the skin sterile but reduces the bacterial growth substantially.

Skin disinfection consists of the mechanical rub and the chemical agent. The methods by which the antiseptics are applied vary between countries. The general principle of applying skin disinfection is that the antiseptic applicator should be sterile and should move with friction from the incision site outwards towards the periphery (Figure 1).

There are three main antiseptic compounds: alcohol, iodine/iodophors, and chlorhexidine gluconate. These can occur in different combinations. Which of these antiseptics is the most effective in preventing SSIs is not...
clear, but to use any of these antiseptics has been shown to reduce the amount of bacteria on the skin of the patients.88

In Sweden chlorhexidine 5mg/ml in 70% ethanol is widely used, but the choice differs greatly between and within countries.91 The ideal skin disinfection agent should kill all types of bacteria, viruses, fungi, and spores, and have residual activity. The agent should at the same time be patient-friendly, in terms of being non-toxic/allergenic. Skin disinfection agents’ main mode of action is through interfering with the cell wall of different microorganisms.92

Figure 1. Photo of the skin disinfection process prior to a pacemaker implantation. Photo by Stefan B. Larsson ©
Preoperative hand disinfection
With the intention to prevent cross infection during surgery, the surgical team performs preoperative hand disinfection. Preoperative hand disinfection prior to surgery should be performed with hand disinfection agents and methods that comply with the individual skin type. Skin disinfection duration varies, depending on the agent and method used. Preoperative hand disinfection is important due to the risk of puncture of the gloves. The three kinds of methods for preoperative hand disinfection are alcohol rubs, alcohol rubs with active agents, and aqueous scrubs.

An alcohol rub consists of a simple soap wash at the start of the first procedure or when hands are soiled, with an additional rub with alcohol 60% to 90% in strength. Alcohol rubs with an active agent are similar to the alcohol rub, but an active agent such as chlorhexidine is added to the alcohol, with a suggested prolonged inhibition of bacterial regrowth. An aqueous scrub contains of water instead of alcohol, with an active agent as chlorhexidine gluconate or povidone–iodine. The scrub involves repeatedly applying the agent with a sponge, scrubbing hands, nails, and forearms under running water. In the past the norm has been to use a scrub, but the trend has moved toward alcohol rubs. Rubs seem to cause less skin irritation and dryness and are sometimes considered more effective in reducing bacteria.

Maintenance of patient temperature
Perioperative hypothermia is an inadvertent loss of core body temperature to less than 36°C, and is a problem during surgical procedures when patients undergo general anaesthesia. The patient’s body temperature should be maintained by the use of preheated fluids and warming blankets of different types. Hypothermia during surgery may result in several complications, including increased rate of SSIs, impaired coagulation and blood loss. These complications have an association with prolonged hospital stay. Although evidence exists that hypothermia is associated with a series of adverse effects, there is still a lack of high quality evidence for the effects of warming devices to prevent severe complications. Nonetheless, active warming of the patient has shown to significantly shorten time to achieve normothermia and less heat loss and tends to improve thermal comfort if patients are awake.

Skin disinfection can enhance heat loss. Different kinds of skin disinfection solutions have different impact on heat loss. If the skin disinfectant used contains alcohol, the heat loss is more enhanced, since
alcohol evaporates more readily than water, resulting in a potentially greater heat loss.107

Patient experience
Reports of patients’ experience of skin disinfection are lacking, as well as reports on the effects of increasing the temperature of disinfectant solutions. Most patients are satisfied with the care they receive in the OR.108-111 However, some patients experience the sensation of being cold, especially when undergoing surgery with local anaesthesia.106, 108, 111, 112 In a pilot study by Wistrand and Nilsson (2011),113 preheated and room-temperature skin disinfection was performed on ten healthy volunteers. The study showed that preheated skin disinfectant was experienced as more pleasant and less cold compared to room-temperature disinfectant. Furthermore, there was a significant difference in skin temperature before and after disinfection when using a room-temperature solution, whereas there was no significant difference in skin temperature before and after disinfection with preheated skin disinfectant.113
Rationale

According to Swedish law (SFS: 2017:30), patients should receive health care with good standards and on equal terms. The Swedish National Handbook for Healthcare aims to guide the HCW to maintain safe and high quality care nationally. The clinical work at the OR departments is designed to have a high hygiene standard to prevent bacterial contamination of the wound and thereby prevent SSIs. SSIs are a major problem in terms of both suffering for patients and high costs for society. Surgical complications increase the risk of SSIs, and as a complication due to surgery can never totally be foreseen, SSIs are still therefore unavoidable. One way of reducing SSIs is to reduce the bacterial growth in the surgical patient. SSIs have historically decreased, but despite enhancements, there is much to learn about the different factors involved in the development of SSIs. To improve patient safety alongside comfort and maintain the number of SSIs at a minimum, knowledge about bacterial growth and the interventions performed by OR nurses is essential to enhancing the health care of the surgical patient.
Aims of the thesis

The general aim of this thesis was to test and describe interventions performed by OR nurses to increase patient comfort, prevent bacterial growth, and reduce SSIs.

The specific aims of each study were:

I. To test if preheated (36°C) skin disinfectant was non-inferior to room-temperature (20°C) skin disinfectant regarding skin colonization. The secondary aim was to investigate whether gender had an impact on differences in bacterial colonization in the surgical wound or surgical site infections among patients undergoing surgery;

II. To compare preheated (36°C) with room-temperature (20°C) skin disinfectant solution. Focusing on changes in skin temperature before and after skin disinfection and on patients' experience with the skin disinfection;

III. To investigate if there were differences in bacterial growth and recolonization of hands between operating room nurses and non-health care workers as well as to investigate if bacterial growth existed at the surgical glove cuff and gown interface during surgery; and

IV. To describe the daily clinical interventions guided by national guidelines that Swedish operating room nurses performed to prevent surgical site infections.
Methods

All studies in this thesis are quantitative in design. Variables that are not quantitative have been operationalized into quantitative labels. The studies will be referred to by their Roman numerals as studies I–IV throughout the text (Table 1).

Table 1. Overview of design and method, studies I–IV

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<td>II</td>
<td>Randomized controlled trial</td>
<td>Pacemaker device surgery patients $n = 220^*$</td>
<td>Skin temperature in °C Patients’ thermal comfort</td>
<td>Student’s t-test Mann-Whitney U test Chi-square test</td>
</tr>
<tr>
<td>III</td>
<td>Exploratory, comparative, clinical trial</td>
<td>Operating room nurses $n = 12$ Non-health care workers $n = 13$</td>
<td>Bacterial growth Bacterial species</td>
<td>Mann-Whitney U test Chi-square test Wilcoxon signed rank test</td>
</tr>
<tr>
<td>IV</td>
<td>Descriptive Cross sectional survey</td>
<td>Operating room nurses $n = 890$</td>
<td>Questionnaire measuring operating room nurses preventive interventions</td>
<td>Descriptive</td>
</tr>
</tbody>
</table>

*Studies I and II were based on the same sample.

Settings

Data for studies I and II were collected at the OR Department of Cardiothoracic and Vascular Surgery, University Hospital in Örebro, Sweden. Data collection for studies I and II took place between January 2013 and November 2014. For study III, data were collected at an OR
department between March 2014 and June 2014 (OR nurses), and between December 2014 and April 2015 (non-HCWs) at the same OR department in Sweden. Study IV data collection was carried out from December 2015 to the end of January 2016.

**Participants**

**Studies I and II**
All 220 participants consisted of patients scheduled for pacemaker device surgery under local anaesthesia. The same sample base were used for studies I and II. Inclusion criteria were age 18 years or older and ability to read and understand Swedish. Exclusion criteria were infection in an existing implanted pacemaker device.

**Study III**
Study III consisted of two groups, one group of 12 OR nurses and another of 13 non-HCWs as a control group. The 13 non-HCWs consisted of healthy volunteers without any recent contact with medical care. Exclusion criteria for both groups were artificial nails, hand eczema, jewellery, or surgical hand disinfectant solution other than that stated as protocol.

**Study IV**
Email addresses were accessed for 2264 of the approximately 4000 OR nurses in Sweden. Respondents were 967 OR nurses (43%). Inclusion criteria were OR nurses. Exclusion criteria were OR nurses who no longer fulfilled OR nurses’ tasks. Of these 967 OR nurses, 77 were excluded due to having other work positions such as chief of staff, leaving 890 OR nurses.

**Intervention and randomization**
In studies I and II, patients were included consecutively when arriving at the OR. Patients were randomly allocated to either preheated (36°C) or room-temperature (20°C) skin disinfectant solution (chlorhexidine 5mg/ml in 70% ethanol, Fresenius Kabi AS, Halden, Norway). Allocation took place directly after patients provided informed consent. The randomization was stratified by gender, and an independent statistician
provided the randomization lists. The patient and the laboratory technician who performed the analyses were blinded to the allocation.

Outcomes

**Bacterial growth on patient skin and in the wound**

In study I cultures were obtained at four time points using a nylon-flocked swab (ESwab, COPAN Italia S.p.A., via Perotti 10, Bescia, Italy):

1. Before skin disinfection on the skin surface (Figure 2);
2. After skin disinfection on the skin surface (Figure 2);

![Figure 2. Photo illustrating swabs taken on skin surface for cultures one and two.](image)

Swabs for cultures of the skin (1 and 2) were moistened with two drops of sterile saline, then rubbed for 15 seconds on the skin surface (incision site, approximately 10 mm × 50 mm).
3. Directly after incision, subcutaneously in the wound (Figure 3) and
4. Before closing sutures, subcutaneously in the wound (Figure 3).

