

# **Patient Safety in the Operating Room**

## **Focus on Infection Control and Prevention**

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**UNIVERSITY OF GOTHENBURG**

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Ineko

Två sanningar närmar sig varann.  
En kommer inifrån, en kommer utifrån  
och där de möts har man en chans att få se sig själv.  
Den som märker vad som håller på att hända ropar förtvivlat:  
Stanna! Vad som helst, bara jag slipper lära känna mig själv.

Thomas Tranströmer, Preludier: Mörkerseende 1970.



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### ABSTRACT

**Aims:** The overall purpose of this thesis was, in the light of patients' experiences of acquiring a deep SSI, to explore the air quality during orthopedic implant surgery and the application of intraoperative measures to reduce risk factors associated with SSI.

**Methods:** In Paper I, 14 patients were interviewed using a qualitative approach. In Papers II and IV, during elective and fracture implant operations, 284 active air samples were taken in displacement and laminar (unidirectional) airflow-ventilated operating rooms. Door openings and other events occurring during surgery were recorded. In Paper III, to obtain data on the application of infection-prevention measures, structured and participant observations were carried out during 69 surgical procedures.

**Results:** Paper I, revealed that developing a deep infection after surgery was seen as a life-changing event, negatively affecting all parts of life. Feelings of pain and not being taken seriously by the health-care providers dominated the experiences. Paper II found that the mean levels of CFU/m<sup>3</sup> in displacement-ventilated ORs exceeded the recommended levels for implant surgery (m=15.9). A strong correlation was found between door-opening rates (m=17.4) and CFU levels ( $r=0.74$ ,  $p=0.001$ ). Every door opening resulted in an increase in CFU/m<sup>3</sup> of 5.3. Sixty-eight percent of the variance in CFU/m<sup>3</sup> could be explained by: length of surgery, door openings and the number of people present in the OR. Paper IV showed that the laminar airflow system observed in this study offered high air quality with very low levels of CFU/m<sup>3</sup> during surgery (md=1.0). No significant relationship between door openings and CFU/m<sup>3</sup> was observed, but the median door-opening rate was found to be low (md=8). Paper III revealed that evidence-based measures, such as the correct timing of prophylactic antibiotics and normothermia to reduce the risk of postoperative infections, were not sufficiently implemented. The overall adherence to hand hygiene guidelines was 10.3%.

**Conclusions:** Every unnecessary door opening and failure to implement protective measures during surgery potentially enables the development of an SSI that could result in serious consequences for the patient. Using patients' narratives as a diagnostic tool could reduce the risk of delayed treatment. Finally, without a display in every OR that shows the current airflow and pressure gradient, the safety of patients cannot be guaranteed.

**Keywords:** Patients' experiences, Patient safety, Surgical site infections, Orthopedics, Air sampling, Operating room, Nursing, Surgery, Complexity, Culture

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# SAMMANFATTNING PÅ SVENSKA

**Syfte:** Det övergripande syftet med denna avhandling var att med utgångspunkt från patienters erfarenhet av att drabbas av en djup postoperativ sårinfektion, utforska luftkvalitén under ortopedisk implantatkirurgi samt tillämpningen av evidensbaserade åtgärder för att minska risken för infektion.

**Metoder:** I studie I, deltog 14 patienter där öppna intervjuer användes för att utforska hur en postoperativ infektion kan påverka det dagliga livet.

I studie II och IV, togs sammanlagt 284 aktiva luftprover under pågående ortopedisk implantatkirurgi i operationsrum utrustade dels med deplacerad ventilation, dels med laminärflödes tak. Planerad kirurgi, som höft- och knä artroplastik, och akut kirurgi som höft och underbensfrakturer inkluderades i studien. Under luftprovtagningarna utfördes även strukturerade och deltagande observationer. I studie III, undersöktes hur ofta och på vilket sätt, ett urval av infektionspreventiva åtgärder (normotermi, aseptisk teknik och handhygien, användning av antibiotikaproylax, perioperativ urinvägskateter samt del av WHO's checklista för säker kirurgi ("time out")) tillämpades interoperativt. Data samlades in via strukturerade och deltagande observationer.

**Resultat:** Studie I, visade att en djup postoperativ infektion har en negativ påverkan på livet, fysiskt, känslomässigt, socialt och ekonomiskt under lång tid. Deltagarna beskrev hur de var tvungna att söka hjälp i sjukvården upprepade gånger, ofta under flera månader, innan de fick en korrekt diagnos och behandling. Fysisk och emotionell smärta samt känslan av att vara övergiven och inte bli tagen på allvar dominerade patienternas berättelser.

Studie II, visade att medelvärdet av bakteriekolonier (CFU)/m<sup>3</sup> i deplacerad ventilation överskred rekommenderat gränsvärde för implantatkirurg (<10 CFU/m<sup>3</sup>) (m=15,9 range:0-55). Det existerade ett starkt samband mellan antal dörröppningar och CFU/m<sup>3</sup> i närheten av operationssåret ( $r=0,74$ ,  $p=0,001$ ). Då det finns en samvariation mellan medelvärdet av CFU/m<sup>3</sup> och operationens längd, kontrollerades för detta i sambandsanalysen. Varje dörröppning genererade en ökning av CFU/m<sup>3</sup> med 5.3. Dörröppningar, antal personer på sal och operationens längd förklarade 68 % av variansen i totala CFU/m<sup>3</sup> värdet ( $P=0,001$ ).

I Studie IV framkom att den undersökta typen av laminärflödestak erbjuder hög luftkvalité med mycket låga halter av (CFU)/m<sup>3</sup> under pågående operation (MD=0 range:1-18), förutsatt att samma förhållande råder som under datainsamlingen. Inget statistiskt säkerställt samband observerades mellan dörröppningsfrekvens och CFU/m<sup>3</sup> i denna studie, dock var frekvensen av dörröppningar relativt låg (md/operation=8) likaså variabiliteten. I båda ven-

tilationssystemen påverkas CFU värdena av *var* och *hur* luftinsamlingsdonet placeras.

Studie III, visade att evidensbaserade åtgärder för att minska risken för infektion, såsom antibiotika profylax given i korrekt tid och normotermi, inte implementerades i full utsträckning. Tjugonio av 59 patienter erhöll antibiotikapofylax inom rekommenderad tidsintervall. I 10 fall av 29 erhöll de patienter som genomgick frakturkirurgi första dosen av antibiotikapofylax *efter* det att operationen påbörjats. Dessa patienter var även något sjukligare än de patienter som genomgick planerad kirurgi. Skyddsåtgärder mot infektion tillämpades i lägre grad vid intra-operativ vård och omvårdnad av patienter som genomgick akut implantat kirurgi jämfört med patienter som genomgick planerad implantat kirurgi ( $p=0,004$ ). Tillämpningen av basala hygienrutiner peri-operativt var i genomsnitt 10.3%. WHO's checklista för säker kirurgi fungerade som en viktig påminnelse för profylaktisk antibiotika, men var inte i sig någon garanti för att korrekt åtgärd genomfördes i de fall där man upptäckte att patienten inte fått antibiotikapofylax.

**Slutsats:** Vårdgivare och vårdens professionella måste ha i åtanke att varje onödig dörröppning samt åsidosättande av infektionspreventiva åtgärder kan resultera i postoperativ infektion som kan leda till allvarliga konsekvenser för de patienter som drabbas. Att använda sig av patientberättelsen som ett diagnostiskt verktyg kan bidra till att förhindra fördröjd diagnos och behandling när infektion tillstött. Slutligen, utan tydliga displayer som visar aktuellt luftflöde och tryckgradient på varje operationssal och i uppdukningsrum kan patienters säkerhet inte garanteras.



## LIST OF PAPERS

This thesis is based on the following studies, referred to in the text by their Roman numerals.

- I. Andersson EA, Bergh I, Karlsson J, Nilsson K. **Patients' experiences of acquiring a deep surgical site infection: An interview study.** American Journal of Infection Control. 2010 Nov;38(9):711-7.
- II. Andersson EA, Bergh I, Karlsson J, Eriksson BI, Nilsson K. **Traffic-flow in the operating room – an explorative and descriptive study on air quality during orthopedic trauma implant surgery.** American Journal of Infection Control. 2012 Oct;40(8):750-5
- III. Andersson EA, Bergh I, Karlsson J, Eriksson BI, Nilsson K. **The application of evidence-based measures to reduce surgical site infections during orthopedic surgery - report of a single-center experience in Sweden.** Patient Safety in Surgery. 2012 Jun 14;6(1):11
- IV. Andersson EA, Bergh I, Karlsson J, Eriksson BI, Nilsson K. **Exploring the protective ability of parallel airflow systems** (in manuscript).



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# ABBREVIATIONS

ASA	American Society of Anesthesiologists' preoperative assessment score
CDC	Centers for Disease Control and Prevention
CoNS	Coagulase-negative staphylococci
CFU	Colony forming unit
CT	Complexity theory/thinking
DV	Displacement ventilation
DRI	Device-related infections
HAI	Hospital-acquired infection
HCW	Health-care worker: nurses, physicians and nursing assistants
HD	Hand disinfection
HEPA	High efficiency particulate air
LAF	Laminar airflow ventilation
LOS	Length of stay (in hospital)
NNIS	The National Nosocomial Infections Surveillance System
OR	Operating Room (USA)
OT	Operating Theatre (Great Britain)
SSI	Surgical site infection
THR	Total hip replacement
THA	Total hip arthroplasty

TKR	Total knee replacement
TKA	Total knee arthroplasty
TJA	Total joint arthroplasty
UTC	Urinary tract catheterization
UTI	Urinary tract infection
VRE	Vancomycin-resistant enterococci
MRSA	Methicillin-resistant <i>Staphylococcus Aureus</i>
FS	Fracture surgery







# 1 INTRODUCTION

About eighteen years ago, while studying to become a nurse, I worked as a nursing assistant in home-based care during my vacations. One of the most deeply imprinted memories of this was the visit I made to a middle-aged woman on a daily basis. She used to sit in her living room in the same chair all day long. Around her leg I had tried to cover the little wound with double layers of diapers in an attempt to prevent the large amount of clear liquid that ran from the wound reaching her shoes and subsequently wetting everything she came in contact with. I was extremely puzzled about what was causing this ongoing leakage and so was the woman. I knew that she had had a surgical procedure, but how the leak was related to this remained a mystery to me for a long time. It never struck me that this could be a sign of an infection, as there was no redness, swelling or pus involved.

In 2006, when I started to think about the possibility of writing a thesis, my main interest and focus lay in the prevention of infections related to surgical procedures. However, the area to focus on and the questions to answer were somewhat unclear. Writing a thesis meant spending a great deal of time and energy, so I had to find a field of research that would produce an interest strong enough to drive me for many years in the future.

It is definitely clear that surgical site infection (SSI) is a major problem and a burden on both economic and human resources. However, the views on infections can differ; a senior doctor once said to me, “No, we don’t consider infections to be an adverse event, we give them seven days of antibiotics and that’s the end of the problem”. Remembering the woman with her leaking leg, I felt that there must be something more to it than that. It also raised questions about the way different perspectives have an influence on how we look at things happening around us. Moreover, who is to say if something is or is not a problem? What kind of knowledge is regarded as the truth in relation to treatment, care and clinical outcome? Is the perspective of the patients and their experience-based knowledge something that is considered in today’s health care? If not, is there something we could gain by trying to shift perspectives?

These personal thoughts became the starting point for the first study of how patients experience a surgical wound infection. Subsequently, the result of this study worked very well as the motivator I was looking for.

As an RN specializing in operating room (OR) nursing, the choice of context problematization was obvious. Someone else could argue that the result should lead to further research in another direction. I decided, however, that my experiences and skills as an OR nurse, both technically and socioculturally, could offer unique opportunities to explore the area of preventing infections.

As a result, the papers included in this thesis address issues and problems about which I have thought a great deal and discussed with surgical team members and managers on many occasions. In addition, the years when I was given responsibility for working on hygiene-related questions at the department of surgery helped to shape the questions that were asked. Moreover, my conclusion from this experience is that, in some respects, infection control and prevention has little to do with bacteriology. This does not mean that bacteriology does not offer important knowledge. However, if we fail to understand the spread of bacteria and the development of infections in relation to the environment in and around the OR and the interacting complexity that constitutes the world of hospitals, we are likely to lose the battle to prevent hospital-acquired infections. I believe that there are no simple solutions or “quick fixes” that easily resolve the problem that approximately 10% of all patients will acquire an infection because of treatment and care (1-3). I believe that the challenge in working with infection prevention lies in gathering and bringing together the state of the art in different scientific fields such as epidemiology, medicine, pedagogics, nursing, psychology and sociology, in order at least to begin to understand the complexity of hospital-acquired infections (HAI) and how they can be prevented or reduced.

My hope is that this thesis will offer some additional understanding of the complexity of the problem and identify some possible future directions when it comes to the way we can create a safer operating environment. The focal point is patients undergoing planned or acute orthopedic implant surgery and first and foremost the intra-operative period.

## 2 THE HISTORY OF INFECTION CONTROL AND PREVENTION

There are many reasons why infection control and prevention is still a subject causing controversies and provoking professional healthcare workers. A recent example is the heated debates regarding the traditional doctor's white coat with long sleeves. The Swedish National Board of Health and Welfare banned its use in direct patient care, since coats of this kind are potential carriers of bacteria and cause cross-transmission between patients. This resulted in massive protests and several articles in the press. Looking back in history will perhaps provide some interesting clues to the reasons behind a phenomenon of this kind.



*Figure 1. The young Florence Nightingale. From Encyclopedia Britannica Online, use allowed without formal permission.*

*The very first canon of nursing, the first and last thing upon which a nurse's attention must be fixed, the first essential to a patient is to... keep the air as pure as the external air, without chilling him (the patient)*

Nightingale F. from Notes on Nursing: what it is and what it is not, 1898.

The first chapter in the very first book on nursing talks about *Ventilation and Warming*, subjects that more than 100 years later are still interesting and important for the prevention of infections in relation to surgery.

Florence Nightingale was born in 1820 into a wealthy English family. At an early stage, she nurtured the idea of doing something important with her life. She wanted to become a nurse, to make a difference to the sick and poor. Åsa Moberg, who wrote the biography *She was no Florence Nightingale – the person behind the myth* (4), points out that this must have been considered a bizarre idea in her time. During the Crimean War, at Scutari in 1854, Nightingale was given the opportunity to practice her ideas regarding the importance of ventilation, hygienic principles, nutrition and professional nursing skills in order to support the natural process of healing in sick and wounded patients (5). This was before the introduction of the germ theory, i.e. the theory that microorganisms may cause diseases. However, Nightingale insisted that every soldier/patient's wound must be bathed and that a fresh, clean cloth should be used for each patient. Moreover, only *one* patient per bed! (6). Today, we know that this is essential in order to avoid cross-contamination. Nightingale worked hard to create safe care and her tools were good organization, well-functioning logistics, strong leadership and good nursing skills. Her interventions in Scutari led to a striking reduction in mortality rates, from 40% to 2%. In addition, she kept meticulous records of everything she did and saw. With descriptive statistics, she was able to prove that the soldiers did not die from war wounds but from infectious disease (6) and she concluded that poor systems were to blame (7). Nightingale was strongly influenced by the Sanitarian movement and she used all her skills to convince national leaders of the need for change, not only in army hospitals but also most importantly in the areas of civil care and public health. Today, we would perhaps characterize her as a "whistle blower" and as such she acquired enemies.

Truth and myth about Florence Nightingale are entangled and difficult to separate and incoherent portraits of Miss Nightingale are found in the literature (7). As proof of the importance of her work in science, she was the first woman to be elected as a member of the Royal Society, mainly because she was a brilliant epidemiologist and statistician. At the end of her life, she was

regarded as a heroine and she received the Order of Merit in 1907, one of England's finest honors. Despite the controversies regarding her person, she has undoubtedly made major contributions to the development of what we now call infection control. She argued in favor of the prevention of infection by means of asepsis rather than antiseptics long before germ theory was accepted (7). Moreover, today's measures to prevent cross-transmission are based to a great extent on Nightingale's practice and findings.

Let us now walk further along the pathway of history. The story of Semmelweis is probably well known to nursing and medical students, so just briefly: he was a Hungarian doctor working at the Allgemeine Krankenhaus in Austria. At this hospital, there were two maternity wards and the story goes that the women begged not to be admitted to the first ward, as it was well known that women died more often from puerperal fever on that ward. In the first ward, physicians and medical students delivered the women with a post-delivery mortality rate of 13-18%, while the second ward was managed by midwives, with an associated mortality rate of 2%. Semmelweis' analysis of the situation led to the conclusion that the different mortality rates were related to the handling of corpses. He initiated several interventions based on hand disinfection to test this hypothesis. The results were astonishing; the mortality rate went down to 2%. After including the disinfection of medical instruments, the rate declined even more, down to 1% (8-10).

It could be assumed that this fantastic and convincing result brought him both fame and admiration. Instead, he was opposed and put to scorn by his superiors and some colleagues. His conclusion that their hands were carriers of diseases was not well received by superiors and colleagues and it was taken as an offence against the entire profession. He fled Vienna and, before he died in an insane asylum at the age of 47, he published a book; *Die Aetiologie, der Begriff und die Prophylaxis des Kinderbettfiebers* (11). It was not until after Pasteur presented clear evidence in favour of germ theory that his reputation was somewhat restored.

Pasteur also inspired Lister in his work on antiseptics and, in 1867, he publicly introduced the concept and methods (12). He started to test his methods of antiseptics on compound fractures and abscesses. At a later stage, he continued to experiment with different types of chloride acid solution for cleaning wounds, surgical instruments and the skin of patients prior to incision, plus the hands of the surgeon. Lister was the first to understand that bacteria could be inoculated during surgery by contaminated air. In order to prevent this, he tested saturating the air with a carbolic acid spray (8). He demonstrated a reduction in mortality rates following lower limb amputation from 46% to

15%, subsequently published in the *Lancet* (13). To understand the importance of his achievements, it is crucial to recognize that, before the introduction of surgical antisepsis, the associated death risk was extremely high. As Sir James Simpson (discoverer of the anesthetic properties of chloroform) stated “*the man laid on the operating-table in our surgical hospital is exposed to more chances of death than the English soldier on the field of Waterloo*” (14).

So what about today? Are the legacies from Nightingale, Semmelweis and Lister out of date and all the lessons already learned? The continued introduction to the area of infection following surgery will show hopefully offer some answers.

## 3 SURGICAL SITE INFECTIONS

In the following chapters, an overview of the incidence and consequences of SSI, with special emphasis on orthopedic implant-related infections, is presented. This is followed by descriptions of bacteriology and a delineation of risk factors in relation to the patient and the surgical environment. The definition of SSI according to the Centers for Disease Control and Prevention (CDC) (15) is given in Table 1, as this is the definition most frequently referred to in the literature.

