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Operating theatre quality and prevention of surgical site infections

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Summary

Surgical site infections (SSI) account for 14% to 17% of all hospital-acquired infections and 38% of nosocomial infections in surgical patients. SSI remain a substantial cause of morbidity and death, possibly because of the larger numbers of elderly surgical patients or those with a variety of chronic and immunocompromising conditions, and emergence of antibiotic-resistant microorganisms.

Factors causing surgical site infection are multifarious. Several studies have identified the main patient-related (endogenous risk factors) and procedure-related (external risk factors) factors that influence the risk of SSI. The rate of surgical wound infections is strongly influenced by operating theatre quality, too. A safe and salubrious operating theatre is an environment in which all sources of pollution and any micro-environmental alterations are kept strictly under control. This can be achieved only through careful planning, maintenance and periodic checks, as well as proper ongoing training for staff.

Many international scientific societies have produced guidelines regarding the environmental features of operating theatres (positive pressure, exchanges of filtered air per hour, air-conditioning systems with HEPA filters, etc.) and issued recommendations on healthcare-associated infection, including SSI, concerning surveillance methods, intervention to actively prevent SSI and approaches to monitoring the implementation of such strategies.

Therefore, the prevention of SSI requires a multidisciplinary approach and the commitment of all concerned, including that of those who are responsible for the design, layout and functioning of operating theatres.

Key words: Operating theatre, Surgical site infections, Quality

Introduction

Surgical care is an integral part of health care throughout the world, with an estimated 234 million operations performed annually [1]. However, surgical care is also associated with a considerable risk of complications and death.

A study on the incidence and nature of in-hospital adverse events has shown that 1 in every 150 patients admitted to a hospital dies as a consequence of an adverse event and that almost two thirds of in-hospital events are associated with surgical care [2].

Surgical site infections (SSIs) remain one of the most common causes of serious surgical complications [3]; they account for 14% to 17% of all hospital-acquired infections and 38% of nosocomial infections in surgical patients [4, 5].

Each SSI is associated with approximately 7-10 additional postoperative hospital days and patients with an SSI have a 2-11 times higher risk of death, compared with operative patients without an SSI [6, 7].

In a nested-cohort study carried out in a 750-bed tertiary- care hospital in North Carolina, US, elderly patients with SSIs due to *Staphylococcus aureus* were at increased risk of mortality (odds ratio – OR: 5.4), increased post-operative hospital days (2.5-fold increase) and increased hospital charges (2.0-fold increase) compared with controls (uninfected elderly patients) [8].

Surgical site infections

Surgical site infections (SSIs) are defined as infections occurring up to 30 days after surgery (or up to one year after surgery in patients receiving implants) and affecting either the incision or deep tissue at the operation site [9].

Particularly, SSI can sometimes be superficial infections involving the skin only. Other surgical site infections are more serious and can involve tissues under the skin, organs, or implanted material.

There are 3 different types of surgical site infection defined by the Centers for Disease Control and Prevention (CDC): *superficial* infections, *deep incisional* infections and infections involving *organs or body spaces* (Tab. I) [10].

Tab. I.

Surgical site infection classification.

Superficial Incisional SSI

Infection occurs within 30 days after the operation and infection involves only skin or subcutaneous tissue of the incision *and* at least one of the following:

Superficial Incisional SSI

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision.
3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat and superficial incision is deliberately opened by surgeon, unless incision is culture-negative.
4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).
2. Infection of an episiotomy or newborn circumcision site.
3. Infected burn wound.
4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Note: Specific criteria are used for identifying infected episiotomy and circumcision sites and burn wounds.

Deep Incisional SSI

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 and infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision and at least one of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (> 38°C), localized pain, or tenderness, unless site is culture-negative.
3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Superficial Incisional SSI

Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.
2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/Space SSI

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 ***and*** infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation and at least one of the following:

1. Purulent drainage from a drain that is placed through a stab wound** into the organ/space.
2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.
3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
4. Diagnosis of an organ/space SSI by a surgeon or attending physician

*National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery;
**If the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection, depending on its depth. Reproduced with permission from Horan TC [10].

Severe SSIs in deep incisions or organ spaces account for almost half of all SSIs [11].

The degree of surgical site contamination at the time of surgery influences the probability of surgical site infection.

According to the presence and degree of contamination, wounds can be classified as: "clean wounds", "clean-contaminated wounds", "contaminated wounds", "dirty or infected wounds" [10, 12, 13].