Swabs taken in the wounds (3 and 4) were rubbed along the inside of the incision and along the edges for 15 seconds with a dry swab.

**Surgical site infections**

All patients in study I were followed up after three months to detect SSIs, with the help of a nurse who accessed the Swedish ICD (Implantable Cardioverter-Defibrillator) and Pacemaker Registry and provided the data regarding patients diagnosed with SSI. The Swedish pacemaker registry
is a national registry for quality, started in 1989. About 5000 pacemaker implants are performed every year in Sweden, and all implanting hospitals or units reports to the registry. The national ICD and Pacemaker Registry compiles and reports annually. These reports contain data with more than 95% of all procedures reported, validated against The National Board of Health and Welfare. The National Board of Health and Welfare is a government agency under the Ministry of Health and Social Affairs.

**Skin temperature**

In study II skin temperature was measured at two time points, before and after skin disinfection, at the planned incision site on the left side below the clavicle, with an infrared (IR) thermometer (CIR 8819; Injector, Stockholm, Sweden) held approximately 10 cm from the skin. The IR thermometer had two IR dots that indicated where on the skin the temperature was being measured (Figure 4).

![Figure 4. Photo of the infrared thermometer used to measure skin temperature.](image)

*Photo by Stefan B. Larsson ©*
Experience
In study II patients’ experience of the disinfection process was measured by means of a numeric rating scale (NRS) with anchor words from positive to negative (0, pleasant to 10, unpleasant). The following questions were asked in accordance with a written protocol at the start of the skin disinfection procedure:

- ‘On a scale from 0 to 10, where 0 is pleasant and 10 is unpleasant, how are you experiencing the temperature of the skin disinfectant?’
- ‘Are you cold now?’ Yes or No.
- ‘If you could choose, would you like the skin disinfection solution to be (a) warmer, (b) colder, or (c) as it is?’

Bacterial growth and recolonization on the hands
In study III, skin cultures were taken at two time points, directly after preoperative hand disinfection when the hands were dry, and again after wearing sterile surgical gloves and gowns. The OR nurses were sampled in total at seven sites, and the non-HCWs at six sites. The non-HCWs had six cultures taken, because the culture from the glove cuff and gown interface was excluded. At the first time point both groups were cultured

1. In the right hand palm (Figure 5a);
2. Between the right index finger and middle finger (Figure 5b);
3. At the nail/cuticle of the right index finger (Figure 5c).

Figure 5a  Figure 5b  Figure 5c
Photos 5a to 5c illustrate sampling sites on the hands. Photos by Stefan B. Larsson
After the cultures were taken the participants continued to don the gowns and gloves. When the two groups were finished with their tasks the second time point for cultures began. For the OR nurses’ one culture was obtained before removing the gloves. This culture was obtained at the glove cuff and gown interface (Figure 6).

This swab was rubbed around the interface of the right inner glove and gown sleeve.

![Figure 6. Photo illustrating the OR nurses culture site at the glove cuff end. Photo by Stefan B. Larsson ©](image)

Thereafter, the second time point proceeded with both groups being cultured at three sites as above (Figure 5a to 5c), once again. All cultures were taken using a nylon-flocked swab (ESwab, Copan Italia S.p.A.,
Preventive interventions to reduce surgical site infections

In study IV, the study-specific questionnaire was based on an extensive review; on evidence from earlier research produced by the research group regarding skin disinfection effects, both of patient skin and of the hands of the staff; and from existing Swedish guidelines as well as from the research group’s own clinical experiences working in an OR setting as OR nurses and OR anaesthetist. The following guidelines were selected for the study-specific questionnaire:

- Recommended skin disinfection solution, chlorhexidine 5mg/ml in 70% ethanol or similar, with a prolonged effect;
- Duration of the skin disinfection process to be two minutes, and then the site allowed to dry;
- Sterile draping material for single use, which should stay adherent throughout the surgical procedure;
- Two methods for preoperative surgical hand disinfection: method 1, rub – the use of plain soap and water and thereafter rubbing of the hands and forearms fluidly with alcohol; and method 2, scrub – the use of soap, containing 4% chlorhexidine or similar solution, and water;
- Sterile gowns and gloves to be worn by all within the sterile area of surgery, and double gloves recommended;
- Special work suit designed to prevent the spread of bacteria from staff to the surrounding air, that is, a clean air suit;
- Maintenance of patient body temperature perioperatively by the use of warm fluids and blankets; and
- Preoperative shower with a chlorhexidine-containing soap at least twice before surgery, the cleansing to begin the day before surgery at home and be completed the morning of the surgery at the ward or at home by the patient.

The questions were arranged as an online questionnaire by a professional web survey company. The questionnaire addressed the daily activities an OR nurse does to prevent bacterial growth, such as preparing the patient skin (n = 12), maintaining the patient temperature (n = 10), and preparing OR materials (n = 10). The response form included a five-point scale with
the answer options always, often, sometimes, seldom, or never (n = 19); a four-point scale regarding recolonization – large, moderate, small, or none – and puncture of glove, long duration, use of single glove, or open-ended (n = 2); a fixed set of three choices with an open-ended alternative regarding double gloving and reasons for changing outer glove – yes, no, unsure, or open-ended (n = 2); a five-point scale regarding source of information on patient skin disinfection with the answer options educator (university), supervisor (OR nurse), Handbook for Healthcare, colleagues, unsure, or open-ended (n = 1); and finally, eight open-ended questions, for example, Which preoperative hand disinfectant do you use? and Which OR temperature is usually set? The questionnaire also included six sociodemographic variables such as age, type of hospital, work experience, educational level, type of surgical specialty, and in what part of Sweden they worked (Table 2).

Table 2. The response alternatives in the questionnaire

<table>
<thead>
<tr>
<th>Answers using five-point scale, n = 19</th>
</tr>
</thead>
<tbody>
<tr>
<td>Always</td>
</tr>
<tr>
<td>Answers using four-point scale, n = 2</td>
</tr>
<tr>
<td>Large</td>
</tr>
<tr>
<td>Puncture of gloves</td>
</tr>
<tr>
<td>duration</td>
</tr>
<tr>
<td>Answers with a fixed set of three choices with an open-ended alternative, n = 2</td>
</tr>
<tr>
<td>Yes</td>
</tr>
<tr>
<td>Answers using a five-point scale regarding education, n = 1</td>
</tr>
<tr>
<td>Educator</td>
</tr>
<tr>
<td>Open-ended questions, n = 8</td>
</tr>
</tbody>
</table>

Procedures

Patients in studies I and II were undergoing elective surgery and arrived at the hospital on the morning of the surgery. Patients showered twice with Descutan®, a 4% chlorhexidine soap (Fresenius Kabi AB, Uppsala, Sweden), prior to surgery. Patients waited at the ward and were brought to the OR immediately before the procedure. Following standard procedures, intravenously administered antibiotic prophylaxis (cloxacillin 2 g) was given in the ward 15–30 minutes prior to surgery. The patient was placed upon an operating table under a blanket, and wore a gown.
backwards so that the chest could be easily exposed. Data collection was performed in the OR, with a temperature of 19°C with upward displacement ventilation. The patient’s skin was disinfected from the cheek downward over the sternum and toward the left shoulder, which was in accordance with the clinic’s routine. Both groups underwent skin disinfection with the same amount (250 ml) of solution on 10 cotton swabs. The preheated disinfection solution was stored in a warming cupboard and kept at 36°C (Figure 7), while the room-temperature skin disinfection solution was stored at room temperature, and measured to maintain 20°C. The patients were not informed as to whether they received preheated skin disinfection or not. All the surgical procedures were performed by two cardiologists. The main side for surgery was the patients’ left side. Patients either received a pacemaker, an implantable cardioverter–defibrillator, or cardiac resynchronization therapy, or had an existing pacemaker device (battery) changed. All the pacemaker device implantations were performed with the
Seldinger technique. The wound was closed with resorbable monofilament sutures for the subcutaneous tissue and intracutaneous layer. After wound closure, a dressing was applied while sterile conditions were intact. Patients were instructed to leave the dressing on for 10 days before changing it. Patient flow through studies I and II is shown in a flow chart (Figure 8).

Figure 8. Flow chart showing patients’ inclusion in studies I and II.
In study III, 12 OR and 13 non-HCWs performed the preoperative hand disinfection. They performed the preoperative hand disinfection according to clinic routine by washing their hands under running water with soap and cleaning their nails if necessary for one minute, and then drying their hands and forearms properly with paper and rubbing hands and forearms with a fluid alcohol (Dax preop 80, CCS Healthcare AB, Sweden). Both the OR nurses and the non-HCWs wore caps, masks, nonwoven disposable surgical gowns (BARRIER, Mölnlycke Health Care, Gothenburg, Sweden), and double gloves (Biogel PI indicator system, Mölnlycke Health Care, Gothenburg, Sweden). The OR nurses prepared and assisted at a clean surgery procedure until they were either relieved or the surgery was completed. To simulate nearly the same workload as preparing and assisting a patient for surgery, the non-HCWs performed a heart and lung resuscitation (HLR) course while dressed in gowns, caps, and gloves. The course consisted of information and practice, at the end of which the participants were offered lunch. OR nurses were compared with a control group of non-HCWs regarding bacterial growth and outcome variables analysed, shown in a flow chart (Figure 9).

