Microbiological risk in operating rooms: new strategies for infections surveillance

A. Frabetti[1], A. Vandini[1], S. Pantoja Rodriguez[1], F. Margelli[1], M. Cavicchioli[4], M. Migliori[3], D. Arujo Azevedo[1], P. Balboni[2] & S. Mazzacane[1]
[1]CERTECA Laboratory, Air Technology Research Center, Department of Architecture, University of Ferrara, Italy
[2]Department of Diagnostic and Experimental Medicine, University of Ferrara, Italy
[3]Hospital Manager, Emilia Romagna Region, Italy
[4]CENTO HOSPITAL Manager, Italy

Abstract

In this paper the authors describe the program of epidemiological overseeing of the surgical site infections activated in the operating department of the Cento Hospital (Ferrara).

The purpose of the program is to systematically collect the data related to the frequency and distribution of the infections contracted during a surgical intervention and to analyze the environmental factors correlated to them, the concentration of particles and of UFC, the characteristics of the ventilation system, the number of people in the room, the type of clothing, the systems of cleaning and disinfection, the type of intervention etc.

The objective of the research consists of identifying the actions for prevention of the infections and to get an indicator of the quality of the surgical activities.

Since the greatest obstacle to this kind of activity is related to the man-hour cost for the information collection, researchers of the University of Ferrara and the Cento hospital have setup an electronic system of automatic acquisition of the field data using computer technologies of different types (RFID-Radio Frequency IDentification sensor, PC pocket, net computer and programs).

The management of continuous relief of the pollution level established in the operating rooms during every intervention, the automatic acquisitions of the main environmental parameters (temperature, relative humidity, instant air flow rate of climatization plant, state of the doors, level of pressurization of the room, level of stoppage of the absolute filters etc.) and of the clinical overview of the patient allow detailed knowledge of the conditions in which every surgical intervention is developed. Particular attention is paid to the state of hypothermia of the patient that is monitored in continuously before, during and after the operation, since according to some authors this determines an increase in the probability of contamination of the wound. The surgical wound is controlled daily in the hospital up to the moment of patient release and every three months for one year from the intervention, so as to record possible complication.

This adopted strategy allows to verification in the respect of the behavioral protocols of the medical and nursing personnel.
Keywords: surveillance, infection rate, microbiological and physical pollution.

1 Introduction

Nosocomial infections (NI) are acquired during hospital care which are not present or incubating at admission. Infections occuring more than 48 hours after admission are usually considered nosocomial. Definitions to identify NI have been developed for specific infection sites and they derived from those published by CDC of Atlanta [1-3].

Studies throughout the world document that nosocomial infections are a major cause of morbidity and mortality [4-11]. A high frequency of nosocomial infections is evidence of a poor quality of health service delivery, and leads to avoidable costs. SSIs represent the second most common type of nosocomial infection at a rate between 20% and 30% of the total events [13,14]. SSIs develop in 2% to 5% of patients undergoing surgical procedures each year in the United States, resulting in at least 500,000 infections (100,000 in Italy), and high costs extra hospital charges [12,13]. In Europe the SSI rate varied widely from 1.5-20% of patients undergoing surgical procedures often unspecified in consequence of inconsistencies in data collection methods, surveillance criteria and wide variations in the surgical procedures; the SSI's healthcare cost estimated range from € 1.47-19.1 billion. The development of a surveillance process to monitor this rate is an essential first step to identify local problems and priorities, and evaluate the effectiveness of infection control activity. Surveillance, by itself, is an effective process to decrease the frequency of hospital-acquired infections [16-18] and their costs.

Since 1970s CDC's National Nosocomial Infection Surveillance (NNIS) system has been serving as an aggregating medium to collect data of NI in USA and in the North of Europe. NNIS system is a voluntary, hospital-based reporting system established to monitor HAI and guide the prevention efforts of infection control practitioners. NNIS establishes a national risk-adjusted benchmark for NI rates and invasive device-use ratios [19,20] by using uniform case definitions and data collection methods and computerized data entry and analysis.

For a long time in Italy the problem of hospital-acquired infection was to be an interesting object of investigation for SSN and other national and international institutions.

In 1984 OMS had just indicated the priority to control the developing of nosocomial infections (NI) within year the 2000; successively were produced two national Ministerial Circulars (n° 52-20/12/85, n° 8-30/01/88) with the same aims.

Finally were emanated Ministerial Acts (PSN 1998-2000; PSR 1999-2001) that declared the necessity to reduce the incidence of NI of 25%; these acts were addressed to characterize systems for prevention and surveillance of NI.