### 3.1 Incidence and reflections on registration

Hospital-acquired infections are estimated to affect approximately 10-11% of all patients as a result of care and treatment (2, 16). The most common infections are, in descending order, the urinary tract, the lower respiratory tract, surgical wounds, followed by the blood stream. The prevalence reported in Sweden and internationally is similar, showing more or less the same differences in prevalence based on specialty (17, 18). Intensive care units (ICU) and the surgical specialties typically report a higher prevalence than the medicine-based specialties (16, 19).

For SSIs, the reported rates vary greatly; from 1-3% after major joint implant procedures (20-23) to 17-25% after large bowel and colon surgery (22, 24). Superficial SSI is more common than deep SSI (22). In spite of the relatively low rates related to orthopedic implant surgery, the problem must nevertheless be regarded as serious, since the total number of people undergoing this type of procedure is large and is expected to increase in relation to the aging population. Recent data indicate that revision surgery due to deep infection is an increasing problem. The Swedish National Hip Register from 2008 (21) reports a continuous increase in revision rates due to infection. Similar trends are reported from the Norwegian Arthroplasty Register (25) and the US (23). Regarding SSI rates following surgery on hip fractures, the Swedish national quality registry "Rikshöft" 2011 reported that the reasons for re-operation on cervical fractures operated with hemiarthroplasty were 73% for luxation, 23% for infection and 1% re-fracture (26). The reported incidence of SSI for fracture surgery is typically higher than that for elective orthopedic surgery, ranging from 2-9% depending on different factors (22, 27-29).

The extensive variations in the prevalence and incidence of SSI have multifactorial explanations. The variation can be related to differences in methodology and the duration of follow-up. Prevalence studies offer a single day snapshot-based picture, for example, but, when attempting to estimate the “real” infection rates, it is important to take account of the fact that more than 50% of SSIs have an onset after discharge and therefore not available for most hospital infection control surveillance programs (30-32). Some studies collect their data based on diagnostic code systems, others on the direct recording of infections among hospitalized patients. There are also differences regarding post-discharge surveillance. Moreover, some registries report infection rates only in relation to re-operation rates or revision rates. Another aspect that complicates direct comparisons is the diversity of classification systems, along with differences in the reporting of patient-related risk factors in relation to infection rates. The conclusion is that the confounding factors can be substantial. Consequently, direct comparisons between studies or registries are neither fruitful nor fair, since registries that implement accurate follow-ups have a tendency to report higher infection rates (24, 33, 34). The Swedish Hip Arthroplasty Registry analyzed 49,219 procedures in order to capture the “true” incidence of early prosthetic infections (within two years after surgery). The incidence was found to be 1.2% and the discrepancy between reported infections and actual infections was substantial. It was concluded that the registry covers 67% of re-operations due to infection (35).

The CDS definitions of SSI from 1999 are commonly used throughout the world, together with the risk index score ranging from 0 to 3, developed by the National Nosocomial Infections Surveillance System (NNIS). This index is based on the American Society of Anesthesiologists’ (ASA) preoperative assessment score, together with wound class and duration of operation (36). It might not be the best or the most accurate system available (37), but it offers a comprehensive understanding of how infection rates are linked to other factors. As an illustration: patients undergoing coronary artery bypass with risk index 0 were found to have an SSI incidence of 2.5 per 100 operations compared with 8.0 per 100 operations with risk index 2-3 (22).



Table 1. *The CDC's definition of surgical site infections.*

<b>Superficial incisional SSI</b>
<p>Infection occurs within 30 days after the operation <i>and</i> infection involves only skin or subcutaneous tissue of the incision <i>and</i> at least <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>Purulent drainage, with or without laboratory confirmation, from the superficial incision.</li> <li>Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.</li> <li>At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat <i>and</i> superficial incision deliberately opened by surgeon, <i>unless</i> incision is culture-negative.</li> </ul> <p>Diagnosis of superficial incisional SSI by the surgeon or attending physician.</p>
<b>Deep incisional SSI</b>
<p>Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation <i>and</i> infection involves deep soft tissues (e.g. fascial and muscle layers) of the incision <i>and</i> at least <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>Purulent drainage from the deep incision but not from the organ/space component of the surgical site.</li> <li>A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (<math>&gt;38^{\circ}\text{C}</math>), localized pain, or tenderness, unless site is culture-negative.</li> <li>An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.</li> </ul> <p>Diagnosis of a deep incisional SSI by a surgeon or attending physician.</p>
<b>Organ/space SSI</b>
<p>Infection occurs within 30 days after the operation if no implant is left in place or within 1 year if implant is in place and the infection appears to be related to the operation <i>and</i> infection involves any part of the anatomy (e.g. organs or spaces), other than the incision, which was opened or manipulated during an operation <i>and</i> at least <i>one</i> of the following:</p> <ul style="list-style-type: none"> <li>Purulent drainage from a drain that is placed through a stab wound into the organ/space.</li> <li>Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.</li> <li>An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.</li> </ul> <p>Diagnosis of an organ/space SSI by a surgeon or attending physician.</p>

Adopted and modified from Mangram et al. (15) and published with permission from the Journal of Infection Control Hospital Epidemiology and the University of Chicago Press.

Finally, the surveillance of infection rates is first and foremost an important tool for surgeons and nurses, along with infection-control practitioners, to assess a local baseline in order to detect deviations, offering an opportunity to act on them at an early stage (38). Moreover, an active surveillance program has been shown to be an important component in reducing hospital-acquired infections (HAI) (39) and clinics that have interrupted their program have subsequently experienced increased HAI rates (40).

The definition of an HAI by The Swedish National Board of Health and Welfare (41):

*An infection that occurs during in-hospital care or as a result of interventions in the form of diagnostics or nursing in other forms of care or which staff working in health care and nursing acquire as a result of performing their duties.*

Author translation.

## **3.2 Impact on economic and resource utilization**

SSI is found to be associated with increased postoperative length of stay (LOS), increased costs, hospital re-admission rates and the use of antimicrobial agents (2, 42). However, the adverse effect related to SSI varies depending on the category of surgery and type of SSI. Superficial incisional SSI is more common than deep organ/space SSI and the cost of SSI increases with the depth and extent of infection (43). Moreover, superficial SSI has shown a strong correlation to the subsequent development of deep infection (44, 45). De Lissovoy et al. (46) used administrative data from the US Nationwide Inpatient Sample to examine some common surgical procedures, such as cardiovascular, gynecologic and orthopedic surgery (with the exception of major joint surgery), with the aim of analyzing the effect of SSI on LOS and cost. The greatest increase in LOS was observed for cardiovascular surgery, with a mean extension of 13.7 days. Costs attributable to SSI were shown to increase in parallel with the LOS. On average, any SSI extended the length of stay by 9.7 days and produced increased costs of USD 20.84 per admission. In addition, nearly one million extra inpatient days and USD 1.6 billion in excess costs were documented.

For major joint surgery, significant differences in the total number of days in hospital, number of operations, total hospital costs and total outpatient charges were found, in a single institution study, between patients undergoing two-stage revision for infection after hip replacement with revision for aseptic loosening and total primary hip replacement (47). To illustrate the magnitude of the problem, the total average hospital costs for the infected group were USD 96,166 compared with USD 34,866 for aseptic loosening and USD 21,654 for primary total hip arthroplasty (THA) (47). A more recent study confirms these results; the average LOS for primary THA was 7.5 +/- 1.8 days and 30.6 +/- 14.9 days for revisions due to infection. The costs due to infection were found to be 3.6 times higher than those for primary THA (48). Registry data from the US show that the annual cost of treating periprosthetic

infections increased from USD 320 million in 2001 to USD 566 million in 2009. Based on this, the authors have calculated that the costs will exceed USD 1.6 billion in 2020 (23).

One common factor when it comes to the type of calculations of cost and resource utilization made above is that neither the overall societal costs, such as loss of income and so on, nor the price paid by the affected patients are taken into account.

### 3.3 The human aspect of SSI

*The short-term effects of infection are well known to medical and nursing staff, but the long-term effect on the patient, months and years after infection has taken its toll, may be less well known. It is to be hoped that everyone concerned and responsible will take these problems sufficiently seriously to bring about the improvements so desperately needed.*

Simanowitz A (49).

Many aspects of SSI have been investigated thoroughly and repeatedly, but the patients' perspective and experiences have remained largely unknown and are rarely selected for scientific investigations. There are, however, some published studies in related areas such as descriptions of the way patients experience isolation due to MRSA carriage (50). From Australia, Gardner has published two articles with an interpretative qualitative approach. The first (51) found that a patient suffering from a wound infection caused by multiresistant organisms experiences no sense of order about his/her illness and remains stuck somewhere between sickness and health and lives a life defined by limitations. The scientific value of this study is limited as it lacks a description of methodology. The second study (52) also focuses on patients with an SSI caused by antibiotic-resistant organisms. It has a sociological framework for interpretation, with the goal of connecting the meaning-making experiences with cultural criticism. This study found that the main issue for the patients (causing much frustration) was that both doctors and nurses were reluctant to engage in a full and meaningful discussion about the new and unwelcome diagnosis of infection. In most cases, SSI was not discussed at all or no information whatsoever was given. Patients' feelings "that something was wrong" were met with disbelief or not taken into account. Similar results were reported in a study of patients' experiences of mediastinitis (53). These patients also described feelings of uncertainty due to the lack of information and feelings of being neglected by the medical staff.

In addition, a few studies have investigated quality of life (QoL) in relation to infection occurring after surgery, indicating a significant reduction in health-related QoL in the affected patients. Moreover, these results deviate significantly from normative data for the general population (54). The largest decrements have been found in the domains of physical functioning, role-physical domains (55) and mental health (56). The reasons for the low scores in these domains are unknown.

### **3.4 SSI – risk factors and preventive measures**

Risk factors can be categorized into three major areas in relation to their origins. This means that they can be described and studied in relation to the patients, the hospital environment and the surgical technique.

### **3.5 The patient**

It is important to identify risk factors independently found to be significantly correlated to SSI in relation to patient characteristics, as they provide an opportunity to optimize the patient prior to surgery. The following risk factors have been reported in the literature; remote preoperative skin infection, perioperative urinary tract infection, smoking, diabetes and high perioperative blood glucose levels (57-59). Further, advanced age, use of steroids and comorbidity reflected by an ASA classification score of 2 or higher, presence of malignancy, malnutrition, obesity and previous episode of SSI (37, 60-65). Conversely, smoking cessation four weeks before surgery has been proven to reduce postoperative complications (66, 67).

The orthopedic trauma patient carries an extra burden of preoperative soft tissue and skeletal damage, as well as a minimal opportunity to be optimized in terms of co-morbidities. Chronic heart failure, chronic obstructive pulmonary disease and diabetes have been shown to be major risk factors for this group of patients (68). Adding old age, common among the osteoporotic hip fracture patients, produces a clear picture of a vulnerable group of patients.

### **3.6 The surgical technique**

One of the most important risk factors for SSI regarding the surgical technique has been found to be prolonged surgical time, which means that the length of the operation exceeds the approximated 75th percentile for any type of surgery (36, 37, 63). Moreover, intra-operative bleeding (63), as well as

(allogeneic) blood transfusions and postoperative hematoma, constitute a significant risk (69, 70). The surgical technique is in fact very difficult to assess in an objective manner, but surgical volumes could be used as a proxy for experience. In orthopedic surgery, a larger volume has been associated with lower rates of complication (71, 72).

## 3.7 The environment

All infections have one common prerequisite in spite of all the above-mentioned risk factors: the inoculation of microorganisms into bodily sites/organs where they do not represent a part of the normal flora. The following subchapters will give an overview of risk factors for SSI found in the OR. This includes a brief overview of the etiology and treatment strategies, as well as possible preventive measures in relation to peri-prosthetic joint infections.

### 3.7.1 Etiology and treatment

One of the most effective defense systems is the skin and mucosa, working as a barrier protecting the body from infection. The prerequisite is an unbroken barrier. Surgical patients typically suffer from multiple breaks in this system. The patients receive different venous lines in order to control the fluid balance and the anesthesia. Epidural anesthesia with an indwelling catheter is sometimes used in major orthopedic surgery, since this offers good pain relief for a longer period of time. For vulnerable patients, a central venous line might be a necessary tool to provide safety during general anesthesia. These medical devices are necessary, but the natural defense barrier will be broken and this might result in an infection. The surgical patient also has medical devices inserted into natural body openings such as the upper respiratory and urinary tract, which are normally protected from pathogens by natural defense systems. These devices can work as a highway for unwanted bacteria and can cause urinary tract infections and infections in the respiratory system. The most common means of pre-insertion contamination of medical devices is through the hands of health-care workers (73-76).

The most common causal agents in implant-related infections, such as infections following THA and total knee arthroplasty (TKA), are coagulase-negative staphylococci CoNS and *S. aureus*, followed by enterococci and, more rarely, streptococci. *Propionibacterium acnes*, an anaerobic gram-positive rod commonly found on the skin, oropharynx and the female genital tract, has also been associated with peri-prosthetic joint infections (73, 77).

Stefansdottir et al. (78) studied deep infected primary TKA reported during a period of 15 years to the Swedish knee arthroplasty register. CoNS was found to be the most prevalent pathogen in early, delayed and late infections and twice as common as *S. aureus*. In addition, it was found that the methicillin resistance among CoNS increased during the study period, along with a reduction in infections caused by *S. aureus*, whereas infections caused by enterococci increased. CoNS and *S. epidermis* belong to the human normal flora and are regarded as pathogenically low. However, due to their ability to colonize the surfaces of medical devices, such as intravascular catheters and implants, and, on these surfaces, to form a thick multilayered biofilm which makes penetration by antibiotics difficult (79), they can cause difficult infections. *S. aureus* is found on the skin and the mucosal membranes as a transient flora. However, about 15% of healthy adults carry *S. aureus* as a part of their resident normal nasopharyngeal flora. Hospitalized patients and medical personnel are found to be overrepresented in this group.

Staphylococci are known to cause serious infections in bone and blood tissues, as well as being responsible for many HAI. As they have the ability to produce enzymes and toxins, they have the potential to increase their pathogenesis. In 1941, 90% of all staphylococci isolates were susceptible to penicillin. However, resistance to penicillin grew quickly due to the ability of the organism to produce beta-lactamase (80). Today, *S. aureus* and CoNS have once again become a problem, especially in the hospital setting and for patients with an impaired immune system. This category includes the orthopedic trauma patient, often elderly, osteoporotic and with skeletal and soft tissue injuries. The injury per se causes an inflammatory process (81). In addition, the surgical trauma causes both hyper-inflammation and immunosuppression (82). The combination of risk factors makes this patient group especially susceptible to infections.

Enterococci colonize the gastrointestinal tract and are commonly recovered from feces (80). Treating infections caused by enterococci in orthopedic patients can be problematic, as resistance to ampicillin, penicillin and vancomycin has become a major problem. The restricted use of antibiotics is necessary, in combination with thorough infection-control practice. The emergence of  $\beta$ -lactam resistance in gram negative bacteria, such as *Enterobacteriaceae*, *Pseudomonas aeruginosa* and *Acinetobacter baumannii*, is problematic due to increasing resistance to both 3rd and 4th generation cephalosporins, as well as carbapenems, which leads to minimized treatment options (83).

The treatment of infections following THA and TKA includes the combination of different drugs (dependent on the causal pathogen) and surgical treat-

ment. For deep infections, different types of surgical approach are available: one-stage and two-stage revision. The gold standard for both infected THA and TKA is a two-stage procedure (84): the prosthesis is removed, followed by the thorough debridement of tissue, after which the patient receives an antibiotic-loaded cement spacer. Inflammatory markers are then followed and the revision prosthesis is inserted when the markers have reached an acceptable level. One-stage revision has the major advantage of requiring only one surgical procedure and, if the specimen is known and the patients have no other risk factors, there is a good chance of a successful outcome (85).

Which of the two regimens is preferable from a re-infection point of view has been studied in a systematic review and meta-analysis (86) and the conclusion was that there is no clear evidence that two-stage revisions are superior to one-stage revisions due to the lack of reliable data. Early aggressive implant-saving debridement has attracted more interest, as some studies have reported positive effects from this regimen (87, 88). A prerequisite for this type of treatment is of course an early diagnosis.

For some patients, the infection becomes chronic and, for others, amputation is the only remaining treatment option (89).

In order effectively to manage peri-prosthetic infections, the choice of treatment should be based on bacteriological etiology, duration of infection and patient characteristics. Needless to say, all treatment should be based on a diagnosis. Achieving this, however, can be a major challenge, as low pathogenic infections typically produce vague, non-specific clinical signs and inflammatory parameters are often found to be near normal (90).

### **3.7.2 Airborne contamination and ventilation systems**

The work by Blower and Crew (91) and Charnley in the late 1960s (92) and Whyte et al. and Lidwell et al. (93) at the beginning of the 1980s is currently regarded as classical studies which produced knowledge of the importance of airborne wound contamination and ventilation systems. They established the linear relationship between the level of bacterial air contamination rates and the frequency of “deep sepsis” following joint replacement surgery (94). These studies have been criticized for not controlling for the prophylactic use of antibiotics. Repeating this type of large-scale study must be considered a difficult task, since the large number of possible confounders in combination with low infection rates would require an enormous sample to reach sufficient statistical power to be able to draw conclusions.

The basic aim of ventilation systems in the OR is to prevent airborne microbial contaminants from entering the surgical wound. The secondary aim is to provide reasonable working conditions for the OR staff. This is obtained by filtration of the air, air distribution, air dilution and room pressurization (95).

There exists, in principle, three different OR ventilation systems: turbulent, upward displacement and laminar (parallel) air flow. Displacement and turbulent, they differ primarily in the methods that are used to supply clean air, but it has been pointed out that both are sensitive to movements leading to the formation of local eddies (95). The design features of ventilation systems can differ in terms of air velocity (m/s), volumes ( $\text{m}^3/\text{h}$ ) of airflow and the location of the inlet and outflow devices. This will influence the airflow patterns and the protective ability. Common is that the air inflow should be adjusted to exceed the outflow in order to maintain positive pressure with respect to the surrounding areas. A positive difference in pressure secures air cleanliness by reducing the risk that contaminated air will leak into the OR. It is probably unrealistic to think that the OR can be a hermetically closed space; it is therefore assumed that the design and utilization of surrounding spaces influences the air cleanliness of the OR. In this thesis, the focus is on laminar airflow systems (LAF) and upward displacement ventilation systems (DV). The term "LAF" will be used even if a more accurate description would be "unidirectional, low-turbulent airflow".

### **3.7.3 Displacement ventilation systems**

The upward air-displacement system supplies cool air ( $2\text{-}3^\circ\text{C}$  below room temperature) above the floor in each corner of the room. Via thermal convection, the air is subsequently evacuated via exhaust air outlets at the ceiling, see Figure 2.



Regarding the capacity of the upward displacement system, it has been demonstrated that it is more effective in removing particles compared with the mixed turbulent system (96). An experimental study (97) comparing mixed turbulent ventilation and upward displacement ventilation confirms that the upward displacement system is more efficient in removing small particles ( $<10\ \mu\text{m}$ ), whereas no differences were found between the two ventilation systems for particles larger than  $10\ \mu\text{m}$ . More importantly, the bacterial air counts were found to be generally higher in the displacement systems than in the turbulent systems.