In study IV, the questionnaire was sent to 2264 of a total of approximately 4000 OR nurses’ work email addresses in Sweden. IT departments at the participating hospitals or regions delivered the lists of all email addresses of the OR nurses to the author. The remaining email addresses were not retrieved. The web-based questionnaire was distributed via email together with information about the study. Information about the study was also published in the Swedish journal for OR nurses (Uppdukat) as well as in a closed Facebook group (Operationssjuksköterskor, 1668 members).
Figure 9. Flow chart of participants in study III.

Bacterial cultures

All cultures taken were sent to the Department of Laboratory Medicine, Clinical Microbiology, University Hospital, Örebro, and analysed according to specific study protocols.

The swabs were vortexed for a few seconds, and for studies I and III, 50 and 100 μL aliquots, respectively, of the liquid transportation medium were subcultured on haematin agar medium 4.3% (w/v); (Columbia Blood Agar Base, Acumedia Neogen Corporation, Lansing, MI, USA) supplemented with 6% (w/v) cholcolatised defibrinated horse blood and
incubated at 36°C under aerobic conditions. Samples were also subcultured on FAA plates (LAB 90 Fastidious Anaerobe Agar 4.6% (w/v; LAB M Ltd., Lancashire, UK), supplemented with 5% (v/v) defibrinated horse blood and incubated under anaerobic conditions (10% H2, 10% CO2, 80% N2) at 37°C. After 24 and 48 hours of aerobic incubation and 5 days of anaerobic incubation, bacterial growth was determined quantitatively (CFU/mL). Culture diagnostics and species verification were performed based on characteristic colony morphology and using routine diagnostic procedures. Additionally, for study III, MALDI-TOF mass spectrometry (MicroflexLT and Biotyper 3.1, Bruker Daltonics, Bremen, Germany) was used.

**Statistical analysis**

Statistical analysis was performed with SPSS, version 22 (SPSS Statistics, IBM, Armonk, NY).

**Study I**

A sample size of 102 participants per group provided 80% power at a one-sided significance level of 5%, with an expected proportion of bacterial growth of 0.09 and the maximal allowable difference of 0.10 non-inferiority limit. Absolute difference and CI were manually calculated. Bacterial counts and other non-normally distributed variables were analysed with the Mann-Whitney U test, and normally distributed variables with an unpaired t-test. Categorical variables were evaluated with chi-square test or Fisher’s exact test, as appropriate. Descriptive statistics are presented as mean, median, number, percentage, confidence interval, and standard deviation. A p-value of <0.05, two tailed, was considered statistically significant.

**Study II**

Study II was a part of study I, and the power calculation was based on the expected proportion of bacterial growth from a pilot study by Wistrand and Nilsson. The pilot study detected differences in both skin temperatures and in experience; thus, we decided that the sample size of 220 was sufficient. Student’s t-test was used for analysis of skin temperature, and the NRS was analysed with Mann-Whitney U test. Categorical variables were evaluated with chi-square test or Fisher’s exact test, as appropriate. Descriptive statistics are presented as mean, median,
number, percentage, confidence interval, and standard deviation. A $p$-value of <0.05, two tailed, was considered statistically significant.

**Study III**
No sample size was calculated; hence, this was a pilot study, which can provide data for future power calculations. The bacterial counts and other non-normally distributed variables were analysed with Mann-Whitney $U$ test and Wilcoxon signed rank test comparing repeated measurements. Categorical variables were evaluated with chi-square test or Fisher’s exact test, as appropriate. Descriptive statistics are presented as mean, median, number, percentage, confidence interval, and standard deviation, and interquartile range (IQR). A $p$-value of <0.05, two tailed, was considered statistically significant.

**Study IV**
No sample size was calculated; hence, the aim was to have as high a response rate as possible of OR nurses in Sweden. Descriptive statistics were presented as mean, median, number, range, percentage, confidence interval, and standard deviation.

**Ethical considerations**
All studies were conducted in accordance with the Helsinki Declaration regarding ethical principles involving humans.

All participants in studies I, II, and III were given oral and written information about the studies, and all gave written informed consent before the start of data collection.

The Regional Ethical Review Board of Uppsala, Sweden, approved studies I, II, and III (reference number 2012/255 and 2013/283). Registrations were made in ClinicalTrials.gov for studies I and II (NCT02260479) and for study III (NCT02359708).

As study IV did not involve patients or sensitive data, ethical approval was not required according to the Swedish Act concerning the Ethical Review or Research Involving Humans (SFS, 2003:460). No sensitive data means no information was retrieved regarding ethnicity, political opinions, union membership, or religion, or information regarding health and sexual preferences. Written information was given regarding the study, and participation was voluntary. Study IV was conducted with respect for the participants’ integrity, and the data were stored...
depersonalized on data files at the hospital servers, protected with firewalls and private codes. No key codes existed to connect the answers with any individuals, and the results were presented groupwise with no possibility for recognition.
Results

The results in this thesis showed that preheated skin disinfection reduces skin heat loss and increases patient comfort (study II), whilst not being less effective in reducing bacterial growth or SSIs (study I). There was no conclusive difference between OR nurses and non-HCWs regarding bacterial growth on their hands, but there was a possible risk of bacterial contamination at the glove cuff during surgery (study III). The proportion of the OR nurses who complied with the preventive interventions recommended in the national guidelines was high (study IV). The results are presented following the outcomes. An overview of patients’ characteristics for studies I and II is presented in Table 3.

Table 3. Patients’ baseline characteristics between preheated and room-temperature skin disinfectant groups

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Preheated</th>
<th>Room temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine 5 mg/ml in 70% ethanol</td>
<td>Preheated</td>
<td>Room temperature</td>
</tr>
<tr>
<td>Age (years), mean ± SD</td>
<td>72 ± 11.9</td>
<td>74 ± 12.5</td>
</tr>
<tr>
<td>Body mass index, mean ± SD</td>
<td>27 ± 4.5</td>
<td>27 ± 5.4</td>
</tr>
<tr>
<td>Colony-forming units, median ± IQR</td>
<td>1180 ± 4690</td>
<td>2080 ± 4770</td>
</tr>
<tr>
<td>Skin temperature (°C), mean ± SD</td>
<td>32 ± 1.2</td>
<td>32 ± 1.1</td>
</tr>
<tr>
<td>Length of surgery, minutes, mean ± SD</td>
<td>37 ± 24</td>
<td>39 ± 24</td>
</tr>
<tr>
<td>Men, n (%)</td>
<td>62 (57)</td>
<td>62 (55)</td>
</tr>
<tr>
<td>Women, n (%)</td>
<td>46 (43)</td>
<td>50 (45)</td>
</tr>
<tr>
<td>Bacterial growth, %</td>
<td>95</td>
<td>96</td>
</tr>
<tr>
<td>Eczema, %</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Incision site hair shorten, %</td>
<td>31</td>
<td>26</td>
</tr>
<tr>
<td>Diabetes, %</td>
<td>14</td>
<td>18</td>
</tr>
<tr>
<td>Type of surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device (battery) change, %</td>
<td>45.4</td>
<td>46.4</td>
</tr>
<tr>
<td>DDD, %</td>
<td>35.2</td>
<td>36.6</td>
</tr>
<tr>
<td>VVI, %</td>
<td>6.5</td>
<td>6.3</td>
</tr>
<tr>
<td>ICD, %</td>
<td>1.9</td>
<td>3.6</td>
</tr>
<tr>
<td>CRT, %</td>
<td>1.9</td>
<td>1.8</td>
</tr>
<tr>
<td>Other, %</td>
<td>9.2</td>
<td>5.4</td>
</tr>
</tbody>
</table>

SD, standard deviation; IQR, interquartile range; DDD, dual chamber rate adaptive pacemaker; VVI, single ventricular rate adaptive pacemaker; ICD, implantable cardioverter–defibrillator; CRT, cardiac resynchronization therapy. Continuous and dichotomous variables were analysed using t-test and Mann Whitney U test; no significant differences between groups.
Bacterial growth on patients’ skin and in the wound

In study I, the absolute difference in bacterial growth between the patient groups was zero (90% CI, -10.1 to 10.1). The bacterial growth was reduced by the skin disinfection process, but recolonization occurred during the surgical procedure. Cultures showed that males had significantly more bacteria at the four time points than females, irrespective of the temperature of the skin disinfectant (Table 4).

<table>
<thead>
<tr>
<th>Chlorhexidine 5 mg/ml in 70% ethanol</th>
<th>All</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>36°C</td>
<td>20°C</td>
<td>36°C</td>
<td>20°C</td>
</tr>
<tr>
<td>n = 106</td>
<td>n = 112</td>
<td>n = 62</td>
<td>n = 62</td>
</tr>
<tr>
<td>Absolute difference (90% CI)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Before skin disinfection, %</td>
<td>95.3</td>
<td>100</td>
<td>88.6</td>
</tr>
<tr>
<td>After skin disinfection*, %</td>
<td>28.6</td>
<td>40.3</td>
<td>11.6</td>
</tr>
<tr>
<td>After incision (wound), %</td>
<td>24.5</td>
<td>40.3</td>
<td>2.3</td>
</tr>
<tr>
<td>Before wound closure (wound), %</td>
<td>53.8</td>
<td>74.2</td>
<td>25.0</td>
</tr>
</tbody>
</table>

*Primary outcome. No statistical difference between the preheated and room-temperature skin disinfection groups was found. Differences between genders regarding bacterial growth existed at all four time points but not within genders, analysed with chi-square test.

The most commonly identified pathogens after skin disinfection both on the skin and in the wound (ordered by frequency) were *P. acnes* and CoNS (Table 5).
Table 5. Species of microorganism identified, before and after skin disinfection with chlorhexidine 5 mg/ml in 70% ethanol, at the four time points: (1) on the skin before skin disinfection, (2) on the skin after skin disinfection, (3) in the wound after incision, and (4) in the wound before skin closure. Number of patients with growth of bacteria.