Following these formatives, Azienda USL of Ferrara (Delibera n° 58-13/01/2000), had instituted the "Prevention and Infection Control Committee" with the aim to characterize, organize and verify the strategy to pull down NI in any kind of health-care environment.

Considering that the responsible health authority should develop a national (or regional) programme to support hospitals in reducing the risk of NI.

At this aim, we are monitoring the internal conditions "at rest" and "in activity" of the 4 operating rooms of Cento Hospital under different profiles:

- physical pollution (particulate concentration in the air) by KANOMAX GEO-α instrument;
- air, material surfaces and wound microbiological pollution (active and passive monitoring using Surface Air System (SAS), Contact plate dishes, tampons);
- characteristics of ventilation system (supply and extraction air flow rates, pressurization level, type of filters, air distribution and velocity on the wound field, air temperature and relative humidity and so on);
- hypothermia phenomena for the patient, sweatiness index and comfort degree of medical staff (Dallas Semiconductors I-BUTTONs and BABUC/A system LSI Lastem);
- morbosity of the patient, antibiotic profilaxis and anaesthetic infusion;
- environmental contest (number of persons, clothing and drapes, state of the doors, if opened or closed, operating protocols and so on).

Until now all data were collected in a writing-papers, but in the future they will collect into a central server by a supervision system and electronic devices utilizing RFID sensors (Radio Frequency IDentification) and bar code readers (Figure 1).

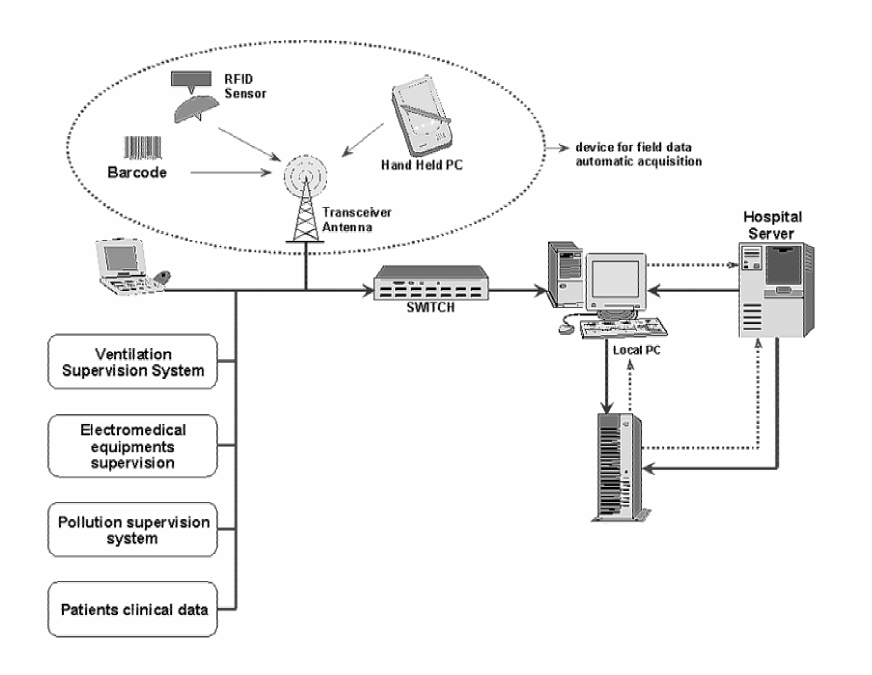

Figure 1.

2 Materials and methods

2.1 Period and setting

The results reporting in this paper were collected in a period of two month (February and March 2005) but the study is yet in progress and it will continuing for a period of three years.

The study was carried out in the operating room (OR) of Orthopaedic Department in Santa Annunziata Hospital in Cento (Ferrara-Italy), which has a turbulent air flow circulation system (22 air changes/h) that includes two HEPA filters (1 on every air terminal and 1 on central unit).

2.2 Microbiological monitoring

2.2.1 Air monitoring

Nowadays the evaluation of the level of air microbial contamination in places at risk is considered to be a basic step toward prevention [21-27]. However, there are still problems to be solved relating to methodology, monitoring, data interpretation and maximum acceptable levels of contamination.

At the moment, the only effective means of quantifying airborne microbes is limited to the count of cfu. The cfu count is the most important parameter, as it measures the live micro-organisms which can multiply. Air samples can be collected in two ways: by active air samplers or by passive air sampling (the settle plates). Both methods are widely used.