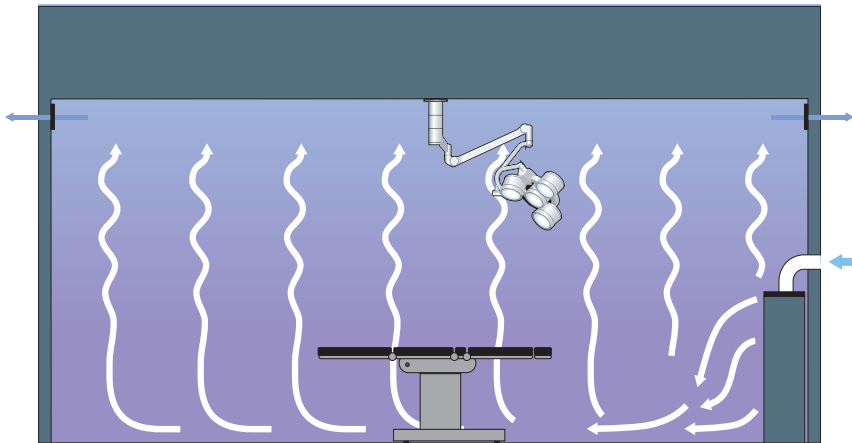


Figure 2. Air distribution patterns produced by upward displacement ventilation systems, Picture: Annette E Andersson ©.

### 3.7.4 Laminar (unidirectional) airflow systems

In LAF systems, the high efficiency particulate air (HEPA) filtered air enters the operating room (from the wall or ceiling) in a parallel manner, Figure 3. The aim is to create a zone over both the operating and instrument tables with a lower level of contaminants compared with the surrounding area. This is achieved by supplying large volumes of air with a uniform airflow over the clean zone compared with the surrounding area. The idea is to “wash out or swipe away” the contaminants from the clean zone and prevent contaminated

air entering it (98). In some ORs, the diffusers cover the total area of the ceiling, which results in only one zone.

Many different parameters influence the efficacy of the ventilation systems. The airflow velocity at the supply diffuser has been shown to be one of the most important factors when it comes to controlling distortions in airflow patterns produced by OR lamps, for example. Chow et al. (99) showed that, if the supply velocity is higher than 0.38 m/s, the buoyant forces from medical lamps and equipment have a minimal effect on airflow patterns and the transportation of contaminants can proceed undisturbed towards the exhaust outlet. In contrast, an experimental study (100), simulating different air velocities with the same supply vent area, demonstrated that increasing the air velocity beyond a certain rate resulted in an increase in CFU deposition. Moreover, if the supply air velocity rate exceeds 0.3 m/s, this results in the development of a vortex above the patient. In addition, it was concluded that, with a supply vent area of 2,400 x 2,650 mm, the optimal air velocity rate was 0.25 m/s.

Several studies of ultra-clean air have demonstrated the ability to reduce the number of infections related to implant-related surgery (92, 101-104). However, the importance of the airborne bacteria as a source of infection and the use of ultra-clean air/LAF systems are still the subject of debate (105-107). In a retrospective cohort study, Brant et al. (108) found that laminar airflow systems do not protect patients from SSI in orthopedic and abdominal surgery. In fact, a higher risk was found for SSI in ORs with LAF ventilations for THA and TKA procedures. One interesting finding was that LAF systems significantly reduced the risk of SSI in relation to colon surgery. This study controlled for patient-based risk factors, as well as possible hospital-related confounders. Similar results regarding the altered risk of SSI in LAF-ventilated ORs, as well as the use of "space suits", were presented by Hooper et al. (109), based on data from the New Zealand Joint Registry.

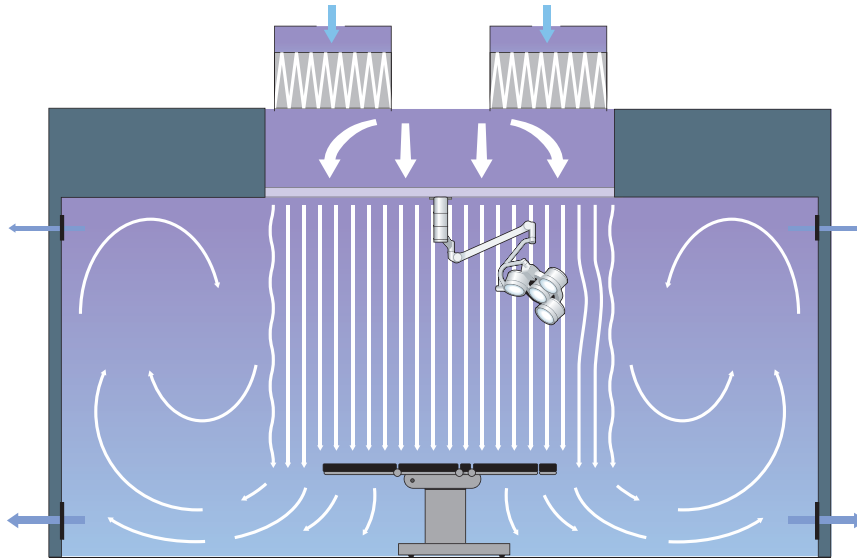


Figure 3. An OR equipped with a laminar airflow ventilation system and air distribution patterns. Picture: Annette E Andersson ©.

### Door openings and intra-operative movements

The impact of door openings with respect to temperature and pressure gradients has been focused on in some work (110, 111), but the clinical impact and relevance have rarely been studied. Ritter et al. (112) were unable to demonstrate any significant difference between air counts in the OR when comparing closed doors (mean = 15.2 CFU) with swinging doors (mean = 14.5 CFU). A more recent study by Stocks et al. (113) supported these findings, as door openings could not be used as a predictor of air contamination rates. Before drawing any conclusion, it is important to note that the study by Stocks et al. was carried out in turbulent ventilated ORs, where the door leading to the “non-sterile” corridor was locked during surgery. Only one study has reported a correlation between door openings and raised bacterial counts (114). The results were based on settle plates and active air samples taken outside the clean surgical zone. The question of how door openings affect the air quality close to the surgical wound still remains to be answered. Recent studies have focused on the heavy traffic in and out of ORs, reporting high rates of door openings for all types of surgery (115-117). For TJA, it has been reported that the door into the OR was opened every 1.5 minutes and supply issues produced most of the registered door openings (118).

### 3.7.5 Clothing systems and dispersal of microorganisms

Our knowledge of the human dispersal of microorganisms is mainly based on studies from the 1950s by Nobel and Ayliff, for example, and Hoborn in the 1980s. During walking activity, it is said that a human releases approximately  $10^4$  skin scales/min and it is estimated that 10% of these scales carry clusters of viable microorganisms – not only aerobes, such as *S. aureus*, but also anaerobes, such as propioni bacteria and anaerobic cocci, comprising about 30% of the total number of airborne bacteria. Hoborn (119) found that men release about 7 times more skin flakes than women and that the lower abdomen is the major source of dispersal. Moreover, socks were found to work as a reservoir for CFU. From a study by Hambreaus, Bengtsson and Laurell, it was calculated that, in the OR, fewer than 15% of the bacteria found in the air were re-dispersed floor bacteria (120). From this it was concluded that contaminated floors are insignificant as a source of airborne bacteria. Taking a closer look at the importance of clean floors in today's ORs, it is possible that we will come to a different conclusion. Especially if we take account of the consistently reported large number of door openings (19-50/h), when people pass in and out of the OR (115-117), together with the findings that walking produces the highest re-dispersal rates (120). In addition, OR shoes and floors have been found to present a potential source of postoperative infection (121). It is therefore necessary to reconsider the importance of contaminated floors when developing SSI prevention strategies.

To summarize, the most important source of airborne contamination relates to the dispersal of particles from the individuals present in the OR and their movements (122-124). By using clothes with lower air permeability compared with conventional clothing, the dispersal of microorganisms by the OR staff can be reduced, thereby significantly reducing the airborne contamination (125-127).

## 3.8 Intraoperative nursing and care

Current knowledge suggests that, by applying evidence-based measures during surgery, major contributions can be made to reducing the risk of SSI and device-related infections. This includes securing the correct timing of prophylactic antibiotics, maintaining intra-operative normothermia during surgery, avoiding the inadequate use of urinary tract catheterization (UTC) and, above all, avoiding the cross-transmission of microorganisms between

HCW and patients, as well as between different body sites on the same patient. In order to construct a safe environment, all the members of the OR team need to have a sufficient knowledge of the way this can be accomplished, as well as being motivated to act accordingly.

### **3.8.1 Normothermia**

The normal body temperature of healthy adults varies from approximately 36.5-37.5°C. Hypothermia has been defined as a core body temperature of less than 35°C (128).

Evidence of the relationship between SSI and mild hypothermia has been presented and, accordingly, the protective effect of normothermia during surgery (128, 129). Patients have been found to be adversely affected by regional and general anesthesia causing impairment of the thermoregulatory system (130). Even mild perioperative hypothermia produces a series of adverse effects in patients undergoing surgery. It is associated with an increased risk of blood loss and the need for blood transfusion (131), as well as a risk of increased cardiac morbidity (132), altered drug metabolism (133) and prolonged hospitalization (128). Forced air-warming systems, warmed intravenous fluids and electric blankets are different tools commonly used to reach normothermia (134) and novel products are being continuously evaluated (135). Questions have been raised about whether forced air warming systems could actually be a vector of infection, but this has not been possible to verify (96, 136).

### **3.8.2 Urinary tract catheterization**

Urinary tract infection (UTI) is the most common health-care-associated infection and a frequently observed complication after major joint surgery (1). In hospital settings, almost all these infections develop as a result of urinary tract catheterizations (UTC) (137). It has been demonstrated that catheter-related UTI contributes to an increased length of stay, costs, morbidity and excessive antimicrobial drug use (138, 139). Moreover, the urinary drainage systems can work as reservoirs for multidrug-resistant microorganisms and this has been shown to be of great importance in relation to implant surgery and is most probably also relevant to emergency procedures (137). If UTC during surgery is used on strict indications alone, postoperative UTI and the use of antibiotics will decrease (137, 140).

### 3.8.3 Timing of prophylactic antibiotics

In Sweden, the first choice of antibiotics for the prevention of SSI following orthopedic surgery is presently cloxacillin (2g x 1-3 iv). The Swedish Council on Health Technology Assessment has concluded that there is strong scientific evidence (grade I) in favor of the use of prophylactic antibiotics in orthopedic surgery, with 1-4 doses being given within 24 hours. In addition, gentamicin-loaded bone cement in total joint arthroplasty (TJA) provides protection from deep SSI when combined with systemic antibiotics.

Systematic reviews support the use of antibiotic prophylaxis in relation to TJA, as well as fracture surgery, stating that, for every 13 patients who are treated correctly, one wound infection would be prevented (141, 142). The timely administration of prophylactic antibiotics is of the utmost importance, as a study of 1,992 patients undergoing total hip arthroplasty showed that those that received prophylaxis after incision had the highest odds of developing an SSI (143). Achieving optimal tissue levels at the time of incision has been shown to be crucial (144). Current knowledge suggests that this is approximately 30 minutes prior to incision in relation to the type of antibiotics with a half-life of 30 minutes (145, 146). Stefansdottir and coworkers investigated the timing in relation to total knee arthroplasty (TKA) and, based on register data, found that 45-57% of the patients received their prophylaxis 15-45 minutes prior to incision and 53% within the recommended time span prior to inflation of the tourniquet (147). The practice of optimal timing in relation to THA and fracture surgery has rarely been studied, but the available data show extensive inaccuracies in timing (148).



*Figure 4. Normal working conditions during surgery.  
Photo by Annette E Andersson, published with permission  
from anesthesiologist Per Persson.*

### **3.8.4 Hand disinfection**

Today, hand hygiene is regarded as the most important tool for preventing the spread of pathogens in health care and reducing the risks of HAI (149, 150). In order to shed some light on why this simple action is so important, a brief overview is given below.



If we look more closely at our hands (Figure 5), we find a resident flora of microorganisms, where *S. epidermis* and different types of CoNS dominate. These bacteria are often characterized as low pathogenic, but they can cause serious infections if they reach sterile body cavities, such as joints. They are extraordinary in their ability to develop resistance; this is especially true of strains found on health-care workers' hands. The other type of flora found on our hands is the transient flora. These microorganisms reach the hands during every day work; they stay and sometimes they multiply, but they can be removed by hand disinfection.

Figure 5. Hands as carriers of disease.  
Photo by Annette E. Andersson

The transient flora consist of different pathogens such as *S. aureus*, *Klebsiella pneumonia* (colonizes the intestines and often causes UTI) and enterococci (*E.*) (151). Microorganisms are typically transmitted to nurses' and physicians' hands during patient care activities, not only when hands come in contact with mucosal membranes and body fluids but also when touching contaminated surfaces and during "clean" patient care activities, e.g. touching the patients' hands, taking the pulse or blood pressure or simply touching the bed linen (152, 153). The pathogens found on inanimate surfaces vary in their ability to survive; for instance, vancomycin-resistant enterococci have shown the ability to survive on gloved and ungloved fingertips for at least one hour. *E. faecalis* was recoverable from countertops for 5 days and *E. faecium* survived for 7 days (154). Several studies provide strong evidence that environmental contamination plays an important role in the transmission of vancomycin-resistant enterococci (VRE), methicillin-resistant *Staphylococcus aureus* (MRSA) and, more recently, the nosocomial transmission of norovirus, *Clostridium difficile* and *Acinetobacter spp* (155). The environment works as a reservoir for surviving bacteria; the vectors are the hands of health-care workers and patients. The most common way of transmitting microorganisms



to patients is by the hands of health-care workers. It therefore follows that both the decontamination of inanimate objects and hand hygiene are of the utmost importance when it comes to reducing the spread of pathogens (73).

The relationship between increased hand disinfection rates and reduced rates of HAI has been proven in several studies, despite the lack of randomized control trials – starting with Semmelweis in Vienna in 1847 (9) and continuing to contemporary studies by leading figures such as Pittet in Europe and Larson and coworkers in the United States, along with many others (156-159). Moreover, hand disinfection has been proven to be one of the most effective methods for reducing the distribution of multidrug-resistant pathogens in health-care settings (160-162). In conclusion: the act of hand disinfection is a fast and very effective means of reducing the risks of transmitting microorganisms and thereby preventing HAI and enhancing patient safety. More than 150 years have now passed since Semmelweis' discovery of the importance of hand disinfection and, in the light of the overwhelming evidence, it could easily be assumed that the hand hygiene guidelines recommended by the WHO (149) are widely used and non-controversial. However, there is a great deal of evidence to suggest that adherence to hand hygiene guidelines continues to be low. Adherence rates of well below 50% are often reported in the literature (163-166). Several factors that influence adherence have been observed. Table 2 gives a list of factors, found by Pittet et al. (156) to be associated with low adherence. Figure 4 gives a glimpse of the working conditions in which hand disinfection should be carried out.

Table 2. *Factors found to affect adherence to hand hygiene practice.*

Self-reported factors	Observed factors
Low risk of acquiring infection from patients	Physician status (rather than a nurse)
No role model from colleagues or superior(s)	Nursing assistant status (rather than a nurse)
Skepticism about the effectiveness of hand hygiene	Male gender
Lack of awareness of definitive impact of improved hand hygiene on hospital-acquired infection rates	Activities with high risk of cross-transmission
Disagreement with the recommendations	Large number of opportunities for hand hygiene per hour of patient care
Wearing of gloves/beliefs that glove use substitutes for hand hygiene	Wearing gloves
Hand hygiene agents cause irritation and dryness	Working during the week (rather than during the weekend)
Sinks are inconveniently located; shortage of sinks	Working in critical care
Lack of soap, paper, towels	
Often too busy/insufficient time	Understaffing/overcrowding
Lack of knowledge of guidelines/protocols	
Patient needs take priority	
Hand hygiene interferes with healthcare worker-patient relationship	

Reprinted from, J Hosp Infect. 2001;48 Suppl A:S40-6, Pittet D. Compliance with hand disinfection and its impact on hospital-acquired infections, with permission from Elsevier.

In Swedish hospital settings, the use of an alcohol-based hand rub with glycerol is the gold standard, as it has been found to be effective, keeps the skin soft and rarely results in allergic reactions (167). However, in the event of contact with patients with viral gastroenteritis, hand washing with plain soap and water is recommended prior to disinfection. Moreover, hand disinfection should always be carried out before and after direct contact with patients, regardless of whether gloves are used, before clean aseptic procedures, after body fluid exposure risk and after touching patients' surroundings. Figure 6 shows when hand disinfection is indicated. Below the National Board of Health and Welfare's (168) regulations on basic hygiene in the Swedish health service is given:

*2 § In conjunction with examinations, care and treatment or any other direct contact with patients, health-care and medical staff should observe the following in order to limit the risk of care-related infections.*

- *Working clothes should have short sleeves.*
- *Working clothes should be changed every day and more frequently, if necessary.*
- *Hands and forearms should be free from watches and jewelry.*
- *Hands should be disinfected with an alcohol-based hand rub, or some other agent with the corresponding effect, immediately before and after every direct contact with a patient.*
- *Hands should be disinfected both before and after using gloves.*
- *If they are visibly dirty, hands should be washed with water and liquid soap before being disinfected.*
- *When caring for a patient with gastroenteritis, the hands should always be washed with water and liquid soap before being disinfected.*
- *Hands that have been washed should always be dry before being disinfected.*
- *A disposable apron made of plastic or a protective coat should be used, if there is a risk that working clothes will come into contact with bodily fluids or any other biological material.*
- *Protective disposable gloves must be used in the event of contact with or the risk of contact with bodily fluids or any other biological material.*
- *Protective gloves should be removed directly after a working procedure and replaced between different working procedures (168).*

Author translation.

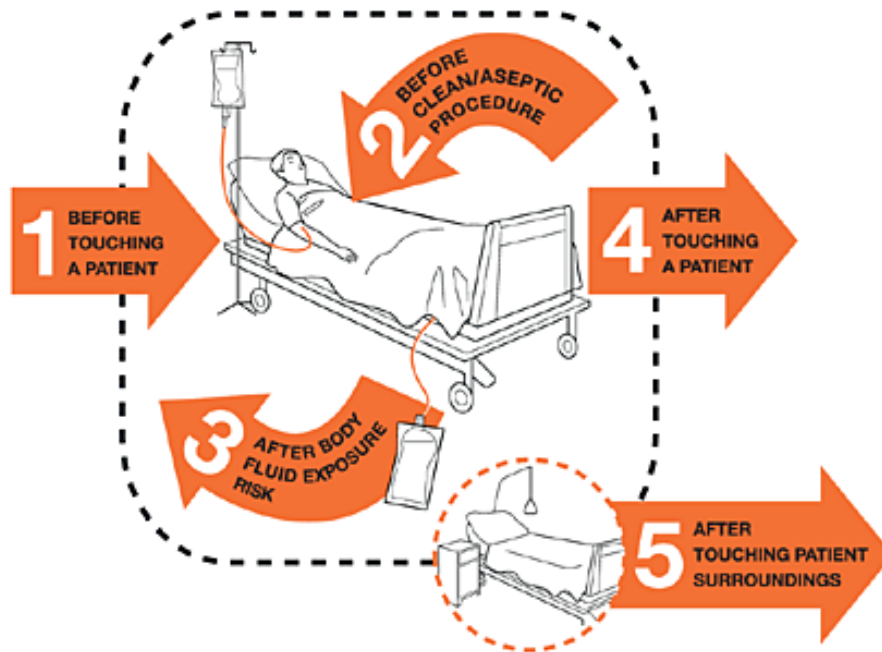


Figure 6. Indications for hand disinfection, from WHO “My five moments of Hand Hygiene” from “Save Lives Clean your Hands” – A Guide to the Implementation of the WHO Multimodal Hand Hygiene Improvement Strategy. Published with permission from the World Health Organization.