<table>
<thead>
<tr>
<th>Microorganism</th>
<th>Culture 1</th>
<th>Culture 2</th>
<th>Culture 3</th>
<th>Culture 4</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>36°C 20°C</td>
<td>36°C 20°C</td>
<td>36°C 20°C</td>
<td>36°C 20°C</td>
</tr>
<tr>
<td></td>
<td>n=106</td>
<td>n=112</td>
<td>n=105</td>
<td>n=112</td>
</tr>
<tr>
<td>P. acnes</td>
<td>83 86</td>
<td>25 25</td>
<td>22 29</td>
<td>47 52</td>
</tr>
<tr>
<td>CoNS</td>
<td>83 90</td>
<td>2 4</td>
<td>2 6</td>
<td>23 29</td>
</tr>
<tr>
<td>S. aureus</td>
<td>2 2</td>
<td>1 1</td>
<td>- -</td>
<td>- -</td>
</tr>
<tr>
<td>Alpha-haemolytic</td>
<td>9 9</td>
<td>- -</td>
<td>- -</td>
<td>- 1</td>
</tr>
<tr>
<td>Anaerobic diphtheroid rods</td>
<td>5 3</td>
<td>- 1</td>
<td>1 1</td>
<td>1 1</td>
</tr>
<tr>
<td>Bacillus sp.</td>
<td>2 1</td>
<td>- -</td>
<td>- -</td>
<td>- -</td>
</tr>
<tr>
<td>Micrococi</td>
<td>4 -</td>
<td>- -</td>
<td>- -</td>
<td>- -</td>
</tr>
<tr>
<td>Anaerobic Gram-positive cocci</td>
<td>1 2</td>
<td>- 1</td>
<td>1 -</td>
<td>- 3</td>
</tr>
<tr>
<td>Proteus sp.</td>
<td>2 -</td>
<td>- -</td>
<td>- -</td>
<td>1 -</td>
</tr>
<tr>
<td>R. mucilaginosa</td>
<td>- 1</td>
<td>- -</td>
<td>- -</td>
<td>- -</td>
</tr>
</tbody>
</table>

No significant differences between study groups were found for any microorganism at any time point. Chi-square test was used as statistical method.

**Surgical site infections**

In study I, there were no significant differences regarding SSIs three months postoperatively between patients who received preheated compared to room-temperature skin disinfectant. In the preheated group 0.9% (1/108, female) was diagnosed with a SSI, while 1.8% (2/112, one female and one male) in the room-temperature group were diagnosed. Cultures taken for diagnostics showed no growth for the women, but the men showed growth of *S. aureus*, CoNS, *P. acnes*, and beta haemolytic streptococci group G.
**Skin temperature**

In study II, patients who received preheated skin disinfection had a higher mean skin temperature than the room-temperature group by 0.74°C ($p = 0.001$, 95% CI, -1.2 to -0.3), 27.25°C versus 26.51°C. There were no significant differences in skin temperature between men and women.

**Experience**

According to study II, using the NRS, patients experienced preheated skin disinfectant as more pleasant than room-temperature skin disinfectant, median score for NRS was 2 in the preheated group, whereas median NRS score for room-temperature solution was 5, $p \leq 0.001$ (Table 6).


<table>
<thead>
<tr>
<th>Skin disinfection</th>
<th>NRS, 0 = pleasant to 10 = unpleasant</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0</td>
</tr>
<tr>
<td>Preheated, 36°C, %</td>
<td>29.2</td>
</tr>
<tr>
<td>Room-temperature, 20°C, %</td>
<td>9.1</td>
</tr>
</tbody>
</table>

Zero represent a pleasant experience regarding the temperature of the skin disinfection solution while 10 represents an unpleasant temperature.

Patients who received preheated skin disinfection solution felt less cold during the skin disinfection procedure. Fewer patients’ desired warmer solution when the solution was preheated, and more patients were satisfied with the temperature of the solution they received compared to the room-temperature group (Table 7). None desired cooler skin disinfectant. There were no significant differences between genders in either disinfectant group.
Table 7. Experienced differences between receiving preheated versus room-temperature skin disinfectant solution

<table>
<thead>
<tr>
<th>Chlorhexidine 5 mg/ml in 70% ethanol</th>
<th>Preheated 36°C</th>
<th>Room-temperature 20°C</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients n = 99</td>
<td>Patients n = 100</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Felt cold during, n</td>
<td>10</td>
<td>25</td>
<td>0.006</td>
</tr>
<tr>
<td>Desired warmer, n</td>
<td>28</td>
<td>55</td>
<td>0.001</td>
</tr>
<tr>
<td>Satisfied with temperature, n</td>
<td>71</td>
<td>45</td>
<td>0.001</td>
</tr>
</tbody>
</table>

Statistical methods used were chi-square test or Fisher’s exact test, as appropriate. A p-value of <0.05, two tailed, was considered statistically significant.

**Bacterial growth and recolonization on the hands**

There were differences between the groups in study III regarding the time the participants wore the gloves after the preoperative hand disinfection (Table 8).

Table 8. Comparison of baseline participant characteristics between operating room (OR) nurses and non-health care workers (HCWs)

<table>
<thead>
<tr>
<th></th>
<th>OR nurses n = 12</th>
<th>Non-HCWs n = 13</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, mean ± SD</td>
<td>46 ± 8</td>
<td>39 ± 13</td>
<td>0.094</td>
</tr>
<tr>
<td>Men/women</td>
<td>1/11</td>
<td>1/12</td>
<td>1.0</td>
</tr>
<tr>
<td>Minutes wearing gloves, mean ± SD</td>
<td>223 ± 34</td>
<td>192 ± 16</td>
<td>0.007*</td>
</tr>
</tbody>
</table>

*Student’s t-test and Fisher’s exact test were used as statistical method.

According to study III, there were differences in bacterial growth and recolonization between the groups at four of the six culture sites, regarding the CFU/mL. After surgical hand disinfection the OR nurses had higher bacterial growth at the palm and finger sites compared to the non-HCWs, *P* < 0.044 and *P* < 0.019, but no difference regarding the nail sites, *P* = 0.434. After wearing surgical gloves, no difference were found
regarding the palm site between the groups, $P = 0.893$. OR nurses had higher values regarding recolonization at the finger, $P < 0.039$, but less recolonization at the nail site, $P < 0.016$ compared to non-HCWs (Table 9).

Table 9. Bacterial growth and recolonization at three culture sites on the hands of operating room nurses and non-health care workers after surgical hand disinfection, and then again after wearing surgical gloves

<table>
<thead>
<tr>
<th>Culture site</th>
<th>Operating room nurses $n = 12$</th>
<th>Non-health care workers $n = 13$</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%) growth</td>
<td>CFU/mL mean</td>
<td>CFU/mL median</td>
</tr>
<tr>
<td>Palm</td>
<td></td>
<td>13</td>
<td>0</td>
</tr>
<tr>
<td>Finger</td>
<td></td>
<td>14</td>
<td>5</td>
</tr>
<tr>
<td>Nail</td>
<td></td>
<td>28</td>
<td>10</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Culture site</th>
<th>Operating room nurses $n = 12$</th>
<th>Non-health care workers $n = 13$</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>After hand disinfection, first time point for cultures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Palm</td>
<td>4 (33.3) 18 0 8</td>
<td>3 (23.1) 29 0 5</td>
<td>0.893</td>
</tr>
<tr>
<td>Finger</td>
<td>4 (33.3) 98 0 10</td>
<td>0 0 0 0</td>
<td>0.039*</td>
</tr>
<tr>
<td>Nail</td>
<td>10 (83.3) 244 55 463</td>
<td>12 (92.3) 1554 780 2940</td>
<td>0.016*</td>
</tr>
</tbody>
</table>

Mann-Whitney U test was used to calculate the numbers of bacterial differences at the different culture sites in CFU/mL between the groups. IQR, Interquartile range. *Statistically significantly more bacterial growth.

In study III, 14 different bacterial species were found. The most common species obtained from the OR nurses hands were (ordered by frequency) *Staphylococcus warneri* followed by *P. acnes*, and in the non-HCWs group *S. warneri* followed by *S. epidermidis* together with *Staphylococcus pasteuri* (Table 10).
Table 10. Bacterial species isolated from the hands of operating room (OR) nurses and non-health care workers (HCWs). Numbers of persons with specific bacteria after preoperative hand disinfection and after wearing sterile gloves.

<table>
<thead>
<tr>
<th>Bacterial species</th>
<th>Bacterial growth after preoperative hand disinfection</th>
<th>Bacterial recolonization after wearing sterile gloves</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR nurses $n = 12$</td>
<td>Non-HCWs $n = 13$</td>
</tr>
<tr>
<td></td>
<td>Non-HCWs $n = 13$</td>
<td>OR nurses $n = 12$</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Non-HCWs $n = 13$</td>
</tr>
<tr>
<td>S. warneri</td>
<td>4</td>
<td>6</td>
</tr>
<tr>
<td>P. acnes</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>Bacillus sp.</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>S. epidermidis</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>S. capitis</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>S. pasteuri</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Micrococcus sp.</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>S. haemolyticus</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Alpha-haemolytic  streptococci</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brevibacteriaceae</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>S. lugdunensis</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gemella haemolysans</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>Gram-positive cocci, non-typeable</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Enterobacteriaceae</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Significant difference between groups regarding minutes, $P = 0.007$; statistical method used was Student’s $t$-test.