Infection rates in the four surgical classifications have been published in many studies. Before antibiotic prophylaxis was routinely used, the rates were about 1-2% for clean wounds, 6-9% for clean-contaminated wounds, 13-20% for contaminated wounds and 40% for dirty wounds. As the level of bacterial burden is the most significant risk factor for SSIs, the use of prophylactic

antibiotics has markedly reduced this risk [14], particularly with surgical procedures at high risk of infection, such as those involving the gastrointestinal tract [15].

However, SSI remain a substantial cause of morbidity and death, possibly because of the larger numbers of elderly surgical patients or those with a variety of chronic and immunocompromising conditions, greater use of prosthetic implants and organ transplantation and emergence of antibiotic-resistant micro-organisms [16]. Over the last decade, there has been little variation in the incidence and distribution of the pathogens isolated from infections [17]; however, an important change in the microbiology of SSIs has been the increasing involvement of microorganisms that are resistant to antibiotic treatment.

Indeed, the number of SSIs caused by methicillin-resistant *S. aureus* (MRSA) has increased dramatically [4].

Microbiology

The pathogens isolated from infections differ, primarily depending on the type of surgical procedure. In clean surgical procedures, in which the gastrointestinal, gynecologic, and respiratory tracts have not been entered, *Staphylococcus aureus* from the patient's skin flora is the usual cause of infection. When mucous membranes or skin is incised, the exposed tissues are at risk of contamination by *endogenous* flora [10].

Approximately 20 to 30% of surgical-site infections are caused by *S. aureus*, and over half of these arise from the endogenous flora [18]. Anderson et al. described a total of 1,010 SSIs occurred after 89,302 procedures in 26 hospitals; *S. aureus* was the organism most commonly isolated, recovered from 331 (37%) of SSIs. Of the 331 *S. aureus* SSIs, 175 (53%) were caused by MRSA, making MRSA the single most commonly isolated pathogen [19]. Furthermore, recent studies have shown that reduced susceptibility to vancomycin and other glycopeptides, is emerging in different MRSA clones all over the world [20, 21].

In other categories of surgical procedures, including clean-contaminated, contaminated, and dirty, the polymicrobial aerobic and anaerobic flora closely resembling the normal endogenous microflora of the surgically resected organ are the most frequently isolated pathogens [22].

Occasionally, the pathogenic microorganisms are acquired from an *exogenous* source, such as the operating theatre environment, surgical personnel [23] and all tools, instruments, and materials brought to the sterile field during an operation.

The most commonly isolated organisms are *Staphylococcus aureus*, coagulase-negative staphylococci, *Enterococcus* spp. and *Escherichia coli* [9, 24]. Giacometti et al. [25] studied 676 surgery patients with signs and symptoms indicative of wound infections, who presented over the course of 6 years. Bacterial pathogens were isolated from 614 individuals. A high preponderance of aerobic bacteria was observed. Among the common pathogens were *Staphylococcus aureus* (28.2%), *Pseudomonas aeruginosa* (25.2%), *Escherichia coli* (7.8%), *Staphylococcus epidermidis* (7.1%), and *Enterococcus faecalis* (5.6%).

Risk factors

The risk of developing SSI varies greatly according to the nature of the operative procedure and the specific clinical characteristics of the patient undergoing that procedure [23].

Several studies have identified the main patient-related (endogenous) and procedure-related (external) factors that influence the risk of SSI [9]. Potential patient-related factors include malnutrition, older age, coexistent infection, and diabetes. A review of Dominioni et al. [26] showed that in the hierarchy of patient-related risk factors, serum albumin concentration and advanced age rank at the top of the list. Apart from endogenous factors, the role of external risk factors in the pathogenesis of SSI is well recognized [10].

External risk factors include the type and duration of operation, surgeon's skill, the quality of preoperative skin preparation, adequacy and timing of antimicrobial prophylaxis, insertion of foreign material or implants, inadequate sterilisation of surgical instruments [10, 27]. The rate of surgical wound infections is strongly influenced by operating theatre quality, too. [15].

Operating theatre quality

A safe and salubrious operating theatre is an environment in which all sources of pollution and any microenvironmental alterations are kept strictly under control. This can be achieved only through careful planning, maintenance and periodic checks, as well as proper ongoing training for staff [28].

Indeed, an operating theatre is an extraordinarily complex system in which numerous risk factors are present, including not only the features of the structure and its fixtures, but also the management and behaviour of healthcare workers.

Structural features

The structural features of the operating unit can influence not only the efficacy of the treatment provided, but also the outcome of the patient in terms of the prevention of surgical infections.