Knowledge of hand hygiene practice in the operating room is almost non-existent, as few studies have been conducted in this area. However, the published results indicate very low adherence rates from 2-8% in combination with high interactions between staff and patient (169). Moreover, it had been found that multidrug-resistant bacterial organisms are transmitted during anesthetic care to the work areas and intravenous stopcocks (74) and hand contamination is an important risk factor for intra-operative bacterial transmission (76).

## 4 THEORETICAL FRAMEWORK

Why a theoretical framework? Well, I believe that a theoretical framework is useful as a mind map, helping to see how successes and failures in the surgical context can be understood and even offering some clues on how to create more patient-safe care. In this thesis, the theoretical framework is used when discussing the results from Papers I-IV.

The choice of framework is important, as different views allow us to see different things. During my years in clinical practice, I have come to adopt a more holistic view of patients and safety, i.e. person and reality are an inseparable entity. However, I have often found it difficult to see the whole picture, even if I strive to do so.

The view that person and reality are an inseparable entity is the most basic and shared assumption within the tradition of social constructionism. In this thesis, infection, risks and safety are viewed as socially constructed and being social, contextual, time and history dependent. Moreover, the knowledge and practice of nursing and medicine are looked upon as constructed within specific cultures, organizational as well as different professional subcultures and hierarchies (158). A number of approaches to social construction exist. The framework of reference in this thesis is mainly based on the theoretical developments of Berger and Luckman (1966) and their work *The Social Construction of Reality – A Treatise in the Sociology of Knowledge*.

The construction of knowledge in everyday life in the OR can potentially help us to understand how certain ways of acting and talking influence the safety of patients. We can begin by taking a closer look at one of the core concepts: *reality*. Reality as a social construct reflects the dialectic process between the social reality as being (at the same time) both subjective and objective, which has been described as processes of *internalization*, *externalization* and *objectification* (170).

It might seem strange to discuss infections and wounds as social constructs, as they can be regarded as an objective reality. However, the way we perceive the infection is something that changes depending on the cultural and historical context, in the same way that the concept of uncleanness and danger is perceived differently depending on culture and time in history, for example (171). It is possible to follow the relativity of the perception or the view of infection in surgery from the days before Lister, when infections were closely related to danger and death, and then to the introduction of asep-

sis and, subsequently, antibiotics in the 1940s, when the concept of surgical infection was reconstructed and perceived as a treatable complication. The process then moves on to the beginning of the 2000s, when the perception of infections was once again a subject of reconstruction due to the emerging resistance to antibiotics slowly turning infections into a potential death threat (172).

According to Berger and Luckman (170), page 70, all human activity is subject to habituation; when repeated frequently, activities are cast into patterns. To understand how infection-control practice in the OR is constructed, the example of peri-anesthetic care can be taken. The procedures surrounding this care are routinely performed every day; they have become the subject of habituation and can therefore be performed with an economy of effort. The OR staff do not need to re-invent or constantly choose how to proceed in this situation, thereby offering important psychological/mental relief. Every day, the individuals in the OR staff *externalize* the agreed peri-anesthetic practice, thereby *objectifying* it, since it is available and can be observed by others. It becomes a shared experience of the way to act in the OR during the induction of anesthesia. Languages also objectify the shared experience and make it available to everyone within this linguistic community of the OR. The individual, e.g. the OR staff, *internalizes* the agreed way of acting by doing so in accordance with the predefined patterns. Internalization refers to the process of socialization that makes all individuals co-creators of the reality they share with others (173). The habituated peri-operative actions become reciprocal typifications. Berger and Luckman state that, whenever there are reciprocal habituations of actions in relation to certain types of actor, *institutionalizations* occur.

Institutionalizations also imply that certain types of actor perform an act such as intubation. It also implies the control of human conduct by predefined patterns for how to proceed. This control of human conduct goes beyond every other type of sanction that is set up to support an institution and the culture developed therein. Moreover, in order to understand an *institutionalization*, it is important to consider the historical process under which the institution was formed. We need not only to look back on the history of infection control per se but also to include the historical process of constructing *typifications* of roles, such as anesthetic nurses and anesthesiologists and how they are socially positioned in relation to each other, in order to understand how potentially harmful actions have been created. This becomes even more important if we want to understand why certain actions and behaviors are so difficult to change in favor of patient safety. Berger and Luckman say that, in the course of action, there is an identification of the self with the action that is

going on, thus influencing the self-experience. It is important to note that the dialectic process of the construction of reality and knowledge is not always harmonic or symmetric. The one with the power has a better chance of imposing his/her definition of reality and knowledge (170).

*The socially constructed reality and the institutionalized habits* constitute the existing culture at the OR. The cultures of interest in this thesis are the different professional/ward subcultures within the hospital. It has been said that a hospital is not a single coherent culture. It can be described as fragmented un-uniformed collections of different ward and professional cultures and subcultures (174) such as OR culture, surgery and anesthesiology. Several researchers have pointed out that within an organization several strong subgroups can exist and they can have conflicting goals (175). There exists a variety of views and definitions of the concept of culture. The one most commonly used in literature (176) is the definition by Edgar Schein (177) page 111:

*(Organizational) culture is the pattern of basic assumptions which a given group has invented, discovered or developed in learning to cope with its problems of external adaptation and internal integration, which have worked well enough to be considered valid, and therefore to be taught to new members as the correct way to perceive, think and feel in relation to those problems*

Schein says that culture can be analyzed at three different levels. The surface level is that of artifacts. Artifacts are visible to the eye and include architecture, language, dress codes, published list of values as well as routines and ceremonies. Easy as they are to observe, they are harder to decipher (178). This level of culture can be equated with the concept of climate (175). The middle layer consists of the espoused values of the culture. This could be strategies, goals and guidelines. If the values can be validated and are found to work as a means of solving problems within the group, a transformation process occurs towards becoming assumptions. Schein says that, at this conscious level, the espoused values could predict what people say in a variety of situations, but they may be out of line with what they actually do. An example of this is given in a study by Jenner et al. (179) that found a large discrepancy between self-reported and observed adherence to hand hygiene guidelines, i.e. the self-reported high adherence to guidelines could not be confirmed by clinical observations. Moreover, the authors concluded that interventions that target attitudes and intentions to change behavior are likely to fail. Schein says that, in order really to understand what is going on, we have to look into the deepest level of culture. Here we find the basic assumptions, they define for us what we need to pay attention to, what things mean and how to react and act in different situations (178). The basic assumptions are

so much taken for granted that they represent the reality, which means that any other behavior based on other premises is incomprehensible. The set of shared assumptions within a culture offers meaning and stability to its members, so challenging them will unleash anxiety. These shared assumptions in the culture are parallel to the way Berger and Luckmann (1966) describe the socially constructed reality. Schein says that, rather than tolerating elevated anxiety levels, we want to perceive events around us in line with our basic assumptions, even if this means distorting, denying or falsifying ourselves (1985) page 22.

Finally, culture is something that is transformed and learned between generations and individuals and learning models should therefore be used to understand how culture is constructed (1985), which brings us back to the social construction of reality (1966). However, we need to look more closely at the concepts of safety culture and the link to the culture at the OR. The roots of culture theories are found in the anthropological research tradition, where the methods are usually qualitative. Törner points out that the lack of a developed theoretical foundation could be the reason behind blurred definitions and the mixing of the concepts of climate and culture in the area of safety research (1985), page 42. I agree with Hale (1980), who suggests that, rather than talking about a safety culture in an organization, one should instead talk about how the culture affects safety (1985). The research area of safety and patient safety is very young and many more studies are needed to establish what it is and what it is not and if and how we can study, measure and interpret safety and patient safety.

In addition to the theory of construction of knowledge and reality, the surrounding context, the operating room and the health-care systems are acknowledged as being characterized by complexity. Further, failure and accidents need to be understood in relation to this complexity (1981, 1982). The great achievements in medicine during the twentieth century were developed under a reductionist paradigm. Being acclimatized and socialized in a tradition means that it is also logical to apply this type of knowledge and basic ontological assumptions to other areas such as risk, management and patient safety. It then follows that investigating failures as adverse events uses the process of reductionist and linear thinking following a chain of reasoning relating to cause and effect and leading to the identification of the malfunctioning component. Assuming that everything that happens has an identifiable cause and an identifiable effect, there is a balance between the two of them, i.e. the effects are in direct proportion to the cause. This paradigm is attractive in its coherence and simplicity. Moreover, it is equated with “scien-



tific thinking” and so integrated in the world view of medicine that this paradigm is regarded as something natural based on good common sense (182).

However, there are some major limitations associated with this thinking, especially when we attempt to understand how adverse events occur in health-care systems. If the health-care system were based on linear relationships between different parts of the system, like a machine, outcomes could easily be predicted. From my experience, I have learned that this is not the case. Let us take an easy example; keeping patients’ body temperature normal during surgery is something that has been identified as very important in order to reduce the risk of SSI and several other complications. A simple solution would be to raise the ambient OR temperature to say 25°. In fact, this practice can be found as local recommendations in some Swedish hospitals today. If the system were machine like, the outcome would be easy to predict; warmer ambient temperature = warmer patient = reduced risks. However, raising the ambient temperature will also lead to other known and unknown results depending on whose knowledge is favored and listened to. If the temperature is raised, this will influence the temperature in the surgical area where the air is additionally heated by the working staff and the lamps. This could lead to sweating surgeons and nurses and subsequently bacteria-carrying droplets falling into the surgical wound, thereby creating a greater risk of infection. The surgical team is also dependent on good working conditions to maintain a high level of concentration throughout the operation in order to maintain safety. Warming the OR air will also affect the airflow pattern of the ventilation system designed to reduce the risk of infection (how is largely unknown). With this example, I want to show how seemingly simple, well-intentioned changes in health care can potentially lead to adverse outcomes, because of the complexity of the system.

Complexity Theory/Thinking (CT) has attracted a great deal of attention during the last two decades in many different scientific areas, such as economics, computer and mathematic sciences, biology, physics and social sciences (181, 183, 184). This scientific development is mainly due to the limited ability of the reductionist research tradition to create an understanding of complex phenomena. However, in CT, it is pointed out that there are no ways fully to understand a complex system. Ciller says (181) that this does not mean that we should not try to understand as much as possible, but it implies an attitude of modesty regarding the knowledge we have.

The conceptual roots of CT are found in Chaos Theory and *Systems Thinking*, indicating thinking in terms of patterns, relationship processes and corre-

sponding context (183). CT has also been inspired by Critical Theory (184) and Hermeneutics (185).

*Complexity science is not a single theory. It is the study of complex adaptive systems – the patterns of relationships within them, how they are sustained, how they self-organize and how outcomes emerge. Within the science there are many theories and concepts. The science encompasses more than one theoretical framework. Complexity science is highly interdisciplinary including biologists, anthropologists, economists, sociologists, management theorists and many others in a quest to answer some fundamental questions about living, adaptable, changeable systems(186) page 3.*

Even if different understandings exist of what CT is (181), a common core concept is found; *Holism*, i.e. the whole is always larger than the sum of the component parts. The Newtonian reductionist way of thinking attempts to understand systems by dissecting their components, assuming equilibrium between input and outcome. Linear systems are well behaved and as such the outcomes are more predictable. In contrast, non-linear complex systems cannot be understood by examining their parts individually. Small changes can produce large unanticipated behaviors (184, 187). In CT, the word *emergence* is used, describing how sudden unexpected properties of the system occur. Complex systems have been found to be self-organizing and adaptive, working at their best at the edge of chaos (187). When traditional Newtonian scientists try to understand parts of systems, the research questions in CT involve relationships and interactions. The *locality* and *historicity* principles of CT are also fundamental when attempting to understand health-care systems. Actors within the system do things that make sense to them from the local perspective. In addition, the actors cannot foresee or even realize the full effect of their actions. They merely respond in an adaptive way to changing circumstances (188). This is in line with the thinking of Schein and Berger and Luckman described above. The historical dimension is important in CT, as the present properties are seen as co-products of past conditions.

*In short, a complex nonlinear system may be viewed as a system consisting of an extremely large and variable number of components. These components are capable of displaying significant temporal and spatial variability but, at the same time, can retain a high degree of interdependence between each other. What we learn from this is that topology and dynamics interact to produce system behaviors. We find that relationships define dynamics, and dynamics can define relationships. Whether form follows function or function follows form becomes irrelevant as form and function are no longer separate entities but, rather, are intimately tied to each other (189) page 22.*

The view of knowledge in CT shares similarities with the theory of knowledge as a social construction; hence, both move away from strict dualism and knowledge is instead seen as relational and (inter) subjective. Berger and Luckman's view of human creations of structures and institutions, defined by interactions, continuous recreations and adaptations, is similar to the ideas of self-organizing systems described in CT (185).

The aim is to see whether CT can be used in viewing both infection control and patient safety in a different way. The need for new conceptual ways of thinking in health care is obvious. So far, extensive efforts have been made to change different parts of health-care systems. However, the outcomes have been very modest or not as predicted (190). At the same time, it is possible to find circumstances in which new interventions are quickly and readily adopted by the system. For me, CT becomes important as it integrates biology and technology with holistic thinking (186). Moreover, it merges (together) quantitative and qualitative research and explanations of life and thereby the necessity for both qualitative and quantitative research methods is acknowledged. In this thesis, both methods are used in order to explore different phenomena.



## 5 AIMS

The overall aim of the thesis was, in the light of patients' experiences of acquiring a deep SSI, to explore the air quality during orthopedic implant surgery and the application of intra-operative measures to reduce risk factors associated with SSI.

The specific aims were:

- to elicit and evaluate patients' experiences associated with acquiring a deep surgical site infection (Paper I);
- to investigate the air quality, expressed as colony forming units/m<sup>3</sup>, during orthopedic trauma implant surgery in a displacement-ventilated OR; to explore how traffic flow and the number of people present in the OR affect the air contamination rates in the vicinity of the surgical wound; and to delineate reasons for door openings in the OR (Paper II);
- to explore and describe the application of intra-operative evidence-based measures designed to reduce the risk of surgical site infections and device-related infections during orthopedic implant surgery. In addition, we aimed to investigate whether the type of surgery, i.e. total joint arthroplasty compared with fracture surgery, affected the use of protective measures (Paper III);
- to answer the following research questions: Do LAF systems provide ultra-clean air during live conditions in orthopedic surgery? How do the OR staff apply OR guidelines designed to improve air quality? Are there any differences in air quality between laminar airflow systems and displacement ventilation systems during orthopedic surgery? (Paper IV).



## 6 METHODS

### 6.1 Design

#### **Paper I**

A qualitative descriptive design was selected due to the exploratory nature of the study. This design was judged to be appropriate, as the knowledge of patient's experiences of SSI was limited and a deeper understanding was desired. Open-ended interviews were regarded as a suitable data collection method in relation to the aim, as they offered an opportunity to explore the subjective experiences from the patients' perspective of acquiring a SSI (191).

#### **Papers II-IV**

Based on the study aims regarding air quality in the OR and the application of measures to reduce the risk of SSI during surgery, a quantitative and qualitative explorative, descriptive and, in some cases, a comparative design was selected. In addition, in order to capture more complex events, a qualitative observational approach was chosen. For an overview of designs and methods, see Table 3.

Table 3. *Overview of designs and methods in Papers I-IV.*

	Designs	Methods	Analysis
Paper I	Descriptive-hypothesis generating study	Open interviews	Latent content analysis
Paper II	Qualitative/quantitative, comparative observational study	Structured observations Participant observations Active air samplings	Descriptive statistic Correlations Hierarchical multiple regression Manifest content analysis
Paper III	Descriptive, comparative and hypothesis-generating study	Structured observations Participant observations	Descriptive and comparative statistics Manifest content analysis
Paper IV	Quantitative/quantitative observational study	Structured observations Participant observations Active air samplings and patient records review	Descriptive and comparative statistics Manifest content analysis

## 6.2 Settings

### Papers II-IV

The studies were set at a Swedish university hospital in an orthopedic center where more than 10,000 surgical procedures are performed every year. Data were collected in the same surgical ward from April 2009 to June 2010. At the time of data collection, 72 OR nurses (27 scrub nurses and 45 nurse anesthetists), 32 nursing assistants, 25 anesthesiologists and 59 orthopedic surgeons worked at the surgical ward.

### Ventilation systems

The ward had three ORs equipped with vertical LAF ventilation systems and three ORs equipped with displacement ventilation systems.

The LAF-ventilated ORs had two entry/exit points each; one of them lead directly to a so-called “non-sterile” corridor. This entry/exit point was a sliding door, giving two options for entrance; a large door opening, suitable for the passage of large equipment, and a smaller opening used by people passing in and out. The other entry/exit point lead through a swinging door directly



into a preparation room. Table 4 shows the room size and technical specifications of the LAF-ventilated ORs.

Table 4. *Technical specifications of the laminar airflow system.*

	OR	Preparation room
Air flow	9,160 m <sup>3</sup> /h	3,900 m <sup>3</sup> /h
Supply vent size	3,600 x 3,600 mm	2,000 x 2,000 mm
Airflow rate	0.25 ± 0.02 m/s	0.27 ± 0.02 m/s
Filter class	EN 1822, H 14	EN 1822, H 14
Room size	44-46 m <sup>2</sup>	5 m <sup>2</sup>
OR lamp size	640 x 640 mm	

The three parallel displacement-ventilated ORs (size 39 m<sup>2</sup>) were equipped with an upward air-displacement system supplying cool air (2-3°C below room temperature) above the floor in each of the four corners of the room. By thermal convection, the air is evacuated via four exhaust fans installed in the ceiling. Each OR is supposed to be maintained at positive air pressure by adjusting the inflow rate to exceed the outflow rate; however, the desired difference in pressure between the “non-sterile corridor” and the OR is not specified. According to the Technical Maintenance Department, the pressure difference should be ~3 Pa and an alarm is supposed to be activated if the pressure is below this value. The alarm is not located in the surgical ward. Each OR has a single entry point, with a swinging door opening inwards, leading directly to the “non-sterile corridor”. The air inflow rates per operating room were reported to be 675, 625 and 600 l/s and the corresponding outflow rates 580, 565 and 560 l/s.