In study III, 9 out of 12 (75%) of the OR nurses had a visible dark area around the glove cuff and gown interface, indicating fluid (Figure 10), and five (42%) had bacterial growth found at the end of the inner glove. Four of five cultures from the OR nurses had the same bacteria at the glove cuff and gown interface as found in the cultures from the hands. Bacteria isolated from the cultures were $P. acnes$, $S. warneri$, $S. epidermidis$, and $Micrococcus$ species. The CFU/mL ranged from 10 to 40 at the interface of the surgical glove cuff and gown.
Preventing interventions to reduce surgical site infections
In total 967 of 2264 OR nurses answered the questionnaire (response rate 43%). Of the 967 OR nurses who responded, 77 were excluded due to having other work positions such as chief of staff. The majority of the OR nurses were women, with a mean age of 47 years and work experience of about 16 years. Educational levels range from licensed OR nurse up to PhD (Doctor of Philosophy) graduate, working at university hospitals, county hospitals, or private hospitals, as described in Table 11. The interventions are structured and presented using the Swedish national guidelines.
Recommended skin disinfection solution, chlorhexidine 5 mg/ml in 70% ethanol or similar, with prolonged effect

Chlorhexidine 5 mg/ml in 70% ethanol was the most commonly used solution for skin disinfection and was used by 93.3% (806/862) of the OR nurses. This was followed by Chlora Prep®, a combination of
chlorhexidine 20 mg/ml in 70% isopropanol used by 2.3% (20/862) of the OR nurses. Finally, 70% ethanol and Sterillium®, containing 75% isopropanol, was used, respectively, by 2.1% (18/862) of the OR nurses. Precleansing of the patient skin at the OR with a 4% chlorhexidine-containing wipe/sponge, Descutan®, of the patient skin was always performed by 29.7% (264/890) of the OR nurses prior to the preoperative skin disinfection (Table 12).

**Duration of the skin disinfection process to be two minutes, and then the site allowed to dry**
The majority of the OR nurses assessed that they performed the preoperative skin disinfection of patient skin for two to five minutes (Figure 11).

![Figure 11](image)

*Figure 11. Operating room nurses’ (n = 877) assessment of time spent on skin disinfection of a patient’s abdomen.*

The majority, 41.1% (366/890), of the OR nurses often let the skin dry before draping, but they often, 34.0% (303/890), wiped the skin dry
where the drapes were to adhere to enhance adherence of the drapes to the patient skin (Table 12).

**Sterile draping material for single use, which should stay adherent throughout the surgical procedure**

Single-use sterile draping was used by 97.4% (867/890) of the OR nurses, and they assessed the draping material to often stay adherent to the patient skin during surgery, 75.8% (675/890). Plastic adhesive drapes were used sometimes by 54.5% (485/890), and iodine-impregnated plastic adhesive drapes were used always by 33.7% (300/890) or never by 37.8% (336/890). A microbial sealant, such as Integuseal®, was never used by 89.4% (796/890) of the OR nurses (Table 12).

Table 12. Operating room nurses’ (n = 890) scaled responses regarding preparation of patients’ skin

<table>
<thead>
<tr>
<th>Preparation of patient skin</th>
<th>Always n (%)</th>
<th>Often n (%)</th>
<th>Sometimes n (%)</th>
<th>Seldom n (%)</th>
<th>Never n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorhexidine soap 4% wipes are used prior to skin disinfection, Descutan®</td>
<td>264 (29.7)</td>
<td>156 (17.5)</td>
<td>329 (37.0)</td>
<td>76 (8.5)</td>
<td>65 (7.3)</td>
</tr>
<tr>
<td>Skin is allowed to dry after skin disinfection</td>
<td>331 (37.2)</td>
<td>366 (41.1)</td>
<td>123 (13.8)</td>
<td>63 (7.1)</td>
<td>7 (0.8)</td>
</tr>
<tr>
<td>Skin is wiped with sterile paper towel for drape adherence</td>
<td>133 (14.9)</td>
<td>303 (34.0)</td>
<td>215 (24.2)</td>
<td>133 (14.9)</td>
<td>106 (11.9)</td>
</tr>
<tr>
<td>Drapes for single use</td>
<td>867 (97.4)</td>
<td>18 (2.0)</td>
<td>2 (0.2)</td>
<td>1 (0.1)</td>
<td>2 (0.2)</td>
</tr>
<tr>
<td>Drapes are adherent to patient skin during surgery</td>
<td>194 (21.8)</td>
<td>675 (75.8)</td>
<td>17 (1.9)</td>
<td>4 (0.4)</td>
<td>-</td>
</tr>
<tr>
<td>Plastic adhesive drapes are used</td>
<td>18 (2.0)</td>
<td>122 (13.7)</td>
<td>485 (54.5)</td>
<td>98 (11.0)</td>
<td>167 (18.8)</td>
</tr>
<tr>
<td>Iodine-impregnated plastic adhesive drapes are used</td>
<td>300 (33.7)</td>
<td>105 (11.8)</td>
<td>99 (11.1)</td>
<td>30 (5.6)</td>
<td>336 (37.8)</td>
</tr>
<tr>
<td>Microbial skin sealant is used</td>
<td>8 (0.9)</td>
<td>4 (0.4)</td>
<td>40 (4.6)</td>
<td>42 (4.7)</td>
<td>796 (89.4)</td>
</tr>
</tbody>
</table>
Almost half of the OR nurses, 48.9% (435/890) responded that they had learned to perform patient skin disinfection from their supervisor and OR nurse at the clinical practice during education, and 41.7% (371/890) from the educator at the university. The remaining 9.4% stated that they had learned it from colleagues and/or the Handbook for Healthcare or did not remember where they had learned it. The assessment of the skin disinfection efficiency by OR nurses regarding the proportion of patients that became free from bacteria after the skin disinfection ranged from 0 to 99%, and the distribution was fragmented. The majority of the OR nurses, 31.7% (187/890), assessed that none of the patients became completely free from bacterial growth after skin disinfection, while 5.6% (33/890) of the OR nurses believed that 99% of the patients became free from bacteria at the skin disinfection area.

Two methods for preoperative hand disinfection
Almost all OR nurses, 96.3% (857/890), stated that they had guidelines at their OR department for how to perform a preoperative hand disinfection. The mostly used preoperative hand disinfectant was an alcohol-based disinfectant solution, 89.6% (763/852), followed by chlorhexidine-based soap, 8.2% (70/852). Some of the OR nurses used both alcohol-based disinfectant solutions and chlorhexidine-based soap, 1.3% (11/852), and only a minority used plain soap, 0.9% (8/852). Many of the OR nurses, 47.2% (420/890), expected a small bacterial recolonization on their hands after the use of sterile surgical gloves while 38.4% (342/890) expected a moderate recolonization. Two per cent (18/890) expected a large recolonization, and the remaining OR nurses, 12.4%, answered that they expected no bacterial recolonization on their hands after the use of surgical gloves. OR nurses assessed the sterile outer glove to always reach over the inner glove, 83.3% (741/890), and 41.0% (365/890) of the OR nurses never noticed an indication of moisture themselves at the glove cuff end (Table 13).
Table 13. OR nurses’ \( n = 890 \) scaled responses regarding surgical gowns and gloves

<table>
<thead>
<tr>
<th>Statement</th>
<th>Always ( n ) (%)</th>
<th>Often ( n ) (%)</th>
<th>Sometimes ( n ) (%)</th>
<th>Seldom ( n ) (%)</th>
<th>Never ( n ) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterile gowns for single use</td>
<td>746 (83.8)</td>
<td>62 (7.0)</td>
<td>47 (5.3)</td>
<td>27 (3.0)</td>
<td>8 (0.9)</td>
</tr>
<tr>
<td>Staff clothing for single use at the OR department (non-sterile)</td>
<td>85 (9.6)</td>
<td>67 (7.5)</td>
<td>180 (20.2)</td>
<td>168 (18.9)</td>
<td>300 (33.8)</td>
</tr>
<tr>
<td>Double sterile surgical gloves are used</td>
<td>650 (73.0)</td>
<td>157 (17.7)</td>
<td>43 (4.8)</td>
<td>23 (2.6)</td>
<td>17 (1.9)</td>
</tr>
<tr>
<td>All sterile staff use double gloves</td>
<td>176 (19.8)</td>
<td>521 (58.5)</td>
<td>141 (15.8)</td>
<td>32 (3.6)</td>
<td>20 (2.2)</td>
</tr>
<tr>
<td>A dark area indicating moisture has been noted at the glove cuff end</td>
<td>24 (2.7)</td>
<td>67 (7.5)</td>
<td>231 (26.0)</td>
<td>203 (22.8)</td>
<td>365 (41.0)</td>
</tr>
<tr>
<td>The outer glove reaches over the inner glove</td>
<td>741 (83.3)</td>
<td>100 (11.2)</td>
<td>22 (2.5)</td>
<td>10 (1.1)</td>
<td>17 (1.9)</td>
</tr>
</tbody>
</table>

**Sterile gowns and gloves to be worn by all within the sterile area of surgery, and double gloves recommended**

Single-use sterile gowns were used by 83.8% \( (746/890) \) of the OR nurses. Of the OR nurses, 40.4% \( (360/890) \) did not know whether they had any guidelines regarding double gloves, and 37.1% \( (330/890) \) stated that they did not have any. Double gloves were used by 73% \( (650/890) \) of the OR nurses (Table 13). Reasons for changing the outer gloves varied, but the most dominant reasons were indication of puncture holes in the outer glove or the use of gloves for a long time (Table 14).
Table 14. Reasons to change the outer gloves, operating room (OR) nurses
(n = 890) total response rate, 1569