Passive air sampling is performed using settle plates at frequency of one sampling for 1 hour during every orthopaedic surgery. Microbes carried by inert particles fall onto the surface of the nutrient, with an average deposition rate of 0.46 cm/s being reported [29]. Followings the CDC's guidelines (8Ascca), we evaluated microbial sedimentation with Contact plate dishes "Agar Clean Room Contact FDA" of 55 mm diameter containing plate count agar TSA (Tryptone Soia Agar) with the addition of Tween-Lecitine. The dishes were left open to air according to the 1/1/1 standard (for 1 h, 1 m from the floor and about 1 m from the patient) over three operating tables [26].

Sampling started in correspondence of the surgical incision. The plates were sent to the bacteriology laboratory at the end of the operation and incubated at 37°C for 48 h and at 25°C for another 24 h before bacterial counts were counted. The number of CFU is measured in cfu/plate. Only the total aerobic bacterial count was evaluated; identification and speciation of bacteria isolated were not performed. The results were compared with index of microbiological contamination of air (IMA index). IMA index was devised in 1978 [31] with the aim of unifying and standardizing the technique of air sampling by settle plates. The IMA classes and the maximum acceptable IMA levels for each environment at risk were empirically defined by performing a large number of tests in different environments [28,30,31,32].

In this study we have selected the Petri dishes of 55 mm diameter because they are useful both for passive and active monitoring and for the control of surfaces (contact plates). Moreover a triple cover of these plates assures a high grade of sterility that is requisite for their use in an operating theater. However in view to uniform our study to international standards, we'll be going to do a comparison between the results obtained by the utilization both Petri dishes 55mm in diameter and 90mm in diameter.

The microbial air contamination can be measured by counting the number of cfu per cubic metre (cfu/m^3) of air. For this purpose active air samplers are used, which collect a known volume of air, blown on to a nutrient medium by different techniques. There are many different types of active samplers, in this study we used Surface Air System sampler (SAS; "SAS SUPER 100" PBI International). SAS was placed nearest the site of surgical incision in according to standard [34].

SAS was programmed to introduce 6000 l of air in one hour and to blow the air on to contact plates of 55 mm in diameters containing plate count agar TSA (Tryptone Soia Agar) with the addition of Tween-Lecitine. After 1 h the plates were incubated at 37°C for 48 h and at 25°C for another 24 h; finally the counts of CFU was performed and compared with the IMA index [32].

2.2.2 Material surfaces monitoring

OR surfaces (walls, floor and electomedical instruments) were monitored by the use of Contact plate dishes at the frequency of 1 hour every 15 days. Then the plate is incubated at 37°C for 48 h and at 25°C for another 24 h before bacterial counts were taken. The number of CFU is measured in cfu/plate.

2.2.3 Wound microbiological pollution monitoring

The rates of wound microbiological pollution were monitored by the application over the surgery wound of a sterile tampon. These tampons were passed by on a contact plate dishes and then incubated at 37°C for 48 h and at 25°C for another 24 h before bacterial counts were counted. This sampling was carried out for 1 month for each orthopaedic surgery at sutured wound before its disinfection.

2.3 Particulates concentration monitoring of air

Particulates concentration monitoring of air (0,3 μm , 0,5 μm, 1 μm, 3 μm e 5 μm) was performed with Kanomax Geo-α instrument (Pollution) according to ISO 14644 norm for a period of one week. In the operating theatre at *rest* measurements were carried out, in 6 points (140cm high) every 2 minutes to define optimum monitoring time(τ) which was resulted to be τ = 30 min. Instead, in active operating theatre this instrument was located only in one place over a bracket 170cm high near operating table and acquired measurements every 2 minutes during all the days' surgeries.

2.4 Ventilation of system data

The collection of ventilation system data was performed by a central supervision system linked to the local equipment which was able to register every state function in real time.

2.5 Hypothermia phenomena monitoring

Hypothermia that develops in patients undergoing operating surgery; hypothermia is join to inhibition of thermoregulator system due to both anaesthetic treatment and low temperature of operating room; for this reason, hypothermia could increase the morbidity and mortality after operating surgery [35]. The sampling was performed by use I-BUTTONs (Dallas Semiconductors) that are small instruments like a buttons to which is possible both capturing and registering the temperature and the humidity of the skin of the patient and medical staff.

Two model of buttons are using:

- DS1921H model that measure the temperature
- DS1923-F5 model that measure the humidity

These buttons are able to register until 4096 data in different moments. Many application forms for the button are codified in literature, but we decided to utilize Olesen's application form [36], where three buttons on the body (chess, arms and legs) are considered. Moreover I-button for humidity was positioned on the epigastric zone.