### Guidelines

All the guidelines relating to infection control were published on the hospital website and could be accessed by all the staff. Printed versions were accessible on the surgical ward.

The local Department of Infection Control had published specific OR guidelines (192). The overall message was formulated as “Be few, don’t move and be quiet”. Further, it was stated that the preoperative preparation of surgical instruments should be carried out in controlled environments with high air quality. Two different clothing regimens were accepted in this hospital; conventional cotton/polyester 50/50 mix shirts and trousers, long disposable surgical hoods tucked into the smock, private shoes and socks, or tightly wo-

ven clothing systems with low air permeability designed to minimize the dispersal of microorganisms. In addition to either regimen, the scrubbed members of the OR team should wear reinforced disposable sterile gowns, facemasks (RII) and double sterile gloves. Regarding hand disinfection, it was stated (in short) that the hands must (not optional) be disinfected with an alcohol-based hand rub before and after every care activity regardless of whether or not protective gloves had been used. Moreover, perioperative UTC should only be used on strict indications, such as an estimated length of surgery of > 2.5 h or in patients with renal insufficiency.

### **Additional circumstances of interest**

Comprehensive organizational changes were carried out in 2006 in all three hospital “bodies” of the university hospital. The changes involved a large-scale expansion of all types of orthopedic surgery and transferring almost all orthopedic procedures to one of the hospital bodies. Financial investments were made in order to convert three displacement-ventilated ORs into three larger ORs equipped with LAF to enhance air quality. However, the results from the Swedish Hip Arthroplasty Register in 2010 regarding this specific hospital (193) showed an unexpected increase in infection rates following THA surgery.

In 2009, the hospital participated in a national quality improvement project (194). The project was based on a collaborative effort between several professional societies aiming to reduce the incidence of SSI in relation to prosthetic joint surgery. The routines and implementation of SSI prophylactic measures at every participating hospital were reviewed and evaluated by peers. In the present hospital, the result was handed over to the hospital management team, which set up a multidisciplinary task force to address the areas identified as being in need of improvement. In the same year, the *WHO Safe Surgery checklist* (195) was also implemented on the surgical ward.

## **6.3 Participants**

### **Paper I**

A person not involved in the study strategically selected 15 patients from the participating university hospital’s local Orthopedic Quality Register. The goal was to form a heterogeneous group in terms of age, gender and socio-economic background to ensure variation in order to capture different experiences. This would enable the exploration of the common and the unique manifestations of experiences in relation to deep SSI. Two non-orthopedic pa-

tients were selected via personal contacts in order to perform a pilot test of the interview questions. Data from these interviews were also included in the data analysis in order to augment variation. An exclusion criterion was ongoing malignancy. Two male patients declined to take part and one participant was excluded from the study due to progressive dementia. The final sample comprised 14 patients. See Table 5 for demographic data and type of index operation.

Table 5. *Demographic and clinical data of the 14 participants (n).*

Gender	Male		9
	Female		5
Age	> 40		3
	40-65		5
	< 65		6
Marital status	Married		8
	Single		4
	Widow/widower		2
Occupation (previous)	Blue-collar	Unskilled/semi-skilled	4
		White-collar	Low position
		Intermediate	1
		High position	4
	Self-employed		2
	Student		1
Index operation	Total hip arthroplasty		6
	Total knee arthroplasty		2
	Hemiarthroplasty		1
	ACL reconstruction		3
	Coronary bypass		1
	Abdominal Hysterectomy		1

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### 6.3.1 Data collection

Annette E Andersson carried out all the data collections for Studies I-IV. Pia Gustavsson participated in collecting active air samples in LAF-ventilated ORs for Study IV.

### 6.3.2 Interviews

#### Paper I

The participants were invited to take part in the study via a letter containing information about the study purpose and an inquiry about their interest in participating. The participants were contacted by telephone after two weeks, giving them the opportunity to ask questions and decide if they would like to take part. After oral consent, the participants selected the location for the interview. The majority (n=11) of the participants preferred to be interviewed

in their own homes. Three participants chose to be interviewed in a private room at the hospital library. Written consent was obtained prior to the interviews. All the interviews began with the question “Please tell me about your experiences of infection after surgery”. In order to ensure that the participants’ comments were correctly understood, ongoing clarifications were made. When participants found it difficult to answer the first open-ended question, they were asked to talk about their daily life situation.

### 6.3.3 Air samplings

#### Papers II and IV

A Sartorius MD-8 air scanner Göttingen/Germany was used to collect airborne microorganisms. Air was sampled at a flow rate of 3m<sup>3</sup>/h (0.83 l/s) in 20-minute periods continuously during surgery. The instrument was placed outside the clean zone and a sterilized flexible hose reached the wound area, with a filter holder attached to the end. The filter holder, with a sterile gelatin filter (pore size 3 µm and a diameter of 80 mm) was placed 20-40 cm from the wound, see Figure 7. When this was not feasible, the filter holder was to be placed on the Mayo stand. The gelatin filter has the ability to retain bacteria at 99.9995% for *Bacillus subtilis niger* at 0.25 m/s inlet velocity (196). The OR nurse or the surgical assistant changed the filter every 20 minutes, throughout the operation from incision to wound closure. The used filters were immediately handed over to the researcher and placed on a non-selective Colombia agar base plate with 5% horse blood. At the end of the operation, the agar plates were incubated at 30°C for four days before the total aerobic bacterial count was measured. The Department of Microbiology at Sahlgrenska University Hospital delivered the agar plates and incubated them subsequently. Head physicians at this department performed the analysis and microbiological results were expressed as colony forming units (CFU)/m<sup>3</sup>. Filters and plates were handled using a strictly aseptic technique. To evaluate the technique, filters that had not been used for air sampling were placed on agar plates, incubated in the same way as the used filters and showed no bacterial growth. Table 6 shows the number of air samples and corresponding observational session.

Table 6. *The number of included active air samples and corresponding observational periods in Papers II and IV*

	Fracture surgery	Total joint arthroplasty	Sum
Active air samples	116 <sup>1</sup>	168 <sup>2</sup>	284
Corresponding observational periods of 20 minutes	119	168	287
Number of operations	30	33	63

<sup>1</sup> Four contaminated samples were removed.

<sup>2</sup> Four samples taken behind the surgeon were removed, as this sampling position was not included in the study protocol.



Figure 7. *The air sampling hose with attached filter just before incision.*  
 Photo by Annette E Andersson.

At the end of the data collection period, it was pointed out that there might be something wrong with the ventilation of the adjacent preparation rooms where all the sterile instruments were unpacked and prepared before use. The airflow rates were checked in all three rooms on different occasions, showing that the flow did not reach the commissioned rates of 0.27 m/s but instead

about 0.03m/s in all the preparation rooms. We investigated the possible impact on air quality by conducting active air samplings during three sham preparations of sterile instruments. To mimic normal conditions, the hospital's standardized sets of instruments (12 instrument trays) and equipment for a THA procedure were used. The sampling filters were placed less than 10 cm from the instrument table and 100 cm above the floor. The assisting nurses wore conventional cotton/polyester 50/50 mix shirts and trousers, long disposable surgical hoods tucked into their smocks, private shoes and socks. The scrub nurse and the researcher wore disposable sterile gowns, facemasks (R11) and double sterile gloves during air samplings. In addition, two control measurements during instrument preparation were made after technical revisions of the ventilation system.

### **6.3.4 Structured observations during air sampling**

#### **Papers II and IV**

During the orthopedic operations when air samples were taken, structured observations were carried out. The observational periods were divided into 20-minute periods to correspond with the air sampling periods. The included variables were:

- Date and time
- ID for the specific OR
- Room temperature
- Type of surgery
- Fixation method
- Current step in the surgical procedure (incision, dissection, implantation and wound closure phase)
- Duration of surgery (from time of incision to completed wound closure)
- Number of door opening and reasons for traffic flow
- Number of people present (patient and researcher excluded)
- Type of ventilation system.

### **6.3.5 Observations of protective measures**

#### **Paper III**

The variables were structurally recorded using a pre-tested observational form. The variables were included on the basis of scientific evidence for risk

reduction in relation to infections. Moreover, the selected measures should also be well known to the OR staff and possible for the non-scrubbed members of the OR team to apply. The OR teams had been informed that a study of infection control was being carried out, but they were not aware of exactly which items were of interest in this study. The variables were:

- ASA classification score
- Length of surgery
- Type of surgery
- Use of WHO checklist (“time out”)
- Type of prophylactic antibiotics: the difference in minutes between completed infusion and incision or application of tourniquet
- Method used for monitoring body temperature and maintaining normothermia
- The use of an indwelling urinary tract catheter and insertion technique
- Clothing regimen/the use of surgical hoods
- Application of hand hygiene guidelines.

### **Hand disinfection and aseptic technique**

For data collection, a pre-tested observational structure was developed based on the WHO observation form (197). The form was modified to match the operating room context. An opportunity for hand hygiene was defined as a situation requiring hand disinfection in accordance with the national and local guidelines (168). A hand hygiene application was defined as the use of an alcohol-based hand rub in relation to an opportunity. The amount of product used and the duration of application were not recorded. Adherence was recorded in relation to professional category and type of indication. Using a single observer meant that it was necessary to select and restrict the items that were going to be observed. We chose to observe hand disinfection and glove use in relation to invasive procedures such as the insertion of a peripheral venous catheter, arterial line, urinary catheter, regional anesthesia and tracheal intubation. Observations of hand disinfection prior to opening and handing over sterile material (such as implants) to the scrub nurse were also included. Observations of the risk of hand transmission of microorganisms were recorded. For example, if, after a urinary tract catheterization, no hand disinfection was applied and the observed individual subsequently touched a clean site such as a stopcock, this was recorded as a risk of transmitting microorganisms.



## **Prophylaxis with antibiotics and the application of the WHO Safe Surgery checklist**

The original WHO Safe Surgery checklist (195) consists of 19 items which should be orally confirmed by the OR team. The checklist is used at three critical transitional phases in care, before anesthesia, just prior to incision and before the patient is transferred from the OR. In this study, we focused on observations in relation to the second phase called “time out” and more specifically the administration of prophylactic antibiotics. The local guideline states that the patients should receive a completed infusion of prophylactic antibiotics 30 minutes prior to surgery. At the time of the study, cloxacillin was recommended as the first-line treatment/prophylaxis and three doses were to be given within 24 h of surgery. The first dose was to be given as an infusion by the anesthetic nurse. The timing of antibiotic prophylaxis was planned to be retrieved from medical records. However, during the initial onsite observations, it was noted that there was a discrepancy of approximately five to 25 minutes between the actual times of completed infusion and the times registered in the patient records. In addition, the time of administration was found to be an inaccurate measurement of timing, as the infusions could last from approximately 15 minutes to about one hour. It was subsequently decided that these data had to be recorded after direct observations of completed infusion to ensure accuracy. In this study, infusions given 45-15 minutes prior to surgery or the application of a tourniquet were considered to be within an acceptable time span.

### **6.3.6 Participant observations**

#### **Papers II-IV**

The aim of participant observations has been defined as understanding the behaviors and experiences of people as they occur in their natural setting (191) page 378. The naturalistic setting in this study was the surgical ward and the ORs with all the people including all professions (except the cleaning staff) working there. Field notes were taken every day after loosely structured observations, in order to capture talks and events in relation to risks of infection as well as safety measures as they naturally occur in the OR environment. Loosely structured observations refer to the pre-defined restriction of data collected; only information relating to infection control and prevention was to be included.

Before conducting participant observations, it was decided that the role of the observer should be primarily that of an observer with minor participation, i.e.

playing a minor part in the ongoing activities. The role of the observer is much different in this type of observation compared with structured observations. In order to gather this type of data, it is essential to gain access, establish a rapport and finally be accepted by people in the group. It was difficult, if not impossible, to be accepted by everyone and the strategy was therefore to find out which of the staff were informal leaders and to start by trying to create a confident relationship with them and from there work on the observer's social position. The aim was to create an atmosphere in which the staff felt free to behave and express themselves as they normally do when not being observed.

### **6.3.7 Medical and nursing records review**

#### **Paper IV**

In May 2012, sixty-three patients' medical and nursing records were screened retrospectively for hospital-acquired infections, i.e. the records linked to surgical procedures in which air samplings had been carried out (LAF  $n=33$  and DV  $n=30$ ) were included. Since the number of included records was limited, the opportunity was taken thoroughly to read all records line by line, beginning with the primary operation and continuing to the date of screening. An infection event was recorded if antibiotic treatment had been given in combination with other described signs, such as a non-healing wound or excessive wound secretion. Additional data were recorded if available; type of treatment, if microbiological analyses had been carried out prior to or after treatment with antibiotics and finally mortality.

## **6.4 Data analysis**

### **6.4.1 Content analysis**

#### **Paper I**

The audiotaped interviews (Paper I) were transcribed verbatim and analyzed by latent content analysis. Latent content analysis has been defined as a method that is used in order to understand what the text talks about, thereby including an interpretation of the underlying meaning of the text. Typically, an emerging theme answers the question how (198).

The text was read and re-read to obtain an understanding and acquire a sense of the whole. With the aim of the study constantly in mind, meaning units

were extracted, condensed and labeled with a code. The code reflected the content of the meaning unit and served as a tool to view the data in a new way. The codes were subsequently compared and grouped. The groups were then analyzed in relation to time sequences. This analysis continued by interpreting the underlying meaning in relation to time and context, thereby creating sub-themes. To keep the analysis close to the core of the content, a return was made to the direct statements within the sub-themes and they were subsequently sorted into tentative themes. The next step in the process included the comparison of statements within the sub-themes with regard to similarities and differences, the unique and the common. The themes were continuously discussed and reflected upon by the authors to obtain agreement as a way of enhancing the credibility of the analysis. The process is shown in Figure 8.

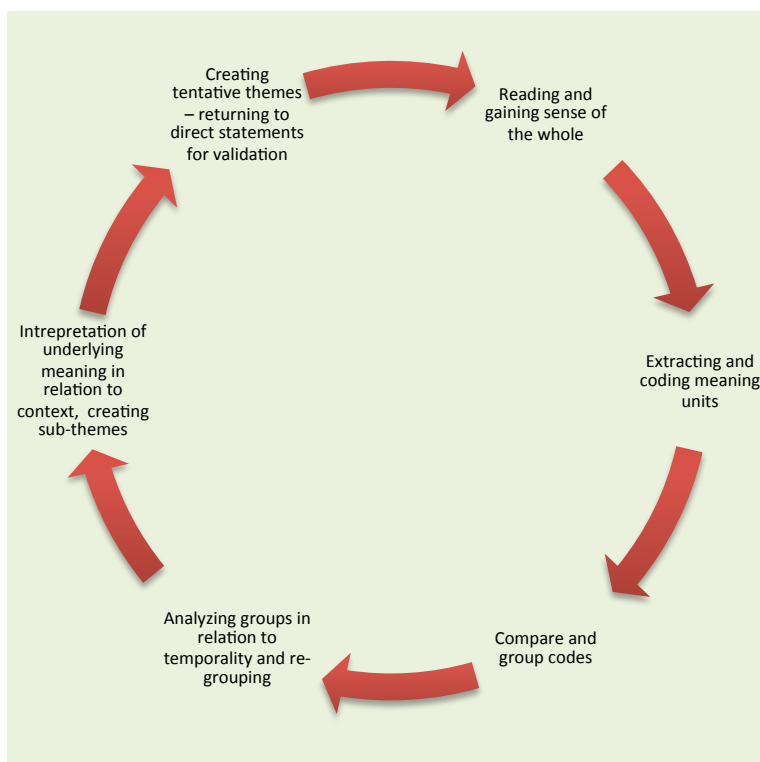


Figure 8. The process of content analysis of texts.

Manifest content analysis (Paper II) was applied to loosely structured observational data regarding traffic flow and the application of the WHO Safe Surgery checklist. The process included coding meaning units, sentences or words. The codes were subsequently formed into categories. Numerical data were expressed in relation to these categories. In contrast to latent analysis, manifest content analysis deals with descriptions of the obvious and visible content of a text, with a low level of interpretation (198).

## 6.4.2 Statistical Analysis

### Paper II

Primary analyses showed that CFU/m<sup>3</sup> could not be regarded as normally distributed and for this reason the linear relationship between CFU/m<sup>3</sup> and traffic flow rate per 20-minute period was investigated using Spearman's rho.

To investigate the strength and direction of the linear relationship between the mean door opening rate and the mean value of CFU/m<sup>3</sup> per operation, analyses of partial correlations were conducted, enabling the removal of length of surgery as a potentially confounding variable and thereby giving a more accurate description of the relationship between the variables.

For investigations of correlations between normally distributed variables (door opening, length of surgery and number of people present), Pearson's product-moment correlation coefficient was used. Significance was defined as  $p < 0.05$ . All tests were two-tailed.

Hierarchical multiple regression analyses were used to assess the ability of traffic flow and number of people present in the OR to explain the variance in CFU/m<sup>3</sup> levels. We chose this analysis because it offered the opportunity to control for duration of surgery, as this variable also correlates to the number of door openings/operation. There are a number of assumptions regarding the data that have to be taken into consideration before deciding whether this type of analysis is appropriate. Preliminary analyses were conducted to ensure that no important violations of the assumptions of normality, linearity and multicollinearity were made. Multicollinearity refers to the situation in which the independent variables of a model are highly correlated,  $r = 0.9$  or more (199). To interpret the regression model, the R-square value x 100 will give an explanation of variance in percent. Hierarchical regressions will also give an R-square value for each step in the model. The standardized beta ( $\beta$ ) value can be used to compare the contribution of each variable, the signifi-

cance value reveals whether the variable makes a unique statistically significant contribution to the model (199).

During intramedullary nailing of the tibia, the knee of the injured leg was flexed at 90°, thereby blocking the sampling filters with the sterile drape, partially or fully, during the main part of the procedure and for this reason these samples were not included in the analysis. Moreover, the mean difference between air samples taken close to the surgical wound and sampling filters placed on the Mayo stand were found to be significant,  $p < 0.01$ . Based on these results, 29 air samples taken on the Mayo stand were removed before the final analysis was conducted, see Figure 9.

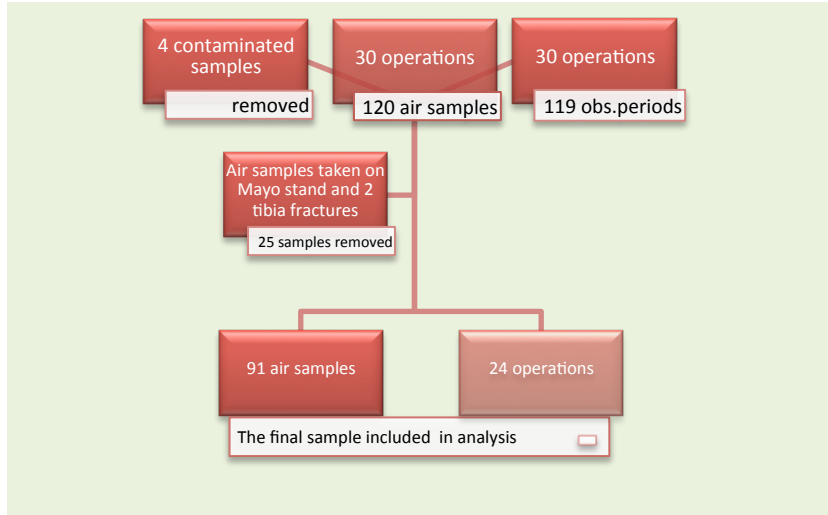


Figure 9. Included and removed samples in Paper II

### Paper III

Descriptive statistics were applied for data analysis. For comparisons of differences in continuous variables between groups, independent sample t-tests were used, reporting the mean, SD and 95% confidence intervals (CI). For examinations of categorical data, we used chi-square tests of independence with Yates' Correction for Continuity (for 2 by 2 tables). Significance was defined as  $p < 0.05$  and all the tests were two-tailed.