<table>
<thead>
<tr>
<th>Reasons for the change of outer glove</th>
<th>OR nurses</th>
<th>Number of responses (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gloves indicated holes</td>
<td>862</td>
<td>(96.9)</td>
</tr>
<tr>
<td>Gloves worn for a long time</td>
<td>264</td>
<td>(29.7)</td>
</tr>
<tr>
<td>Contamination of outer glove</td>
<td>117</td>
<td>(13.1)</td>
</tr>
<tr>
<td>Before contact with implants</td>
<td>105</td>
<td>(11.9)</td>
</tr>
<tr>
<td>After contact with skin disinfectant or cement</td>
<td>83</td>
<td>(9.3)</td>
</tr>
<tr>
<td>From unclean to clean moments</td>
<td>42</td>
<td>(4.9)</td>
</tr>
<tr>
<td>Contact with tumors</td>
<td>20</td>
<td>(2.2)</td>
</tr>
<tr>
<td>Use of single gloves</td>
<td>19</td>
<td>(2.1)</td>
</tr>
<tr>
<td>After patient skin disinfection and draping</td>
<td>17</td>
<td>(1.9)</td>
</tr>
<tr>
<td>Gloves sticky with blood</td>
<td>15</td>
<td>(1.7)</td>
</tr>
<tr>
<td>Tape or glue on the gloves</td>
<td>15</td>
<td>(1.7)</td>
</tr>
<tr>
<td>Before applying the patient dressing</td>
<td>6</td>
<td>(0.7)</td>
</tr>
<tr>
<td>Change of operation field within the patient</td>
<td>4</td>
<td>(0.4)</td>
</tr>
</tbody>
</table>

Multiple answers were possible for each OR nurse.

Staff clothing for single use at the OR departments was never used by 43.8% (390/890) of the OR nurses, but single-use sterile gowns were always used by 83.8% (746/890) (Table 13).

**Maintenance of patient body temperature perioperatively by the use of warm blankets and fluids**

The controlled OR temperature ranged between 18° and 24°C, and the three most common temperatures were 20°C (30.1%), 21°C (28.6%), and 22°C (20.8%). Blankets or mattresses with warm air were used often, 51.9% (462/890), but the incision site was not locally preheated, 82.0% (730/890). Fluids for use in the wound were sometimes preheated by 57.1% (508/890). The skin disinfection solution was always stored at room temperature, 95.5% (850/890), and the majority of the OR nurses did not preheat the skin disinfection solution before skin disinfection, 86.7% (772/890) (Table 15).
Table 15. OR nurses’ (n = 890) scaled responses regarding patient temperature preservation

| Maintenance of patient body temperature perioperative by the use of warm fluids and blankets |
|---------------------------------|----------------|----------------|----------------|----------------|----------------|
| Statement                        | Always n (%) | Often n (%) | Sometimes n (%) | Seldom n (%) | Never n (%) |
| The skin disinfection solution is stored at room temperature | 850 (95.5) | 37 (4.2) | 1 (0.1) | - | 2 (0.2) |
| The skin disinfection solution is preheated | 1 (0.1) | 1 (0.1) | 56 (6.3) | 60 (6.8) | 772 (86.7) |
| Blankets or mattresses with warm air are used | 286 (32.1) | 462 (52.0) | 106 (11.9) | 16 (1.8) | 20 (2.2) |
| Incision area is locally preheated | 16 (1.8) | 25 (2.8) | 37 (4.2) | 82 (9.2) | 730 (82.0) |
| Warm fluids are used in the wound | 31 (3.5) | 96 (10.8) | 508 (57.1) | 116 (13.0) | 139 (15.6) |

The OR nurses who used preheated skin disinfection solution had different ways of preheating it: warming cupboard, 89.1% (98/110), microwave oven, 4.5% (5/110), hot water, 3.6% (4/110), or a mix of all methods, 2.8% (3/110). The temperature of the preheated skin disinfection solution varied from 25°C to 42°C, with a mean temperature of 37°C. Those OR nurses who used preheated skin disinfection solution stated as reasons that the patient was awake, was small (children/infants), or had large areas of skin to disinfect.

**Special clothing designed to prevent spread of bacteria from staff to the surrounding air, that is, clean air suit**

Staff clothing (OR working clothing for all staff present at the OR department) for single use at the OR department was never used by 43.8% (390/890) and always used by 9.6% (85/890) (Table 13).
Discussion

Bacterial growth on patients’ skin and in the wound

It was clear that the skin disinfection did not eradicate all bacterial growth on the skin surface as wanted (study I), and that the bacteria remaining on the skin may be the cause of SSIs, together with possible exogenous bacterial air transmission from the persons within the OR. The proportions of patients with bacterial growth in the wound at wound closure were, respectively, 53.8% (36°C) and 62.5% (20°C) (study I). The amount (CFU/mL) of bacteria had tripled compared to the cultures taken after the skin disinfection (study I). Pacemaker surgery is considered to be clean surgery, but it is clear that the wounds are contaminated by bacteria consisting of \textit{P. acnes} and CoNS (study I). Both these types of bacteria cause SSIs. To reduce SSIs, the key focus should be on improving the skin disinfection process to even further reduce the presence of bacteria, as the presence of bacteria is great both on the skin and in the wound of the surgical patients during surgery (study I). The large amount of bacteria present in the wound during cardiac device implantation in study I indicate that the contemporary skin disinfection process performed might have been insufficient. Together with the knowledge surrounding the formation of biofilm and future antibiotic resistance, it is crucial to find new interventions to enhance the skin disinfection process. Moreover, the bacteria dominating in the wound consisted mainly of CoNS and \textit{P. acnes}, which are highly associated with SSIs involving biofilm. Preventing the skin bacteria from reaching the foreign implanted material may be the best way of preventing possible biofilm-forming SSIs.

Considering that preheated skin disinfection may have less time to affect the bacteria on the patients’ skin because of the faster vaporization, results showed that preheated skin disinfection seemed to generate somewhat less (CFU/mL) bacterial growth in the wound compared to room-temperature skin disinfection, although this was only a trend, and no statistically significant difference was shown (study I). Even though this was a non-inferiority design, analysis for differences was performed, and the statistical non-significance could be due to a type II error. In the future, it would be interesting to have a larger sample size to test whether preheated chlorhexidine leads to significantly less growth of bacteria in the wound and therefore to fewer SSIs. Melling and colleagues have reported that systemic warming of the patient reduced SSIs, and warming
locally even more so. To elaborate, warming the skin locally, together with preheated skin disinfection, could be beneficial in making the skin disinfectant solution penetrate further down into the deeper layer of the skin.

**Skin temperature**

The mean skin temperature was 32°C in both groups before the skin disinfection, which decreased the mean skin temperature in the preheated and room-temperature groups by 4.75°C and 5.49°C, respectively. The skin disinfection process alone had a large impact on the patients’ skin temperature, but preheated skin disinfection solution reduced the skin heat loss significantly. Although, core and skin temperature are different, the skin is involved in core body temperature regulation. Therefore, it is also important to use all interventions possible, including preheated skin disinfection, to prevent body heat loss and thereby to prevent hypothermia in patients, which increases the risk not only for SSIs but also for other complications such as blood loss and cardiac events.

**Experience**

The importance of the patients’ thermal comfort during hospital stay has been showed in numerous studies. The pacemaker patients were awake during the preparation and the surgical procedure (studies I and II). In clinical praxis patients often comment on the uncomfortable cold feeling they experience when the OR nurse performs the skin disinfection. Sessler and colleagues reported that little effect was achieved by preheating alcohol-based skin disinfection solutions and that interventions to reduce heat loss had to be found elsewhere. In 1977, a comment was published that described how awake patients experienced skin disinfection as cold. The comment stated that the response to preheated skin disinfection was overwhelmingly favourable, which is in concordance with a pilot study and study II. Moreover, the publication from 1977 shows that HCWs have for a long time considered room-temperature skin disinfection to be a problem with respect to patient comfort. The patients (28%) that received preheated skin disinfection in study II still desired a warmer solution. The preheated skin disinfection solution was measured to be 36°C directly taken from the warming cupboard, which gives the option to preheat up to 40°C, according to the manufacturer. To increase the temperature of the skin disinfection
solution up to 40°C may have more positive impact both on reducing bacterial growth and on patient comfort, but this has to be further investigated.

**Bacterial growth and recolonization the hands**

Study III originated from observations in clinical praxis, noticing a dark indication for moisture and fluid at the glove cuff end among the surgical team members. However, if the outer glove does not reach over the inner glove or if single gloves are used, this indication will not be visible. The indication of moisture was confirmed visually when the glove cuff ends were turned inside out (Figure 12).

![Figure 12. Moisture at the glove cuff end. Photo by Stefan B. Larsson©](https://example.com/image.png)

The interface of the gown and glove is considered a weak link, as fluids can move from the inside to the outside and vice versa. The intention of the preoperative hand disinfection is to eradicate transient flora and to
reduce resident flora of the hands with a prolonged effect. The prolonged effect is to minimize cross-infection from the surgical team members to patients, for example, in case of punctures in the gloves.

It have been reported that recolonization occurs inside the gloves and that the bacterial counts on the hands increase with time. Study III showed a possible trend that OR nurses had a more difficult task eradicating the bacterial growth on their hands when performing the preoperative hand disinfection. The trend (non-significant) was the opposite after wearing the sterile gloves. The non-HCWs showed higher bacterial recolonization, even though the non-HCWs wore the gloves for a significant shorter period of time.