2.6 Microclimatic monitoring: Babuc

Following ISPESL Italian guidelines (D.P.R. 14.01.97) and UNI EN ISO 7730 norm we performed the microclimatic sampling with the use of BABUC/A system (LSI-Lastem), formed by two parts: one that acquire and elaborate data and the other that its constituted by a group of sensors:

- a psychometric probe for measuring both dry (Td) and wet (Tw) temperatures,
- a globe thermometric probe for measuring mean radiant temperature (Tr),
- an anemometer for air velocity (Va) measuring.

BABUC/A was placed at 1,5 m high from the floor (area: 36 m^2) in OR. The first measurements were collected in operating room at rest in different points.

The verification of microclimatic conditions during orthopedic surgery is going under study.

2.7 Active surveillance of SSI

Patients undergoing total joint knee and hip replacement surgery, hemi-artroplasty were monitored as part of the hospital's overall surveillance programme during February 2005. We used a standardized data collection form to obtain statistic data. Details collected included demographic data, the date and type of procedure, morbidity, American Society of Anesthesiology (ASA) pre-operative assessment score, peri-operative antibiotic prophylaxis, pre e post-operative blood transfusion and type of anaesthesia.

After orthopaedic surgery were reviewed inpatients for postoperative SSIs. Notifications of possible infections were also requested from us to nursing staff, surgical team, and staff in the care intensive unit; they was informed when patients have suspected SSIs. In addition patients undergoing hip and knee arthroplasty were followed up at one, three, six and 12 months after surgery and notifications of suspected infections were collected.

If a SSIs was suspected by the nursing or medical staff, they discussed the case to classify the infections according to the CDC (The Center for Disease Control and Prevention) definitions of surgical site infections (the organ/space and deep incisional categories were combined in this survey).

2.8 RFID technology

RFID system are used in a wide variety of industry applications, including automatic fare collection on bridges, toll roads, and public transit; wireless pay-at-the-pump payment programs, and hands-free access control security systems in offices and factories.

RFID tags consist of an integrated circuit (IC) attached to an antenna; data is stored on the IC and transmitted trough the antenna. Tags can be smaller than a grain of rice or as large as a brick. RFID tags are either passive (not battery) or active (self-powered by a battery). Data transmission speed and range depend on the frequency used, antenna size, power output and interference. Tags can be read-only, read-write, or a combination, in which some data (such as a serial number) is permanently stored, while other memory is left available for later encoding or to be updated during utilization. Information is sent to and is read from RFID tags over RF signals.

RFID tags can be read through packaging, shipping containers, and most materials except metal. An important characteristic of them is that dozens of tags can be read effectively by the same reader simultaneously. Because tags are reusable, they can improve efficiency in many operations by reducing labor and materials costs.

The aim of our study is to reduce the medical staff working time (collecting all data and information, actually hand-taken, with tagging wireless technology), to realize a hands-free control security system for pre/post-operating nursing (medicine administration, disposable control, etc.) and operating (anaesthesia, clinical information, prosthetic components and others) activities and finally to reach a higher information technology level in the clinical managemant to look up the services quality reducing the double-entry and permitting a faster information finding.

3 Results

During two month (February and March 2005) we monitored 104 orthopaedic surgeries of which only 62 were election surgeries interesting for us to use for developing a new method for SSIs survillance. These election orthopaedic surgeries were composed by 29 total hip replacement (ATA), 8 total knee replacement (PTG), 19 shoulder artroscopy (SPALLA) and 6 reconstruction of knee ligament (LCA).

Microbiological data, collected with passive method, was compared with IMA index; OR was placed in IMA1 class because the UFC counts ranged between 0 to 6 CFU/dm^2/h. Only 4 surgeries (3 ATA, 1 LCA) were resulted more contaminate than other with a range between 5-10 CFU/dm^2/h placing OR in IMA2 class (Figure 2).

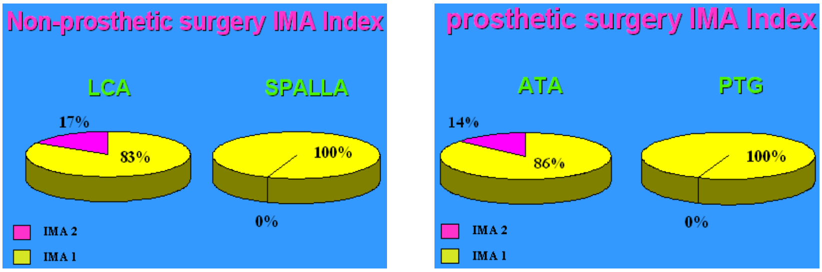

Figure 2: IMA Index values related with different orthopaedic surgery.