Comparisons between sub-groups were not initially a part of the study protocol and the statistical power was therefore retrospectively calculated on the basis of the obtained mean values and SD for the timing of prophylactic anti-

biotics measured in minutes and actual sample size. Using an alpha error level of 5% gave a statistical power of 75%.

In relation to hand hygiene, opportunities for hand disinfection represented the level of analysis. Adherence was calculated by dividing the number of applications of hand disinfection by the total number of opportunities.

According to Sax et al. (197), ~250 observed opportunities per time period would be required in order to have an opportunity to compare an adherence in two time periods. Given that the anticipated adherence at baseline is 20%, this sample size will make it possible to detect a 15% difference before and after an intervention. The sample size was based on this, as we wanted to be able to conduct a future intervention.

#### **Paper IV**

All the included variables were examined using descriptive statistics and plots, assessing normality, distribution and checking for outliers. Pre-analyses showed that four sampling filters had high levels of CFU/m<sup>3</sup> (26, 30, 41 and 71 CFU/m<sup>3</sup>). A closer examination revealed that, during the THA procedure in which these samples were taken, the first sampling filter was placed close to the wound and slightly downwards, resulting in 0 CFU/m<sup>3</sup>, while the following four filters were due to attachment problems placed *behind* the surgeon, resulting in high CFU levels. This measure point was not included in the study protocol. It is expected that the “washout” effect of LAF systems will result in higher CFU values at this point, compared to samples taken close to the wound. These four samples were therefore removed from further analysis.

For comparisons of differences in median values of CFU/m<sup>3</sup> and door-opening rates between the samples taken in the LAF ORs and the DV ORs, the Mann-Whitney U-test was applied to non-normally distributed variables and an independent sample t-test to normally distributed variables. The Kruskal-Wallis test, the non-parametric alternative for one-way between-groups analysis of variance, was used for investigations of more than two groups.

Significance was defined as  $p < 0.05$ . To investigate the strength and direction of the linear relationship between the variables, analyses of partial correlations were conducted, in order to control for potentially confounding variables.

## 7 ETHICS

This study was approved by the Regional Ethical Review Board, Gothenburg, Sweden (Dnr: 773-08, 157-10 and T138-12). Written and oral information was given in line with the four principal requirements of the Helsinki Declaration, autonomy, beneficence, non-maleficence and justice (200). Accordingly, the patients were included after oral and written consent and informed that they could withdraw from the study, at any time without giving any explanations.

Informed consent was obtained from all the OR teams prior to observations and sampling. In addition, the hospital management approved the medical records review.





## 8 RESULTS

### 8.1 Patients' experiences of SSI

The experiences of acquiring a deep SSI can be identified in relation to three main time periods. The interpreted meaning of these periods is reflected in three themes and nine sub-themes (Table 7).

Table 7. *Overview of the results from Paper I.*

Time sequence	Themes	Sub-themes
From emerging problems to treatment	A troubled search for recognition and answers	<ul style="list-style-type: none"> <li>– Insecurity confronting new signs and symptoms</li> <li>– Sudden pain</li> <li>– Searching for answers and help</li> </ul>
The treatment period	Enduring a turbulent period filled with discomfort, suspense and restraint	<ul style="list-style-type: none"> <li>– Transfers and re-operations</li> <li>– Additional suffering due to side-effects</li> <li>– Waiting in a vacuum</li> <li>– Impact on everyday life</li> </ul>
The time after treatment	Changes in life, for good and bad	<ul style="list-style-type: none"> <li>– A changing body</li> <li>– Adapting to new conditions</li> </ul>

Reprinted from American Journal of Infection Control, Patients' experiences of acquiring a deep surgical site infection: An interview study 2010 Nov; 38(9):711-7 with permission from Elsevier.

#### **From emerging problems to treatment: a search for recognition and answers**

This theme emerged from participants' experiences of new and unfamiliar signs and symptoms occurring from days up to years after the index operation. The theme comprises participants' interpretations and reactions, as well as their experience of how health-care professionals interpreted their signs and symptoms. The signs and symptoms varied in intensity, from very obvious, such as leaking wounds and intense pain to more diffuse feelings of not feeling well. Even if the sensations differed, the insecurity relating to how to interpret the symptoms was a common feature among the participants. The next step, when the suspicion that something must be wrong became stronger, was to contact a hospital or a primary care center to get answers about *whether* or *what* was wrong. Almost all the narratives were strikingly similar in their descriptions of how the patients had to seek care on several occasions

before they received help. In some cases, especially for those patients who had undergone a THA with vague symptoms of infection, it typically took several months up to a year before they received a correct diagnosis and subsequent treatment. Patients presenting at the ER with more typical signs and symptoms of infection, such as redness, swelling and high fever, received care within a few days or weeks. This was the case for patients who had undergone TKA, anterior cruciate ligament (ACL) reconstruction and abdominal surgery. All patients undergoing THA described a later and slower onset of symptoms and a delay in the diagnosis of infection.

### **Enduring a period filled with discomfort, suspense and restraint**

This theme was derived from what the participants reported about their experiences related to the treatment period. The dimensions of this theme include repeated transfers between hospitals, wards and doctors, as well as encounters with different health-care professionals. Re-operations and side-effects related to the treatment of the infection and the subsequent impact on everyday life in terms of relationships, work and economy, as well as strategies for handling this difficult situation, were also included. All the narratives contained a description of the period when they all had to wait, such as *in a vacuum*, for the infection to heal. In many ways, this was experienced as a destructive time in life, full of worries. *Will the infection ever heal? When can I go back to work? How will the relationship with my partner survive this?* Feelings of hopelessness and isolation pervaded this long period in suspense.

### **Changes in life, for good and bad**

This theme relates to the time after the period of active treatment and describes changes in life circumstances recognized by both men and women, regardless of differences in age, type of operation and socioeconomic background. These changes included physical impairments and the resulting necessary changes in the physical environment, as well as emotional vulnerability and new ways of looking at life. The bodily changes were an experience shared by all participants. This could involve loss of muscle tone, feelings of bodily weakness, obesity and different degrees of physical disability, ranging from minor problems, such as limping, to a life without a joint. These bodily changes meant different things; for some people, they meant a life in isolation, dependency and a longing for the sense of freedom a functioning body can give.

One core thread ran through all three periods; *pain* as a strong physical sensation, but also the emotional aspect of pain linked to the feelings of having been let down by the health-care system and the practitioners.

During the first phase, before a diagnosis was established, a sudden and new kind of pain manifested itself in 11 of the 14 descriptions and they were all patients who had undergone an orthopedic operation. In some cases, the pain was described as unbearable, no painkillers could ease it, and this created feelings of fear and panic. In addition, these strong symptoms were ignored by the health-care workers and even seen as exaggerated. When no obvious diagnosis was found, these symptoms were explained as “normal” and something one has to learn to live with. Almost all the participants dwelled on the fact that they felt that they had not been taken seriously and even neglected by physicians during this phase. Only one participant described how, when seeking care, he was promptly sent to hospital and received care the same day.

During the treatment period, the pain was something that was always present to some degree. The medication was described as insufficient or associated with side-effects. Vivid descriptions were given of the way patients' perceptions of reality were distorted by hallucinations due to strong painkillers. Experiences of this kind were perceived as very frightening. Living with pain for such a long time, up to several years, was described as destructive and demoralizing. The emotional suffering was also created by a health-care system that abandoned these patients. They constantly experienced changes between wards and physicians and a lack of continuity in care. Information was seldom given on how to use certain drugs or the purpose of different treatments. All the patients expressed the importance of being involved in the treatment plans and, most importantly, having a dialogue with one doctor and being treated as an adult by all health-care professionals.

Those who described encounters and positive relationships with health-care workers, based on dialogue, involvement and trust, expressed gratitude, even though they had suffered greatly due to the infection.

During the third phase, the pain for some of the participants was still there and influenced their everyday life. The physical impairments were handled and the activities of daily life were adjusted accordingly. What really caused the most suffering, even after completed and successful active treatment, were the memories of being neglected, diminished or badly treated by the health-care system.

## 8.2 Air quality and behavioral influences in the two different ventilation systems

Active air sampling was performed during 63 orthopedic implant procedures; 15 THA, 10 TKA, 21 fractures fixed with plates and screws, 8 intramedullary nails, 6 hemiarthroplasties and 3 revisions of THA. This resulted in 284 air samples and 287 observational periods. The variations in CFU/m<sup>3</sup> were found between the operations rather than within the operations. No significant differences in CFU/m<sup>3</sup> were found between different stages of the operation, e.g. incision, dissection, implant and wound closure, regardless of the type of ventilation. No accumulations of CFU were observed. However, in DV ORs, the mean CFU/m<sup>3</sup> value/operation was highly correlated to the length of surgery ( $r=0.62$ ,  $p=0.01$ ;  $n=23$ ). This pattern could not be observed in LAF ORs. See Table 9 for the basic results for CFU/m<sup>3</sup> and related variables measured in DV and LAF ORs.

Where; close to the wound or on the Mayo stand and how; angle, sampling filters were placed influenced the obtained numbers of CFU/m<sup>3</sup>, see Table 8.

Table 8. *Variation in CFU/m<sup>3</sup> values depending on air-sampling position.*

Position	Number of samples		Median & IQR		Range	
	LAF	DV	LAF	DV	LAF	DV
Vertical <sup>1</sup>	10	60	1.0/ 2	12/22	0-7	1-55
Slightly upwards <sup>1</sup>	5	23	2.0/7	10/17	0-10	0-55
Downwards <sup>1</sup>	37	17	0.0/1	14/15	0-9	4-44
Horizontal <sup>1</sup>	68	3*	1.01	7/*	0-18	6-13
Vertical <sup>2</sup>	42	13	0.0/1	6/8	0-4	2-16
Total <sup>3</sup>	162	116				

<sup>1</sup> 20-40 cm from the surgical wound

<sup>2</sup> Mayo stand

<sup>3</sup> In two cases, data on sampling position were missing. Four samples taken behind the surgeon were removed from this analysis.

\*Low number of samples

In LAF ORs, the highest levels of CFU/m<sup>3</sup> were found during THA (md=1, IQR; 3, range 0-18, n 60), followed by TKA (md=00, IQR; 2, range 0-8, n 52) and revision of THA (md=00, IQR 1, range 0-8, n 28), while the lowest levels were retrieved during fracture surgery (md=00, IQR; 1, range 0-1, n 24).

In DV ORs, a variation in CFU levels was observed between types of operation: plates and screw fixation (md=15, IQR; 18, range 1-110, n 71), hemiar-

throplasty (md=6, IQR; 12, range 0-44, n 11) and fixation with intramedullary nails (md=4, IQR; 5, range 1-12, n 10).

Table 9. *Air quality and related variables measured in 20-minute periods and per operation. (n) = Number of samples.*

	Displacement ventilation				Laminar airflow				
	n	M (SD)	CI	MD (range)	n	M (SD)	CI	MD (range)	p <sup>5</sup>
CFU/m <sup>3</sup>	91	15.9 (13.4)	13.1-18.7	13 (0-55)	164*	1(2.1)	0.7-1.5	0 (0-18)	.001
CFU/m <sup>3</sup> /op <sup>1</sup>	24	60.4 (55.9)	36.8-84	33.5 (7-187)	32*	5(5.3)	3.2-6.9	3 (0-21)	.000
People <sup>2</sup>	111	5.4(1)	5.2-5.6	5 (3-10)	163	5(1.1)	5.6-6.0	6 (3-9)	.002
Door opening	119	4.3 (2.9)	3.8-4.8	4 (0-14)	159	2.3(2.3)	1.9-2.7	2 (0-12)	.000
Door opening <sup>3</sup>	30	17.4 (13.5)	12.4-22.4	14 (0-67)	32	11.4(8.9)	8.2-14.9	8 (2-31)	.039
Duration of surgery <sup>4</sup>	29	83.5 (39.7)	68.4-98.5	60 (20-200)	32	101(27)	91-111	100 (40-180)	.009

<sup>1</sup> CFU/m<sup>3</sup> per operation

<sup>2</sup> Number of people present during surgery

<sup>3</sup> Measured from incision to wound closure

<sup>4</sup> Measured in minutes

<sup>5</sup> The Mann-Whitney U-test for differences between groups

\* Four samples taken behind the surgeon removed

### **Air quality and impact of door openings and traffic flow**

The door-opening rates differed significantly between operations, depending on the type of ventilation system. An ANOVA test revealed a significant difference in mean door-opening rates/20-minute period, depending on which type of surgery was performed in DV ORs: plates and screws 4.5 door openings, hemiarthroplasty 2.3 and intramedullary nail 2.2, (p=0.004) see Figure 10.

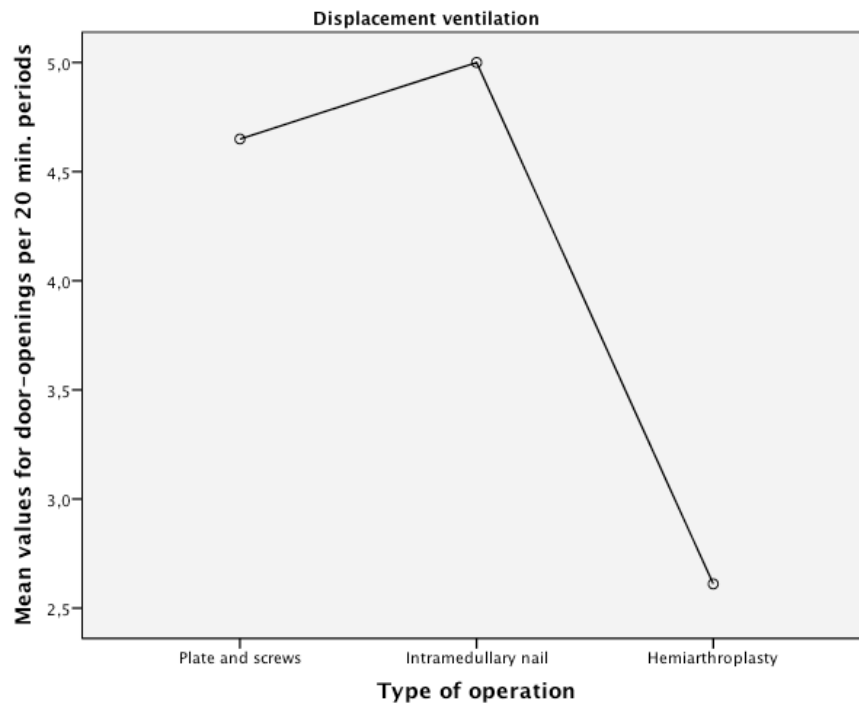


Figure 10. Door openings in relation to type of operation in displacement-ventilated ORs.

In DV ORs, the mean CFU/m<sup>3</sup> value per 20-minute period and mean CFU/m<sup>3</sup> value per operation correlated significantly with door-opening rates measured in 20-minute periods and per operation (after controlling for length of surgery) ( $r=0.31$ ;  $p=0.003$ ) and ( $r=0.74$ ;  $p=0.001$ ).

Door openings/operation were highly correlated to the length of surgery ( $r=0.79$ ,  $p=0.01$ ,  $n=23$ ). For LAF ORs, the correlation between the same variables was ( $r=0.37$ ,  $p=0.036$ ,  $n=31$ ).

In LAF ORs, door-opening levels also differed significantly across the groups, depending on the type of surgery performed ( $p=0.000$ ), Figure 11.

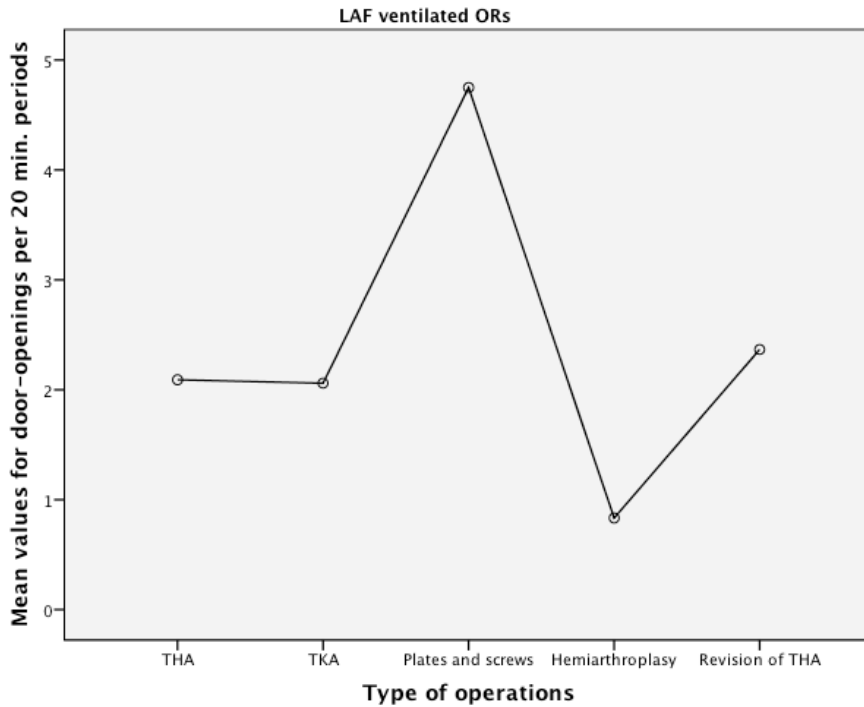


Figure 11. Door-opening rates in relation to type of surgery in laminar airflow-ventilated ORs.

In LAF ORs, no significant correlation was found between mean door-opening values and  $\text{CFU}/\text{m}^3$ . No significant correlation was found between the mean value of  $\text{CFU}/\text{m}^3/\text{operation}$  and the mean value of door openings/operation. The analysis was performed after controlling for the length of surgery and the location of the air-sampling filter.

No correlations were found between traffic-flow rates and the number of people present during surgery, regardless of the type of ventilation system.

A total of 928 door openings were observed and analyzed and grouped into categories reflecting underlying causes, see Table 10. No reason could be identified in relation to 142 of the entries and exits. To exemplify; this could mean that staff entered the OR, took a look around and then walked out. The category “Expert help” refers to occasions where nurses or surgeons needed help from senior colleagues in order to proceed safely.