The amount of bacterial growth found at the glove cuff end was not very high compared with the amount of bacterial growth sometimes found on the hands after wearing gloves, but this shows that the glove cuff end is a danger zone which can transfer bacterial growth, possibly from the hands; the glove cuff may also be contaminated by the hands when donning the glove. It would be interesting to invent and test a new kind of one-piece surgical gown with the gloves attached to the sleeves. Gown size could follow the surgical glove size.

Skin flora of patients may change when they are admitted to hospitals. This raises the question of whether this applies to health care workers too. The surrounding environment is the same, but not the health issues. There may also be differences in bacterial growth and recolonization on the hands of OR nurses compared to those of non-HCWs due to their frequently performed preoperative hand disinfection and possible resulting skin damage.

Preventive interventions to reduce surgical site infections
The national guidelines, in the Handbook for Healthcare, recommend warm fluids to reduce heat loss at the OR departments. Many OR departments in Sweden have warming cupboards where personnel preheat the fluids used for intravenous or intracavity administration. The result in study IV indicated that 57% of the OR nurses sometimes used warm fluids in the cavity. This may seem like a low proportion. However, the reason for not using warm fluids in the cavity was not investigated. The majority of the OR nurses (86.7%) did not preheat the skin disinfection solutions, possibly because of the somewhat contradictory information regarding this possibility. The national guidelines in the Handbook for Healthcare recommend warm fluids but do not specify which fluids or
how to preheat them, nor do they specify how to administer these warm fluids. According to the Swedish environmental classification of pharmaceuticals, the skin disinfectant chlorhexidine 5 mg/ml in 70% ethanol should be stored at room temperature, no higher than 25°C. The manufacturer of chlorhexidine 5 mg/ml in 70% ethanol states that this solution should be stored at room temperature but can be preheated up to 40°C for one week without any negative effects on the product.

To increase the use of preheated skin disinfection solution it seem like the OR nurses need support from the national guidelines, which could clearly state the possibility of preheating the skin disinfection solution. The OR nurses who preheated the skin disinfection solution stated their reasons for doing so as the patient being small or being awake during the skin disinfection process, or having large body areas to be disinfected. These reasons may originate from the idea that preheated skin disinfection solution should reduce heat loss and promote patient comfort.

The intervention regarding the prewash with chlorhexidine soap calls for it to be performed on the whole of the body including the hair, twice before surgery, normally preoperatively at the ward. Study IV showed that the majority of the OR nurses used a 4% chlorhexidine soap-containing sponge at the OR before the skin disinfection procedure started. This intervention to reduce bacterial growth is not mentioned by the national guidelines or supported by recent studies.

The disinfection solution manufacturer and the national guidelines emphasize the importance of the correct duration by which the skin disinfectant should affect the skin surface. Different body parts have different amounts of bacterial growth and different types of bacteria depending on the location and amount of moisture present, such as in the axillae, and therefore the time spent on skin disinfection depends on the location on the body. In study IV the majority of the OR nurses assessed the time spent performing skin disinfection of the abdomen to be from two to five minutes. The patients’ skin should dry before being draped not only for the solution to affect the skin and for the drapes to adhere properly to the skin but also for patient safety, considering that ethanol is flammable. In study IV the result showed that 34% of the OR nurses did not let the skin dry completely before draping the patient, which the research team interpreted to mean when sterile wipes were used to wipe the skin dry prior to draping. The OR nurses did dry only the area that the drapes were to adhere to and not the incision site. Using sterile paper to dry the skin may increase the risk of undetected bacterial contamination.
from the surrounding area into the surgical area, but this has no evidence and needs to be investigated further. The underlying reason for not letting the skin dry was not investigated. Did the OR nurses feel pressed for time and therefore dry the skin, or was the wiping something they had learned from clinical practice? Study IV showed that the skin disinfection process was mostly learned from the supervisor (OR nurse) at the clinical practice or the instructor at the university. This requires up-to-date supervisors and instructors to provide the OR nursing students with evidence-based clinical interventions to prevent wrong and old-fashioned behaviours.

Consensus regarding plastic adhesive drapes is lacking, but the current evidence seem to go against the use of plastic adhesive drapes, with possibly more contamination in the surgical wound occurring with them. The use of plastic adhesive drapes seems to vary internationally, as it did in study IV. The fragmented use of plastic adhesive drapes in Sweden can perhaps be explained by the absence of guidelines in the Handbook for Healthcare. The national guidelines state clearly that the gowns, gloves, and patient drapes should be for single use only, with which OR nurses had high compliance (IV). The OR nurses also assessed the draping material to be highly adherent to patients’ skin during the surgical procedure (IV). This result, however, did not differentiate between the type of draping material, with or without plastic tape.

There is a lack of national guidelines for when surgical gloves should be changed or more specific guidelines to prevent individual interpretations. Studies have shown that puncture holes often occur unnoticed, and that the rate increases with time worn. Study IV showed that double gloves were always used by 73.0% of the OR nurses as recommended by the guidelines. Internationally, the trend is to support the surgical team with guidelines to change the single or outer gloves after 90 minutes of use, if no other reason exists to change them earlier; this strengthens patient safety and reduces individual interpretations, which are not always evidence based. Studies have addressed the glove cuff and gown interface as a possible route for bacterial transmission, and study III showed bacterial growth at the glove cuff end. Furthermore, the manufacturer mentions the moisture at the sleeve being unsterile. OR nurses seldom noticed visible moist at the glove cuff end (IV), which seems to reflect a rather low awareness of this risk for potential bacterial contamination. It is of importance that the outer glove reaches over the inner glove, and according to study IV, 83.3% of the OR nurses always had the outer glove reaching over the inner glove. Study IV showed that
OR nurses assessed a small or moderate bacterial recolonization under the sterile glove. Interestingly, 12.4% thought no bacterial recolonization occurred. However, it is not easy to find out the normality of the bacterial growth on the hands before or after preoperative hand disinfection and after wearing gloves, even after extensive review. The problem is complex because the methods used to discover bacterial growth are different in different studies, and the variation in bacterial growth is large from one individual to another. A conclusion drawn from studies I and III together with numerous other studies is that the skin of humans is never made totally free of bacterial growth, not with the state of contemporary knowledge.27, 37, 38, 89, 90, 113, 146-149

Methodological considerations
The strength of studies I and II was the design, a randomized controlled trial (RCT) with stratification. RCTs provide a strong internal validity because of the randomization and control of bias,150 although every study design has its weaknesses. Some weaknesses in the RCT studies were that different OR nurses performed the skin disinfection, culture swabs, and temperature measurements, which may have led to differences related to these outcomes. Men and women have significantly different amounts of bacterial growth on the skin, and this should be considered when analysing data based on bacterial counts.35 By the use of a randomized block design, the intention was to separate gender so that the groups did not became biased by the differences in skin flora. Analysis was performed between both groups, but also performed with men and women separately to investigate potential different outcomes due to gender (study I). There were significant differences between gender regarding bacterial growth at all four sampling time points, which strengthens the importance of having an equally large sample size of men and women in both groups. However, the effect of the intervention was no different for either gender (study I).

The absolute difference between the groups was zero based on bacterial growth, 28.6%, with a CI that was just outside the preset limit of 10%. Strict statistical non-inferiority has not been proven, but the merged results from study I and the statement from the manufacturer136 suggest that non-inferiority has been reached clinically and that preheated skin disinfection is not less effective than the standard room-temperature skin disinfection (study I). The follow-up regarding SSIs supports the finding that preheated skin disinfection solution was not less effective than the
room-temperature solution, in that the preheated group had one SSI versus two in the room-temperature group.

Study I had a power problem and would have needed a few more participants to reach the preset limit of 10%. The power calculation was based on a lower proportion of positive cultures, which made the sample size lack power. Another weakness of the study design was that the outcome bacterial growth was a surrogate measure for SSI. The reason for using bacterial growth instead of SSIs was to limit the sample size. A further weakness regarding the sampling technique was that the swab was moistened with saline for samples obtained from the skin; however, this was not the case for the samples taken in the wound. This may have affected the amount of CFU/mL, as the fluid in the eSwab tube may have become diluted. However, every sample became equally diluted in both groups. Future research is needed to strengthen these results with larger sample size, including other surgical specialties, and outcomes such as SSIs, with cultures as a complement. Cultures are needed to investigate and explore the understanding of SSIs so that results can confirm or refute current knowledge regarding bacterial growth and SSIs.

The choice of outcome and method for measuring temperature in study II was based on several aspects. Sampling core temperature was not suitable when patients were awake, with the discomfort associated with that kind of measurement. In a previous pilot study, skin temperature was measured using a probe that required contact with the skin and measured continuously. This was found to be time-consuming and not reliable due to the continuous measurements, which never gave a fixed temperature. The required contact of the probe with the skin would also pose a contamination risk for the patients prepared for the surgery. The probe would need to be covered with sterile plastic, which could introduce bias for reliable measurement of the skin temperature. The choice was made to measure skin temperature rather than core temperature because the skin temperature would change while performing the skin disinfection process, but the core body temperature probably would not. Considering the hygienic demands at the OR, an IR thermometer was chosen that had not been tested before in similar settings. To enhance the reliability, a specific distance of approximately 10 cm was set from the patient skin to avoid possible bias. Testing the thermometer unscientifically, repeated measurements yielded very similar temperatures. The procedure and routines for pacemaker surgery are very standardized and performed in an effective way to allow as many pacemaker surgeries as possible to be
performed in the same OR in one day. The average number of pacemaker surgery patients was five to six patients in the same OR. This standardized way of working reduces possible bias, and every patient was treated with the same routine by experienced OR staff.