The design of the operating unit is complex and requires that different areas be correctly integrated. In addition to keeping clean and dirty areas separate, it is important to ensure that patient flow, from arrival to discharge, is orderly and logical.

Specific rooms should be designated for performing surgical procedures and for processing instruments and other items. It is important to control traffic and activities in these areas since the number of people and the amount of activity influence the number of microorganisms that are present and therefore influence the risk of infection.

The operating unit should be arranged in progressively less contaminated areas, from the reception area to the operating theatres. Moreover, organisational/functional and/or structural intervention must be implemented in order to ensure that "dirty" and "clean" pathways be kept separate. The size of storage areas for dirty material, clean material, supplies, instruments, equipment and drugs must be determined in accordance with the type and volume of activity of the operating unit [29].

Moreover, in designing an operating unit, the choice of surface finishes, as well as structural features, is of great importance; surfaces should be easy to clean in order to facilitate infection control. Design, layouts, fittings, furnishings, floor coverings and finishes will have a significant

impact on the cleaning of the unit. Ledges, corners and all other surfaces that are difficult to clean should be minimized.

The surfaces of floors should be impervious to moisture, easily cleaned, stain resistant, comfortable for long periods of standing and suitable for wheeled traffic. In the operating theatres the colour should be such that small items can easily be found, if dropped [30].

The surfaces delimiting the areas inside the operating unit, including those hidden from view (e.g. ceiling panels, rear panels of built-in fittings, etc) should also be smooth and easy to clean and should be compatible with the use of chemical and physical cleaning agents, as well as being waterproof, fireproof and resistant to knocks. Window frames should be designed in such a way that their surfaces are easy to clean and do not collect dust [29].

Ventilation

During surgical procedures, dust particles, textile fibers, skin scales, and respiratory aerosols loaded with viable microorganisms are released from the surgical team and the surrounding into the air of the operating theatre. Bacteria settling on surgical instruments or entering directly into the surgical site may result in surgical site infection (SSI) [31].

Therefore, maintaining a high quality of the air in the operating theatre is essential to controlling the risk of surgical infections. To reduce the morbidity and healthcare costs associated with these infections, airborne bacteria and other sources of contamination must be minimised.

In this regard, a fundamental role is played by the contamination- controlled airflow system (heating, ventilation, air-conditioning system: HVAC). Indeed, in addition to maintaining temperature and humidity at optimal levels, this system provides ventilation that is able to keep the concentrations of gaseous pollutants, particulates and airborne microbes below predetermined levels. HVAC systems perform multiple functions simultaneously, including controlling three known central variables in the airborne transmission of infectious particles: temperature, relative humidity, and air currents.

Therefore, HVAC systems are intended to provide for the health, comfort, and safety of occupants by maintaining thermal and air quality conditions that are acceptable to the occupants [32].

In the operating theatre, the specific features of the airflow system which enable SSIs to be contained are ventilation (dilution), air distribution, room pressurization (infiltration barrier) and filtration (contaminant removal) [33].

The air in operating theatres should be kept at a higher pressure than in corridors and adjacent areas. This positive pressure prevents the flow of air from less sterile areas into more sterile ones [18].

With regard to ventilation, various international scientific organisations recommend a minimum of 15 air exchanges per hour. Specifically, the "Guidelines for environmental infection control in health-care facilities" issued by the CDC [34] recommend a minimum of about 15 exchanges of filtered air per hour, three (20%) of which must be fresh air. The 2008 edition of ANSI/ASHRAE/ASHE Standard 170 ("Ventilation of Health-care Facilities") [35], recommends

a minimum of 20 total air exchanges per hour and a minimum of 4 exchanges of outdoor air per hour in operating theatres.

The main types of airflow systems are: turbulent-flow, unidirectional-flow and mixed-flow. Turbulent flow directly involves the whole environment, the concentration of airborne contaminants being controlled by means of dilution. This type of system increases the effectiveness of air exchange and distribution. However, it has the disadvantage of speeding up microbial dispersion [33]. In several countries, this type of airflow is generally considered adequate for operating theatres in which general surgery or similar operations are performed [29].

In unidirectional-flow systems ("laminar airflow or LAF"), the air travels in parallel lines and contaminants are carried away at the same velocity as the airflow. Low-velocity unidirectional flow tends to minimize the spread of airborne contaminants and direct them towards the exhaust outlets. This system, as opposed to turbulent flow, allows airborne particles to pass the operating area and prevents them from landing in the wound area [33].