Table 10. *Reasons for door openings in displacement- and laminar airflow-ventilated ORs. n=928 (observations).*

Reason	Expert help	Supply issue	Lunch/ coffee break	Staff*	Social visit	No detectable reason	Logistic reasons
DV	40	137	108	76	45	93	30
LAF	30	125	75	108	12	49	0
Total	70	262	183	184	57	142	30

\* Scrubbed member of the team entering after incision or leaving before wound closure.

### People present in the OR and the impact on air quality

In DV ORs, a positive correlation was found between CFU/m<sup>3</sup> and the number of people present (r=0.22, p=0.04, n=23). In LAF ORs, no significant correlation could be detected.

The ability of *door openings* and *number of people present* to explain the variance in CFU/m<sup>3</sup> after controlling for *length of surgery* was analyzed. In step one, *length of surgery* explained 36% of the variance (adjusted R<sup>2</sup>=0.359). *Door openings* and *number of people present* were added in step 2 and explained an additional 34% of the variance, but only *door openings* were statistically significant in this step (standardized β=0.95, p=0.001). The three measurements (*length of surgery*, *door openings* and *number of people*) explained a total of 68% of the variance in CFU/m<sup>2</sup> in displacement-ventilated ORs. Moreover, it was estimated that every door opening generated an increase in the CFU/m<sup>3</sup> value of 5.3. In contrast, no significant patterns of variance in CFU/m<sup>2</sup> were observed in LAF-ventilated ORs.

Qualitative analysis of data showed that, in 52/91 samples taken in DV ORs, the CFU/m<sup>3</sup> values exceeded the recommended levels of <10 CFU/m<sup>3</sup>. During five surgical procedures, the mean values exceeded 25 CFU/m<sup>3</sup>; the highest mean values were 37.5 and 44.3 CFU/m<sup>3</sup>. Moreover, during these operations, the activity levels (movements within the OR, as well as traffic flow) were high, combined with other potentially negative variables, such as staff having failed to tuck all their hair inside their hood, the presence of a sneez-



ing person and more than five people present. Mean values below 5 CFU/m<sup>3</sup> were found during five operations, where the lowest values were 2.3 and 1.6 CFU/m<sup>3</sup>, and field notes taken during these operations revealed that there were no door openings and a overall low activity level.

In LAF-ventilated ORs where the CFU levels exceeded 5, no distinct patterns were observed, but excessive door openings were found to be a common feature.

### **Clothing regimen and surgical hoods**

During the whole study period, the following clothing regimen was used in all the observed operations; conventional cotton/polyester 50/50 mix shirts and trousers, long disposable surgical hoods tucked in, private socks and shoes. In all cases, the scrubbed members of the team wore reinforced surgical gowns and facemasks (RII). Non-scrubbed members of the team did not wear facemasks. In 14 of the 66 observed operations, the staff did not adhere to the practice of wearing a long surgical hood tucked into the smock and covering all their hair. There was no significant difference between DV and LAF ORs regarding this aspect.

### **Preoperative sham preparations of sterile instruments and THA equipment**

The active air samples resulted in high levels of bacterial growth:

- Sham 1) 42 CFU/m<sup>3</sup> with a pressure of 0 Pa in relation to the “non-sterile corridor”
- Sham 2) 44 CFU/m<sup>3</sup> with a pressure of 0 Pa in relation to the “non-sterile corridor”
- Sham 3) 39 CFU/m<sup>3</sup> with a positive/negative pressure of 0 Pa in relation to the “non-sterile corridor”

After a technical revision of the ventilation system, the two control measurements in two different preparation rooms showed:

- 0 CFU/m<sup>3</sup> with a positive pressure of 2 Pa in relation to the “non-sterile corridor”
- 4 CFU/m<sup>3</sup> with a *negative* pressure of -2 Pa in relation to the “non-sterile” corridor.

### 8.3 The application of protective measures

Not all variables were possible to observe during all 69 surgical procedures included. For example, the correct administration of prophylactic antibiotics was not observed during revision of TJA and one patient received antibiotic treatment > 24 hours before surgery. This resulted in a variance in the number of included observations (Table 11).

Table 11. *Variations in observations of variables*

Included variables	Numbers of observations
Use of WHO checklist (“time out”)	69
Type of prophylactic antibiotics	68
The difference in minutes between completed infusion and incision or application of tourniquet	59
Method used for monitoring body temperature	69
Method used for maintaining normothermia	68 <sup>1</sup>
The use of an indwelling urinary tract catheter	66
Adherence to aseptic insertion technique in UTC	11
All hair covered by a surgical hood?	66 <sup>1</sup>
Adherence to hand hygiene guidelines/correct use of protective gloves	254

<sup>1</sup> Missing data

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No significant differences in length of surgery were observed between FS surgery and TJA. A tendency towards a higher ASA mean score was noted among FS patients compared with TJA (FS,  $m=2.16$ ,  $SD\ 0.64$ ; 95% CI 1.87-2.47) and (TJA,  $m=1.75$ ,  $SD\ 0.64$ ; 95% CI=1.5–2.0)  $p=0.03$ . The application of protective measures during TJA and FS is shown in Table 12.

Table 12. *Differences in application of protective measures between patients (n) undergoing fracture surgery (FS) or total joint arthroplasty (TJA)*

	FS	TJA	P <sup>1</sup>
Prophylactic antibiotics	m=13.2, SD 21.6; CI 4.9-29.9	m=24, SD 15.9; CI 18.0-29.9	0.03
Within 45-15 min	12	17	
0-14 min before	5	10	
> 45 min before	2	3	
After incision <sup>2</sup>	10	0	
Type of prophylaxis			
Cloxacillin	28	32	
Clindamycin	3	2	
Cefuroxim	2	0	
Cefotaxim	1	0	
“Time out”	Performed in 28 of 35 operations	Performed in 17 of 34 operations	
Perioperative UTC	20	15	
Normothermia			
Monitored for body temp. (n)	3	5	
Forced air warming	12	18	0.04
Cotton quilt	19	9	
Forced air warming after > 1 hour of surgery	4	6	
Type of ventilation			
DV	91%		
LAF	9%	100%	

<sup>1</sup>Independent sample t-test

<sup>2</sup>or application of tourniquet

### “Time out” and prophylaxis

Field notes taken during qualitative observations showed that the “time out” when used was an accepted practice, causing no notable objections among the surgical team members. The checklist worked as a reminder when prophylactic antibiotics had not been administered before the “time out”. The reasons for prophylaxis not being administered were as follows; antibiotics had not been prescribed, the anesthetic nurse forgot to administer the drug or the prescription was not available due to administrative problems with the computerized medical notes. In those cases when the infusion of prophylaxis had not been completed prior to incision or the application of a tourniquet, this was seldom communicated to the surgeon. If the surgeons received information on inadequate timing, it resulted in no further action and the surgical procedure was initiated with an incision or the application of a tourniquet.

During 10 observational sessions, 254 opportunities for hand disinfection were observed. The opportunities typically occurred in relation to the induction phase prior to incision and after completed surgery. Sterile implant packages are opened by the assisting personnel and handed over to the OR nurse. Hand disinfection before this practice was only performed in 28% of the observed cases.

The technique for urinary-tract catheterization was observed in 11 cases. In one of 11 cases, hand disinfection was carried out by the person who inserted the catheter and, in five of 11 cases, hand disinfection took place after completed insertion. The overall applications of hand disinfection guidelines are shown in Table 13, along with the observed risks of transmitting microorganisms.

Table 13. *The application of hand disinfection before and after invasive procedures across professional categories*

	Before	After	Total (n <sup>1</sup> )
<i>Invasive procedure</i>	6.2%	17.7%	226
Handling sterile products	7.1%		28
<i>Adherence/professional category</i>			
Anesthesiologist	6.5%	3.7%	58
Anesthetic nurses	1.5%	10.3%	136
Nursing assistants	13.9%	27.8%	72
Surgical nurses	2	4	6 <sup>3</sup>
<i>Use of non-sterile protective gloves</i>	Yes (clean)	Yes (used <sup>2</sup> )	
	30.3%	19.2%	132
<i>Risk of transmission of microorganisms</i>		76.6%	141

<sup>2</sup> Gloves already being used prior to the invasive procedure

<sup>3</sup> Few observations

## 9 DISCUSSION

The development of hospital-acquired infections is a complex phenomenon, involving interacting risk factors related to the host/patient and the environment, comprising microorganisms, health-care workers and technique, as well as leadership and organization.

### 9.1 Patients' experiences

The person who chooses to undergo a surgical procedure does so with the expectation of diminishing symptoms that causes difficulties in everyday life, thereby enhancing quality of life (201). The study showed that, when a patient acquires a deep infection, it influences every aspect of life. In the same way that the development of an infection is caused by complex interactions, infections create a multitude of effects in the life of the human who is affected. The experience is not "out there" to be objectively observed; instead, the consequences and the experiences are always constructed in relation to something. This "something" was found to be financial circumstances, family and/or friends, reactions from employers and the social security system. As a result, the experiences are always relative, unique and varied in their constructions, although there are many similarities. In this study, the encounters and relationships with health professionals and the health-care system were found to be one of the most important co-creators of the experience. The degree of impairment due to the infection did not appear to be associated with the degree of suffering experienced by the patient. On the contrary, it was found that those patients that said that they had received respectful, caring treatment and support during the treatment period had a more positive view of their experiences as a whole, regardless of outcome. Not that they suffered less from pain or side-effects, rather that they were able to bear their suffering in another way.

The health-care system and the people working within the system are the main transmitters of postoperative infections. If this statement is agreed with, it means acknowledging the responsibility for the failure as constituted by the HAI. Doing harm to a patient goes against all the basic assumptions that nurses and physicians internalize regarding the meaning of their professions, linking back to the Hippocratic principle of "primum nil nocere" (the first thing is to do no harm). When studying to become nurses and physicians, very little emphasis has been placed on adverse events, mistakes, lapses and failures. Moreover, the students are not sufficiently prepared to handle situa-

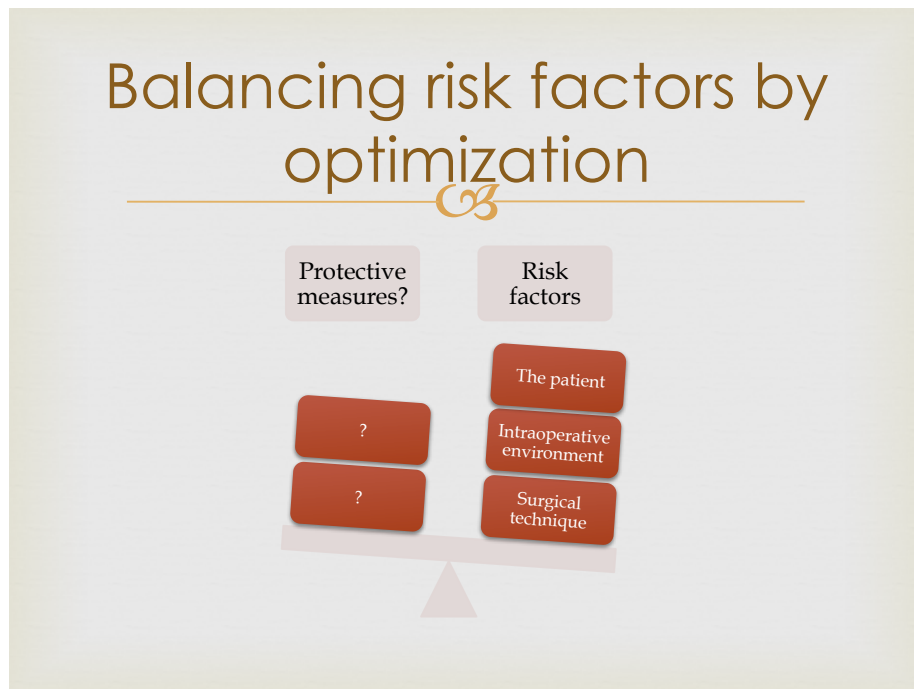
tions when patients have been harmed by care/treatment (202). It is as though errors are something that is not allowed to happen and, since such events are not allowed to happen, they are not recognized and talked about. A result of this is that infections are not systematically registered as an adverse event. New data from the Swedish Hip Arthroplasty Register reveal that only 67% of all THA-related re-operations due to SSIs have been reported to the register (35).

Dekker (203) states that, in medicine, the concept of failure is strongly associated with the incompetence and negligence of the individual. The criminalization of nurses and physicians that have been involved in situations in which a patient has been harmed supports this way of looking at failure (204). In addition, the outcome associated with the failure tends to decide whether or not the individual is to be punished, regardless of whether the same mistake has been made before without any adverse outcome (205). In contrast, adverse events could be looked upon as the result of complex interactions and the focus centered on interactions between staff, patient, workplace/professional culture in order to understand how unintentional harm occurs. From a CT point of view, it is also important to understand why things go well within a system, as the same factors can result in both good and bad outcomes. Due to the complexity, several different perspectives are needed in order to create a more holistic understanding. This could include the perspective and knowledge of patients, nurses, physicians and infection-control practitioners, as well as technicians. One single person seldom has all the knowledge needed to create a more comprehensive understanding of unwanted outcomes due to complex interactions. In Sweden, a general shift has begun in the way adverse events are regarded in the scientific society and in institutions such as the Swedish Board of Health and Welfare. The individualistic view has been replaced by a focus on “Safety Climate and Culture” and “Patient Dialogues” (206, 207). It is largely unknown whether this change of perspective has reached health-care providers and workers.

If responsibility for postoperative infections is to be taken, it is necessary to see and understand the infections. This includes taking the worries of patients seriously and taking the opportunity to listen to the patient’s narratives and broaden the perspective of diagnosis. The subjective symptoms can be useful clues leading to a correct diagnosis. Pain as a symptom of infection was a consistent finding in almost all the narratives related to joint infections in our study. In contrast, pain relief is the most important patient-reported outcome after successful joint replacement, together with improved physical function and amelioration in the health-related QoL dimensions (208, 209). Consequently, a patient’s report of a new or different kind of pain after surgery

should raise the suspicion of an ongoing infection. Allowing and helping patients to tell their story could be an important means of reducing diagnostic and therapeutic errors, as well as creating a satisfactory relationship from both patients' and practitioners' perspective (210). This skill of listening and asking open-ended questions and knowing when the answers are appropriate in clinical practice does not come by itself. It must be integrated in the medical and nursing education and trained in practice (211).

## 9.2 The application of protective measures



*Figure 12. Shows how risk factors for infection can be divided into three main areas: in relation to the patient, the surgical technique and the intra-operative environment.*

The protective measures balancing the risk factors, see Figure 13, will be discussed in relation to the result. Important findings in the present study were that different evidence-based measures for preventing SSI during anesthetic care were not sufficiently implemented either during TJA or during FS.

When attempting to understand this, it could be useful to look for what Schein (178) calls the basic assumptions that are related to perioperative care. To create long-lasting changes in behavior, the basic assumption underlying

the behaviors has to be explored and addressed, bearing in mind that culture is not something that can be implemented, as it evolves over time as a result of successful adaptations and problem-solving (177, 178). At this point, it becomes evident why posters, reminders and guidelines per se do not create changes in behavior. In addition, using the “*Pavlov’s dogs*” type of motivation (212) on highly educated people is probably bound to fail when it comes to creating sustained changes of behavior. Schein says that ultimately culture is something that is learned. New health-care professionals are socialized into the culture and subcultures in the OR, the process of externalization and internalization starts and they learn how things are done around them (170).

The physicians and nurses who work in the OR are highly educated and they therefore have a proven ability to learn. However, reading statements or guidelines cannot be equated with learning. If leaders want to create more than short-lived changes, it is then necessary to articulate the reasons for change and explain how the change in behavior can result in meaningful consequences. Practitioners need to learn both *the why* and *the how* and time needs to be taken to train the new skills or way of working, as well as reflecting on them (213) (page 27). However, production pressure leaving no time for reflection, in combination with worker independence in hospitals, has been found to act as a barrier to learning (214). With too little time and too much information in relation to what everyday work in the OR entails, Hollnagel (215) says that workers have to make a compromise or trade-off between efficiency and thoroughness in order to get the job done. If anyone at an OR were asked, he/she would probably agree that the safety of patients is of the utmost importance. At the same time, he/she would agree that production is what the management values most. This belief of mine has no scientific underpinning and it would therefore be valuable to investigate this further in order to obtain a basic knowledge of the way managers and health-care workers think and reason in relation to the safety of patients.

The results of the present study show that there appear to be unjustifiable differences in the quality of care between patients undergoing TJA and patients undergoing FS. More favorable conditions were created for TJA patients during surgery. They were all operated on in operating rooms equipped with LAF systems, designed to reduce the number of colony forming units (CFU) to well below  $5/m^3$ . Patients undergoing FS, on the other hand, had their procedures performed in displacement-ventilated ORs (91.4%) and, during this procedure, the door-opening and CFU rates were significantly higher compared with TJA procedures in LAF ORs. In addition, the patients undergoing TJA received better intra-operative care compared with the patients undergoing FS; forced air warming to maintain normothermia and the



correct timing of prophylactic antibiotics. These results could be a reflection of the existence of different safety cultures linked to different types of surgical procedure. The OR staff have internalized the agreed basic assumptions regarding the risks of infection in fracture surgery and in total joint replacement surgery and behave accordingly. If a high rate of door openings were understood from this perspective, it would be evident that talking about a lack of discipline (216) is not fruitful when it comes to the desire to enhance safety. The assumptions regarding infection control in the OR have evolved over time and in interaction with the complex systems of the hospital and the economic, political and legal systems. For this reason, blaming the individual for a lack of discipline will not lead to any sustained changes.

The literature typically discusses and reports measurements of safety culture and climate in relation to different professions, such as nurses and physicians, and in relation to different wards and hospitals (217, 218). This could mean that these surveys fail to capture some very important aspects of the way safety is constructed in the OR and possibly in other hospital wards and how this affects the safety of patients. Schein (177) concluded that, until we know more of how culture works, it is preferable to work with qualitative approaches combined with interviews and observations.

### **Hand disinfection**

The hands of nurses and doctors carry a strong symbolic meaning of doing well. It is with our hands that we help, support, soothe and sometimes relieve patients' suffering. The idea that our hands can transmit illness and disease can be provocative and even be perceived as an insult, linking back to Semmelweis' experiences. Moreover, in all cultures, the concepts of uncleanness and its opposite purity are surrounded by rules and/or taboos. The term unclean not only bears the meaning of being visibly dirty; in some cultures, the term is associated with the lowest place in the social hierarchy, or being an outcast to be ignored by the other members of the community. Different religions have several rules in relation to uncleanness. The idea of what is pure and what is unclean is a social construct and not a fact; what is taboo in one culture can be perfectly acceptable in another (171). However, within a specific culture such as the OR culture (consisting of several different professional subcultures), the concepts of purity and unclean are so integrated and taken for granted that they have become a basic assumption (178). This means that what we do with our hands is so self-evident and consequently never needs to be questioned.

What has happened is that the growing interest in how to prevent HAI, in combination with the emerging spread of multi-resistant microorganisms, has challenged people's views of hand hygiene. It is unlikely that some people in the health-care system have failed to come across reminders, brochures and guidelines on adequate hand hygiene practice.