The knowledge sought was whether the larger number of pacemaker patients preferred preheated skin disinfection solution compared with the standard room-temperature disinfectant. A quantitative outcome was regarded to generate a more universal result, rather than the deeper knowledge of understanding the individual experience. With that intent, the questionnaire for measuring the experience was created as a modified NRS with additional questions. A strength of the use of the NRS was that patients selected a number from zero to ten. No material rulers were used because patients’ arms were strictly by their sides to prevent bacterial contamination of the surgical area. Many patients recognize this way of measuring from pain evaluation. The questions were asked while the patients were having their skin disinfected, which reduced memory bias. A weakness of using the modified NRS was that the scale had not been validated or tested for reliability for measuring the thermal experience in these settings. In clinical practice, scales such as visual analogue scales, numerical rating scales, and verbal rating scales are frequently used and have been shown to be valid and reliable regarding pain measurement. The Cold Discomfort Scale (CDS), which is a subjective judgment scale for the assessment of patient thermal state in a cold environment, has been shown to be valid and reliable by Lundgren et al., but this study had not been published prior to the data collection. The NRS with modifications is similar in many ways to the CDS, which can strengthen, but not confirm, the modified NRS in study II. A criticism could also be that some believe that subjective experiences must be measured using qualitative methods. The choice was to operationalize subjective opinions and label them numerically, and create an instrument with certain kinds of preset definitions that the patients had to relate to in giving their answers.

The outcome in study III was bacterial growth, which was measured by the use of cultures sampled from the hands and sleeves. There were many methods to consider when deciding which sampling method to use. Different kind of swabs and methods are used in different studies. Some use agar plates to press fingers on, some use different kind of swabs that are pressed or rubbed, and some use the glove juice technique. The glove juice technique was recommended in a review by the Cochrane Collaboration. The glove juice technique was not applicable to study III
due to the sampling at the glove cuff and gown interface. The choice was to use a swab that allowed the bacterial growth to be quantifiable. Three sites on the hand were selected for culturing that were considered more difficult to disinfect, such as the palm, between the fingers, and at the nails. To increase the reliability and minimize bias regarding the sampling technique, one person performed all the samplings in study III, according to a preset protocol. A weakness in the design was the lack of baseline regarding bacterial growth. However, the hands were thought to be heavily contaminated with a vast number of different microorganisms, both resident and transient. Damaged skin is likely to have larger amounts of bacteria compared to healthy skin. The OR nurses in study III probably had more damaged skin than the non-HCWs due to the extensive hand washing regime that OR nurses performed every day at work. Therefore, it is possible that the OR nurses had higher counts of bacteria at the start of the preoperative hand disinfection procedure, and this may have affected the result. Study III had few statistically significant differences between the groups, probably because of a power problem. The study was planned as a pilot study with few participants, to explore and test our hypothesis. The strength of only using OR nurses was that their glove sleeves did not have contact with the patients as the surgeons’ did. This strengthens the likelihood that the bacteria found under the glove sleeves originated from the OR nurses’ hands and not from the patients’ bodies.

Study IV consisted of a questionnaire constructed by the research group, which was not a validated questionnaire. The choice was made to construct the questionnaire because no suitable validated questionnaire was found that answered the aim. Face validity was reached, which means that the questionnaire seemed to measure what was intended, when tested in 10 OR nurses. In study IV, the use of a web-based questionnaire was considered both a strength and a limitation. The strength was that it was environmentally friendly and inexpensive, and the participants were at work when they answered it, which made it possible for them to control answers. The limitation was the difficulties in obtaining the email addresses. However, the survey had respondents from all 21 counties and regions in Sweden. Two regions, one in the south and the other in the middle of Sweden, had the largest response rates, with 178 and 155, respectively. The other counties and regions were fairly evenly distributed, apart from one region which generated only five respondents. The 890 OR nurses worked at 64 different hospitals from the north to the south of
Sweden. Some of the non-responses to the survey could be explained by the possibility of ‘saving’ the questionnaire while answering it. It seems it was possible to mistake this for ‘sending’. Apart from saving the answers, the respondents had to press a send button when finished. This mistake became apparent when the questionnaire reminders were sent out and respondents notified us by email that they had already answered the questionnaire. Some respondents also replied that they had been told not to open web links of unknown origin.

Clinical implications and future studies

This thesis has mainly focused on interventions performed by OR nurses that reduce bacterial growth on the skin in the surgical patient, with the underlying assumption that reduced bacterial growth on the skin prevent SSIs. The present study showed high compliance with national guidelines, and the implications should be to develop more evidence-based guidelines to maintain good care and enhance patient safety. This thesis has also highlighted patient satisfaction with the intervention of preheating the skin disinfection solution. The implication drawn from these results, and implemented in our OR department, should be the use of preheated chlorhexidine 5 mg/ml in 70% ethanol for patients who are awake during the skin disinfection process; this reduces heat loss and promotes a more pleasant patient experience. Moreover, the potential risk of cross-contamination via the glove cuff and gown interface needs more attention and a future solution.

Future studies should aim to test preheated chlorhexidine 5 mg/ml in 70% ethanol in a larger sample size including several surgical specialties, preferably with the outcome SSIs, but also include samples to assess the bacterial growth.

It would be interesting to enhance and try to develop a new kind of surgical gown with the sterile gloves attached to the sleeves of the gown and to clinically test the functionality of this type of gown.
Conclusions

- Preheated chlorhexidine 5 mg/ml in 70% ethanol is not less effective for skin disinfection regarding bacterial reduction compared with room-temperature disinfectant.

- Males had significantly more bacteria on the skin and in the wound than females, irrespective of the temperature of the skin disinfectant.

- A preheated skin disinfection solution reduces skin heat loss compared with a room-temperature solution.

- A preheated skin disinfection solution contributes to a more pleasant experience for the patients that are awake during the skin disinfection procedure compared to room-temperature solution.

- There were differences in bacterial growth and recolonization between the groups of OR nurses and non-HCWs, but this was inconclusive.

- Bacterial growth exists at the glove cuff and gown interface and may pose a risk for bacterial cross-contamination between patients and surgical team.

- OR nurses have high compliance with national guidelines regarding interventions to prevent SSIs, and implementing guidelines seem to be a key priority for standardizing the preventive interventions performed to reduce bacterial growth.
Svensk sammanfattning (Swedish summary)

Vid en operation finns det alltid risk för olika komplikationer där den tredje vanligaste komplikationen är postoperativ sårinfektion. Postoperativa sårinfektioner orsakas av olika bakterier som kan kontaminera saret under och efter operationen där de vanligaste bakterierna som orsakar postoperativa sårinfektioner är *Staphylococcus aureus* och koagulasnegativa stafylokokker. För att förhindra att bakterier kontaminerar saret hos patienten under operation utförs ett flertal olika åtgärder. Kontaminering och mängd av bakterier kan reduceras genom åtgärder som antibiotikaprofylax men även genom att bevara patientens kroppstemperatur, huddesinificera patientens hud, drapera patienten med sterilt material, aseptiskt handhavande, handdesinfektion, sterilt material och att använda dubbla sterila handskar osv. Syftet med denna avhandling var att testa och beskriva olika åtgärder som svenska operationssjuksköterskor utför för att minska bakterieförekomsten och därmed förebygga postoperativa sårinfektioner hos patienter som genomgår operation samt förbättra patientupplevelsen.

Studie I och II var en randomiserad kontrollerad studie som utgår från samma patienturval, 220 pacemakerpatienter. I studie I jämfördes effekterna av uppvärmd (36°C) och rumstempererad (20°C) huddesinfektionsmedel gällande dess bakteriedödande effekt. Fyra odlingar/patient genomfördes. Odlingarna skedde på det planerat operationssnittet före huddesinfektionen och efter huddesinfektionen när huden torkat samt en odling i saret vid operationssstart och en odling i saret vid operationens slut. Postoperativa sårinfektioner följes upp efter tre månader. I studie II testades det huruvida värmd huddesinfektion kylde huden mindre varvid huden temperaturen mättes före huddesinfektionen och efter då huden torkat. Upplevelsen av huddesinfektionen gällande dess temperatur mättes med en numerisk skattnings skala som sträckte sig från 0 till 10 (0 = behagligt, 10 = obehagligt). Frågor ställdes också gällande om patienten frös och om han/hon önskade varmare, kallare eller om värmén på huddesinfektionsmedlet var bra som den var. Resultatet visade att uppvärmd huddesinfektion var likvärdig gällande reducierung av bakterieväxten jämfört med rumstempererad. Därutöver var värmeförlusterna mindre i huden hos patienterna som blev desinficerade med uppvärmd huddesinfektionslösning samt att patienterna upplevde att uppvärmd huddesinfektionslösning kändes mer behagligt jämfört med den rumstempererade.

Studie IV var en enkätsstudie som syftade till att beskriva vilka preventiva åtgärder svenska operationssjukskötterskor utförde dagligen i sitt kliniska arbete för att minska mängden bakterier hos patienterna som genomgår en operation. Enkätfrågorna riktade sig mot hudförberedelser, värmebevarande åtgärder och olika material som användes. Enkätan skickades ut till ca 2 200 av ca 4 000 operationssjukskötterskor i Sverige. Resultatet baserades på svaren från 890 operationssjukskötterskor. Resultatet visade stor följsamhet till de preventiva åtgärder där nationella riktlinjerna fanns framtagna men att när det saknades riktlinjer så varierade resultaten.
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References


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