Unidirectional airflow is designed to move particle-free air (called "ultraclean air") over the aseptic operating field at a uniform velocity (0.3 to 0.5 μm/sec), sweeping away particles in its path [18].

From a purely technical standpoint, systems that provide laminar flow regimes constitute the best option for an operating theatre, in terms of contamination control, as they result in the smallest percentage of particles impacting the surgical site.

The reason for this is that such systems supply a controlled, constant column of air to the surgical site area; this is effective in sweeping contaminants from the surgical site area, where they might otherwise be deposited [36].

Laminar airflow through HEPA filters, which display 99.97% efficiency in removing airborne particles of 0.3 μm and above, can be supplied to the operating area by ceiling-mounted (vertical flow) or wall-mounted (horizontal flow) units. It has been suggested [37, 38] that improper positioning of personnel in operating theatres with a horizontal and vertical laminar airflow may increase the risk of infection.

In the so-called mixed-flow system, unidirectional airflow regimes are only used to protect critical zones (e.g. the area surrounding the operating field) [29].

Most operating theatres have conventional ventilation and laminar air-flow systems with HEPA filters are generally used for orthopaedic and other implant surgery [27].

Charnley [39] evaluated 5,800 surgical operations; he showed that intraoperative contamination was a major threat to the success of total joint replacements, and revealed that the rate of SSI fell dramatically from 7 to 0.5% when unidirectional airflow regimes with a high number of hourly air exchanges were adopted and surgical staff wore special suits that covered the whole body. Subsequently, other studies [40-42] have shown that fewer infections arise when orthopaedic surgery is performed in operating theatres with ultra-clean air facilities.

Currently, there is no complete consensus in the scientific community with regard to the need to use unidirectional airflows in prosthetic orthopaedic surgery, since no prospective studies comparing air quality with SSI rates are available.

In theory, preventing contamination by flowing particlefree air unidirectionally over the surgical site can potentially reduce the risk of SSI. Although this method is biologically plausible, and some previous studies have supported this concept, a meta-analysis encompassing 26 studies could not ultimately confirm the role of LAF in surgery, and some recent studies have even indicated an increase in SSI after hip prosthesis with procedures performed under LAF [43, 31].

In view of these contradictory results – but, more importantly, in view of worldwide increases in health care costs and increasing difficulties in financing and providing all modern medical advances – it is understandable that the question arises regarding the actual need for LAF ventilation in operating theatres to prevent SSIs [31].

Water

The water distribution system in hospitals may constitute a source of healthcare-associated infections caused by opportunistic pathogens such as: *Pseudomonas aeruginosa*, *Stenotrophomonas maltophilia*, *Burkholderia cepacia*, Acinetobacter spp, fungi, etc. Taps are common sources of *P. aeruginosa* and other Gram-negative bacteria and have even been linked to infections in multiple hospital settings [44].

Other hospital equipment, such as water-cooled highspeed drills in dental surgeries [45] is of particular concern for both inhalation of aerosols and infection of wounds. Indeed, aerosols and droplets produced by dental instruments connected to dental unit waterlines during dental care may contain microorganisms that can be opportunistic pathogens for patients and dentists [46, 47]. Only a small number of published studies deal with cases of infections associated with dental caries. But the obvious concern is that large numbers of potentially pathogenic microorganisms may be swallowed, inhaled or alternatively inoculated into oral wounds during dental treatment with a potential for both colonization and infection [48].

Immunocompromised patients are particularly susceptible to infection by waterborne microorganisms, which can cause bacteraemia, pneumopathy, meningitis, urinary tract infections and surgical site infections [49-51]. Apart from water used in dental surgery, another area of environmental control in operating theatres is the bacteriological quality of water used for surgical handscrubs for which there are no standardized limits at present.

Surgical hand antisepsis with medicated soap requires clean water to rinse the hands after application of the medicated soap.

Indeed, despite the use of surgical gloves, the transmission of microorganisms from the hands of the surgeon to the patient may occur due to microperforations that happen at an average of 18% (5-82%) at the end of the surgery. After two hours of surgery, 35% of all gloves demonstrate puncture, thus allowing water (hence also body fluids) to penetrate the gloves without using pressure. In over 80% of cases, such perforations are not perceived by surgeons, and microperforations can double the risks of infection in the surgical site, thus turning the prior preparation of the hands into a crucial step [52]. A recent trial demonstrated that punctured gloves double the risk of SSIs. Double gloving decreases the risk of puncture during surgery, but

punctures are still observed in 4% of cases after the procedure. Several reported outbreaks have been traced to contaminated hands from the surgical team despite wearing sterile gloves [53].