The hypothesis is that the basic assumptions relating to hand hygiene differ between different professional subcultures. If basic assumptions are reflected by behavior, the differences are supported by several observational studies (164, 219, 220), all showing differences in adherence to hand hygiene guidelines depending on professional status. Nurses typically clean their hands more frequently than physicians. So, if we really want to understand the insufficient application of HD routines, we need look for what Schein calls the deepest level or the core of culture. Only then will we have the tools necessary to address possibly outdated basic assumptions.

The low observed application of hand disinfection in the present study is in line with previous research that has found lower adherence in situations that require repeated hand disinfections within a short period of time and in situations where there is a change in the risk of transmitting microorganisms (164), such as in the OR prior to surgery.

On many occasions, when I have talked about the HD problem, people outside the OR express irritation and say things like *How hard can it be just to clean your hands? What's wrong with people?* My basic belief is that most people in health care want to do good things for the patients. Moreover, and in addition to studying basic assumptions, it is necessary to see how the physical environment and the organization of work either promotes or is an obstacle to HD. Take the example of intubation: the anesthesiologists and nurses have learned to do this task in what is considered to be the correct manner. The procedure becomes habitualized, thus offering important psychological relief, according to Berger and Luckman (170), giving time to focus on keeping the patient in good, stable conditions during induction and anesthesia. Changing this way of working is not easily done, it requires training. If healthcare professionals are ready to change their behavior in a safe way without putting the patient at risk, it seems necessary to offer help. This could include creating chances for training and dialogue between colleagues and experts, such as infection-control practitioners. If we draw knowledge from theories relating to culture, we can see that challenging basic assumptions releases anxiety (178). So, the benefit of creating a trust-filled environment where lifelong learning is accepted, even for specialists, must be substantial. In the literature, we can find evidence that physicians, nurse and nursing as-

sistants have different ways of learning (221) and it is possible that, by customizing the pedagogic approach in the teaching of infection control and prevention, the chances of implementation are enhanced. This means that the appointed person needs to have a variety of pedagogic strategies in her/his toolbox to work with.

## 9.3 Air quality

### Displacement-ventilated ORs

In 57% of all collected samples, the observed air quality was well above the recommended levels of  $<10/\text{CFU}/\text{m}^3$ . The variations in  $\text{CFU}/\text{m}^3$  levels were found between operations rather than intra-operatively, ranging from 0-55, which is a pattern also observed by others (222). In the few cases in which the levels were below 10, field notes revealed that there was a low overall activity rate during these operations and a calm atmosphere in combination with no door openings. This indicates that, even with a ventilation system with a poorer protective capacity, the OR staff can create a safe surgical environment by changing their behavior. However, from a CT point of view, these changes are dependent on conditions over which the individual professional usually has no influence. In other words, the support of facilitators at system level seems to be necessary.

From a patient safety angle, the high levels of  $\text{CFU}/\text{m}^3$  close to the surgical wound are distressing. When identifying the typical trauma patient, we often find an elderly osteoporotic person, likely to have co-morbidities, which per se constitute an increased risk of infection (27, 68). In addition, the patients suffer from a twofold trauma; the skeletal and muscular and the surgical trauma, which increases the risk of infection (82, 223) and constitutes a risk even for essentially healthy patients. In addition, fracture patients suffer from the disadvantage of not being properly optimized pre-operatively in the same way as the elective patient, due to lack of time. Moreover, an SSI in elderly orthopedic trauma patients is a strong predictor of mortality (224). In conclusion, patients undergoing fracture surgery would benefit from the same air quality that is given to patients undergoing elective implant surgery.

The results of the present study show that the level of  $\text{CFU}/\text{m}^3$  during surgery is strongly correlated to door openings. The question is why all these door openings take place during surgery. In an attempt to assess the necessity, we categorized the reasons for door openings. Only 7% of all door openings were for safety reasons, e.g. expert consultations. It was concluded that all other categories were possible to reduce, by better preoperative planning, i.e.

preoperative communication between surgeon and OR nurse and organization of the work. Moreover, it appeared that the basic assumptions regarding door openings during trauma surgery are regarded as something normal and are not associated with any patient-related risks. This pattern was not observed during elective surgery. The observed door-opening frequency for elective surgery in LAF ORs was 50% lower than that for fracture surgery in DV ORs. The largest differences were found in the following categories: social visits, non-detectable reasons, as well as lunch and coffee breaks. This could be an indication of a different set of assumptions among health-care professionals in relation to elective and trauma implant operations. Regarding supply issues, the differences were found to be minor, 137 vs. 125.

### **LAF-ventilated ORs**

The observed air quality in the ORs equipped with LAF was found to be optimal, only very few samples (6 of 164) exceeded 5 CFU/m<sup>3</sup>. The question is why register data (108) have found an increased risk of infection following THR for patients undergoing surgery in ORs equipped with LAF compared with conventional ventilation. These studies do not give any causal explanations. According to the literature, most of the bacteria reach the surgical wound via direct inoculation from the air during surgery, or indirectly when airborne microorganisms settle on surgical instruments and hands. It has also been concluded that the source of contaminants in clean surgery are the people in the OR and their movements. Only a minor part of the bacteria that reach the wound can be traced to the patient (93, 94).

There might be multiple reasons for the reported increased risks of infection for patients undergoing THA in LAF ORs (108, 109). Noteworthy is that these reports do not give any causal explanations. The results raise several questions: Are all LAF systems comparable with respect to air cleanliness, as airflow rates and volume do matter? How and to what extent are LAF ventilation systems affected by real-life conditions such as the number of people present in the OR, their different positions and movements, clothing regimens, lamps, tables, containers, x-ray machines and other devices? What more is needed to understand the complex interactions of people, technical solutions, production pressure and patient characteristics in order to understand how to create a safer intra-operative environment? Consequently, there are more questions than answers in this field.

Humphreys has suggested that advanced technical solutions such as LAF systems could evoke a feeling of false security among OR staff, leading to lapses in OR practice (225). Based on my clinical experience, I agree; there

appears to be a tendency to push the safety limits, as there is a belief that LAF systems somehow replace the application of risk-reducing measures. Moreover, during the observational period lasting more than a year, it became evident that there is a lack of knowledge about how to use ventilation systems in a safe way. For instance, we found that the air inlet devices were partly blocked during almost all the operations (Paper II). The reason was obvious – lack of space. However, it is unclear whether the OR staff were aware of the potential risks associated with this practice. Moreover, during the data collection in the LAF ORs, we observed that the instruments and trays were left outside the clean zone without any cover on occasions when the preparation of sterile instruments was done directly in the OR. The risk of air contamination in circumstances like this is obvious, which is especially alarming, since very low levels of clinically relevant coagulase-negative staphylococci are needed to initiate a device-related infection (226). However, this appeared not to be common knowledge of the OR nurses.

The malfunctioning ventilation in the preparation room was a disturbing finding. The lack of technical maintenance, communication and knowledge at management level and cooperation between the technical and medical departments resulted in high risks for patients of acquiring a SSI.

Another important problem was the organization's lack of ability to recognize signals showing that risks were increasing. Moreover, after technical revisions, the negative pressure in the preparation room was not discovered and corrected, posing a risk of contaminated air leaking into the clean room. The OR is a typical example of a complex system. There are interactions between patients, different professional teams and highly specialized techniques and these systems are characterized by the fact that small mistakes or failures can lead to serious adverse events (182). The present study demonstrates the difficulties that can occur in the interaction between refined technical solutions and everyday work in a surgical department. It seems that there is a gap in knowledge and communication between the "technical world" and the "medical world" and it undoubtedly needs to be addressed. In the future, in order to secure patient safety, it will be necessary to build bridges between these two fields of knowledge and work together more closely. According to the Swedish National Board of Health and Welfare, it is said that: 6 § The caregiver should identify the processes specified in § 2, where interaction is needed to prevent patients suffering care-related injuries (Author translation) (227).

The problem in the example above is that no one in the medical team has the necessary competence to identify the existing problem. A future way to pro-

ceed could be to make sure that all OR wards have one person with special skills related to ventilation systems and infection control, to provide managers with the necessary support for systematic quality improvements in this area. In addition, this person could work in very close contact with both the technical department and the staff at the sharp end.

## **9.4 Methodological considerations**

The strength of both structured and qualitative observational studies is the lack of manipulation of situations and behaviors. This gives the data a high ecological value, as real-life events can be studied in all their complexity in their natural setting (191).

The question is whether the research findings in this study are representative of another sample? Would the same pattern be observed in other ORs, Swedish or international? I am confident that we would find similar levels of CFU/m<sup>3</sup> independently of where the samples were collected (if the same data collection method is used). However, this is only valid if the physical surrounding is designed in exactly the same way, i.e. not only the ventilation system but also the design of the whole OR ward and the clothing systems. The influence of human factors is of great importance for the outcome. If a study were conducted in an environment where there are low levels of performance variability, we would find limited data relating to how different human behavior affects the air quality. This was the case in our study in LAF ORs. For this reason, we could only conclude that, under these specific conditions, LAF ORs with this type of design produce high air quality in live conditions. As a result, we were unable to draw any conclusions about how a higher traffic flow would affect the air quality in LAF-ventilated ORs.

Regarding the observations of human behavior, e.g. the application of measures to reduce the risk of infection, we are unable to say that these results are representative of all existing ORs. The reason for this is that intra-operative behaviors are context bound and dependent on the existing subcultures and the constructed knowledge of risks and safety in complex interaction with the prevailing health-care system. Future research has to explore whether the same patterns could be detected in other ORs.

### **9.4.1 Qualitative interviews and content analysis**

The interview approach with one open question created narratives instead of responses to questions. Almost all the participants talked freely and generously about their experiences and their narratives were strikingly similar in

their structure and temporality. Mishler (228) sees the narratives as a joint construction between the participant and the interviewer. In the present study, the interviewer's role was to find ways that facilitated the narration, to create a comfortable environment and listen carefully to what the interviewees had to say. The participant was, however, the main creator of the narrative. It is worth mentioning that this study did not have a theoretical underpinned narrative approach. In order to construct a result that correctly reflected the participant's experiences in a meaningful way, the temporality had to be included in the analysis. The interview method was found to be an appropriate choice since it gave an insight into the experience of patients that had acquired an SSI and, first and foremost, it added knowledge to an area that was previously largely unknown.

### 9.4.2 Air sampling

Conducting representative air sampling in the OR in live conditions proved to be highly challenging in many ways. There were both methodological and technical issues that needed to be addressed before and during data collection, not to mention the necessary consideration of how air sampling would affect the working conditions of the OR staff. To complicate things still further, there were no national or international standards for air sampling in ORs (229). The choices of sampling velocity, time and culture media were based on recommendations from infection-control practitioners performing surveillance sampling on a regular basis. In addition, we needed to establish a sampling time that would be an acceptable compromise between scientific considerations and the need to interfere as little as possible with the ongoing operation. Studies have reported that the viability of microorganisms might be affected by prolonged sampling times and high airflow rates, suggesting that bacteria should preferably be sampled for three minutes or less (230, 231). On the other hand, an evaluation of the Sartorius air sampler demonstrated no reduction in the viability of cocci after drawing 2.6 m<sup>3</sup> for 20 minutes, but negative effects were found for *Escherichia coli* (196). Various cocci have been found to be the main relevant species found in the OR (124) and these bacteria are also the leading cause of infections related to implanted medical devices (232). Based on this, it was decided that the sampling time of 20 minutes was an acceptable compromise between the purpose and the need to minimize disturbance during the surgical procedures. It is recognized that this compromise could have resulted in a lower ability to reflect the true CFU values compared with using a shorter sampling time.

We regard the wide variety of sampling positions in the studies as a limitation and, in combination with the choice of sampling time, this might have

led to an underestimation of CFU values. On the other hand, different sampling positions created an opportunity to discover that positioning matters and will affect outcome and this has not previously been described in relation to air sampling in a clinical setting. The literature typically reports on the distance from the wound to the sampling device (striving to be as close as possible), sampling velocity and time; unfortunately, methodological issues regarding the position of the sampling device, for example, have rarely been studied or discussed. Future studies are clearly needed in order to address the exact location in which the OR samples should be taken, the positioning of sampling filters and the angle between filters and airflow. Moreover, we require knowledge of the way sampling velocity, in relation to airflow patterns produced by different ventilation systems, affects outcome data. Standardizing an optimal air sampling method for bacteria would produce reliable data and facilitate comparisons between studies to provide an insight into the protective capacity of different ventilation systems during operations. Developing an instrument with a low level of interference with the working environment in combination with a high degree of reliability would facilitate studies in the OR environment. Particle counting is not yet an option for scientific purposes since the correlation between particles and CFU has not been clearly verified (233). In contrast, a particle density of  $\geq 10 \mu\text{m}$  has been found to explain 41% of the variation in CFU density (113). It has been suggested that the cleanroom technology standards based on the measurement of the presence of air particles of a certain size could be used as a routine procedure to ensure the air quality in ORs (229).

### **9.4.3 Observations**

To gain access to the environment, it was necessary to create trust-filled relationships with the people working on the ward. My prior experience as an OR nurse was probably an advantage in the initial phase, when I attempted to gain access. The environment, with its own language, customs, hierarchies and procedures, was therefore familiar and helped me to “melt in” by not violating any basic assumption regarding OR work. The special OR environment does not usually allow visitors to enter, it is a closed world within the hospital. It took about four to five months before my presence was generally accepted by the majority of the staff.

It was necessary to strike a balance between social interactions and objectivity and participating without influencing things. Moreover, it was important not to become emotionally involved and identify with the people who were being observed. The ongoing dialogues I had with my co-authors were very important in identifying potential problems. Reflections on the observational



sessions were made in order to detect potential problems so I could reflect on them later on.

Even structured observational studies have some important limitations, since there is a substantial risk of behavioral changes among the participating staff (191). However, hidden observations are not feasible in the OR. To address this problem, the participating staff did not receive detailed information about the study purpose. In order to secure objectivity, a pre-tested, structured observational form was used. In addition, the researcher who collected observational data did not have any prior connection with the ward. Initially, the use of two independent researchers was considered; however, the risk of affecting the air quality negatively was felt to be greater than the possible scientific value.

Adding comparisons between subgroups after setting the study protocol is a limitation of the study and we need to consider the risk of not detecting differences that actually exist. However, the differences in the use of protective measures were found to be significant between patients undergoing FS surgery and patients undergoing TJA. This result cannot be directly generalized to other OR settings. More studies are needed to investigate whether these unjustifiable differences are part of different safety cultures in relation to different surgical procedures and ventilation systems.

## 10 CONCLUSIONS

The study has shown that acquiring a deep infection after surgery can be a life-changing event. It affects every part of life, physically, emotionally, socially and economically, in a negative way for a long time. Moreover, by using patients' narratives as a complementary diagnostic tool, the risk of delayed diagnosis and treatment could be reduced. Further studies are needed in order to confirm the results. The experience of developing a deep SSI can be seen as a social construct, created in interaction with the health-care system and its professionals. If the patient feels that his or her problems are recognized and that he or she is treated with compassion and as a partner in care, it is possible that the quality of life of these patients will be affected less negatively.

Every unnecessary door opening and failure to implement protective measures during surgery potentially enable the development of an SSI that could result in serious consequences for the patient. The poor adherence to hand-disinfection guidelines is a noteworthy finding, since this protective measure is one of the most important tools in the fight against HAI and the spread of multi-resistant microorganisms. Further studies are needed in order to understand the prerequisites for successful implementation in the OR context. By drawing knowledge from social and implementation sciences, new ways of addressing this problem could be found. Finally, it has become clear that, without systematic, regular monitoring and the maintenance of OR ventilation systems, the safety of patients cannot be guaranteed. Moreover, the competence level regarding the function and capacity of ventilation systems among health-care providers and OR staff needs to be raised in order to create a patient-safe environment.

### 10.1.1 Clinical and educational implications

The results suggest that patients who have undergone orthopedic implant surgery need to be informed, verbally and in writing, about the signs and symptoms of infection. Prior to discharge, patients should have been instructed on how and who to contact if any suspicion of infection arises. If possible, a specialist should evaluate the patient's observed signs and narrated symptoms. This would secure a correct diagnosis with a minimum of delay and facilitate early, aggressive implant-saving debridement.

Based on the findings, it is recommended that orthopedic surgical wards should focus on evaluating and, if necessary, reinforcing or changing their

infection-prevention strategies based on current evidence and clinical experience in combination with patients' perspectives. It is essential to include different paradigms of knowledge in order to create safe care and address problems at system level.

It is crucial that "patient safety" and infection control are recognized as important topics in all medical and nursing education, as well as in-service training at ORs, independent of profession. Knowledge of different ways of understanding, studying and interpreting safety and risks is a prerequisite for safe practice and needs to be included in education. As safety in health care is a complex phenomenon, the use of interdisciplinary teaching appears to be of importance. Including difficult discussions about accountability, blame and shame, along with how to handle situations in which patients have unintentionally been hurt during nursing and medical care, is a step towards enhanced patient safety.

### 10.1.2 Future perspectives

An improved knowledge of how to prevent, detect and treat infections is needed for health-care professionals and providers of all kinds. The future perspective of anticipated difficulties in treating HAI (in some cases, the worst-case scenario is already here) means that there is a real need for scientific developments in the area of infection control and prevention. One of the greatest future challenges lies in the implementation of protective measures. Intervention studies in the field of infection control have received criticism for their lack of theoretical focus, description of context, being small scale, poorly designed and the fact that follow-up data are seldom collected (234). Drawing knowledge from implementation science, in combination with knowledge of how human behaviors are formed in interaction with a hierarchical and complex OR environment, could be a useful way of enhancing the future implementations of safe practice in health care. It is likely that the choice of implementation strategy is dependent on context; for this reason, research with the aim of exploring facilitators of and obstacles to infection-prevention practice in the OR would be of great value (235).

In device-related implant surgery, the evidence base for keeping the levels below 5 CFU/m<sup>3</sup> is strong. However, for general surgery, the recommendation of < 100-180 CFU/m<sup>3</sup> has no scientific underpinning (91). Consequently, in this area, there is also a need for research-based knowledge. In the meantime, it is important to consider the patient perspective when accepting limits only in relation to the type of surgery and not in relation to the patient's vulnerability and susceptibility.

In the future, a dynamic simulation tool could be valuable in order to find the optimal design for the OR in terms of air cleanliness and to visualize how the bio burden changes depending on technical solutions in combination with clothing systems and human behavior. When constructing new ORs, the methods that are used are often empirical and based on (sometimes) unproven hypotheses. This tool could be used to evaluate the protective ability of existing ventilation systems in different conditions. Another important application area is education. It is difficult for humans to react adequately to dangers that cannot be seen or experienced by any of our senses. Visualizing invisible factors, such as airflow and bacteria dispersion, in relation to different behaviors could work as an important motivator for change.

Finally, acknowledging and using patients' experiences and knowledge in health care is still an area that has not reached its full potential; much more could be done to see the patient as a partner in care.

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