However, infections clearly linked to contaminated hands of surgeons after surgical hand scrub with contaminated water have not yet been documented.

In countries lacking continuous monitoring of drinkingwater and improper tap maintenance, recontamination may be a real risk even after correct surgical hand scrub.

Procedural and behavioural factors

Other aspects of the complex strategy to minimize infection risk during surgical operations are procedural and behavioural factors that can also have a negative impact on the surgical outcome.

In general, the strategy for reducing intra-operative contamination involves a systemic and behavioural approach. As already seen, a systemic approach consists of improving the airflow system. A behavioural approach aims to reduce the number of airborne particles in the operating theatre through disciplinary measures. Simple and cheap measures include limiting the number of personnel in the operating theatre and restricting the movements of personnel in the operating theatre to a minimum, as it has been shown that increased activity facilitates the dispersion of bacteria [54].

In addition to the number and movements of personnel in the operating theatre, adverse surgical events may be due to poor communication, bad operative technique, malfunctioning or improperly used equipment, and cognitive errors due to stress or inattention, all compounded by resource and organizational problems. Communication in the operating suite is often poor and may contribute to adverse outcomes [55].

Knobben et al. [56] found that, in patients undergoing orthopaedic implant surgery, adopting a range of measures in the operating theatre had a significantly positive effect on outcomes during the postoperative period. In that study, the measures adopted involved limiting needless activity, correct use of plenum (area of laminar flow), work-up in the preparation room rather than in the operating theatre, and the wearing of proper attire. These Authors observed that the combination of systemic and behavioural measures in the operating theatre led to a reduction in the incidence of intra-operative bacterial contamination and, consequently, of prolonged wound discharge and superficial surgical site infection. Moreover, after one-year follow-up, fewer deep periprosthetic infections were recorded. While it is difficult to determine the relative influence of each individual measure on the final result, the combination of all these parameters evidently creates the most effective weapon against infections. To maintain low bacterial counts, both the airflow system and behaviour have to be monitored by an infection committee. Both positive and negative feedback helps to maintain the reduction in bacterial dispersal.

Finally, it is important to emphasize that all personnel working in operating theatres, including surgeons, operating theatre assistants, anaesthesiologists and cleaning personnel, must follow hygiene protocols very strictly.

In 2008, the World Health Organization (WHO) published guidelines identifying multiple recommended practices (including a "Surgical Safety Checklist") to ensure the safety of surgical patients worldwide [3]. The Surgical Safety Checklist comprises 19 items in three parts to be

completed in a total of 3 min at key points in surgical procedures. The items include measures such as confirming patients' names and procedures, introducing theatre staff to patients, and ensuring that prophylactic antibiotics to prevent surgical-site infection are used appropriately [57].

Basically, the checklist includes three moments of formalized briefings and safety checks: a 'sign in' before induction of anaesthesia, a 'time out' before skin incision and a 'sign out' before the patient leaves the operating room.

Haynes and co-Authors [58] found that introducing the WHO Surgical Safety Checklist into operating theatres in eight diverse hospitals was associated with marked improvements in surgical outcomes. Postoperative complication rates fell by 36% on average, and death rates were reduced to a similar degree. The overall rates of surgical-site infection and unplanned reoperation also declined significantly ($p < 0.001$ and $p = 0.047$, respectively). In order to apply the checklist, surgical staff had to pause before the induction of anaesthesia, before skin incision and before the patient left the operating theatre; in previous studies, these team practices had already been associated with improved safety processes and attitudes and with a marked reduction in rates of complications and death. Checklist implementation encouraged the administration of antibiotics in the operating theatre rather than in the preoperative wards. The checklist provided additional oral confirmation of appropriate antibiotic use, increasing the adherence rate from 56 to 83%. This intervention alone has been shown to reduce the rate of surgical-site infection by 33 to 88% [59, 60].

In conclusion, surgical site infection rates can be improved by acting upon various factors, from the surgical environment itself to procedural aspects and staff behaviour. Moreover, surveillance of SSIs is a well-established, well documented approach to lower the incidence of SSIs. Many hospitals still do not follow this recommendation despite its effectiveness.

The Centers for Disease Control and Prevention guidelines for the prevention of SSIs emphasise the importance of good patient preparation, aseptic practice, and attention to surgical technique; antimicrobial prophylaxis is also indicated in specific circumstances.

Therefore, the prevention of SSI requires a multidisciplinary approach and the commitment of all concerned, including that of those who are responsible for the design, layout and functioning of operating theatres.

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