For a period of one month we monitored and collected data of 40 surgeries with the active air sampling (SAS) and the same results, as passive air sampling were obtained. Moreover we had monitored all 104 surgeries with passive air sampling to determinate the daily total microbial charge; we had registered that microbial charge didn't growth at the end of the day but was maintained constant between first operation and last one. We reported in this text the results of two days (Figure 3). The other results are completely similar.

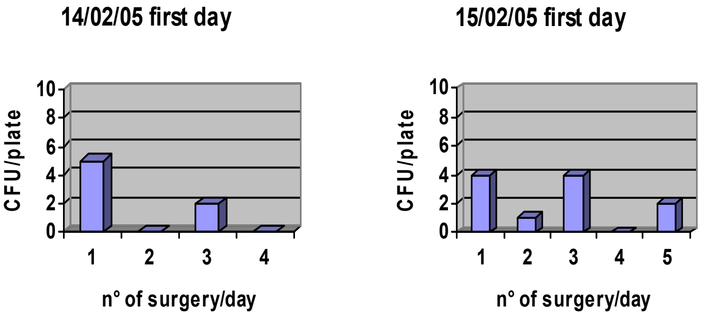

Figure 3: 5 graphic that show the daily total microbiological charge.

During the two months of observation and collection of data we didn't reveal any case of SSIs not even at 30th day after surgery, but is necessary to going on with the monitoring of wound for a much longer period of time especially for election prosthetic surgery that required one year of observation after surgery. The wound tampons results are all negative as the results of surfaces monitoring.

Through the results of particulates concentration in OR *at rest* we had calculated ISO class and as shown in table 1 the values obtained placing room in ISO5 class.

Table 1: ISO classification results

C_n	particle / m^3			
D	Particle diamteter			
N	$N = \log(C_n) - 2{,}08 \cdot \log(0.1/D)$			
diameter	**0.3 µm**	**0.5 µm**	**1 µm**	**5 µm**
CLASS	**4.2**	**3.9**	**4.1**	**5.0**

In activity OR the values collected maintaining the room in ISO6 class. We had noticed that while trend of the particulates concentration curve was the same for every dimensions of particulate, the differences between the values are sensitive to particulates diameter, to different kinds of operations and to different events during the same operation.

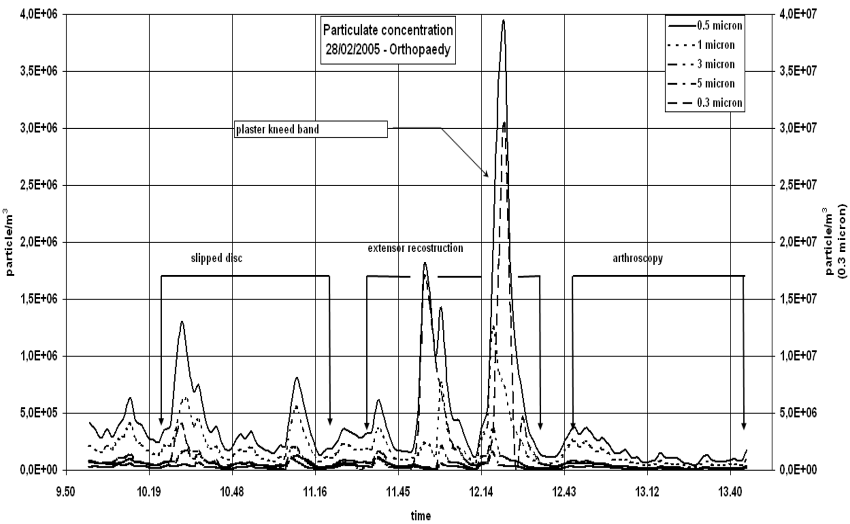

Figure 4: Particulates concentration *in activity* OR.

Regarding the results of termic stress monitoring, their elaboration and analysis are in progress, as the developing and the definition of RFID technology that is in progress too.

4 Discussion

Providing feedback to the use of conventional surveillance methods requires a significant amount of time for the collection, analysis and feedback of data by the operating staff.

One of the aims of our studies is to create and offer another methodology to collect data for surveillance, to identify the actions for prevention of the infections and to get indicator of quality for the surgical activities.

During two month were collected many data of election orthopaedic surgery in the Cento Hospital, about microbiological and physical monitoring of air and active monitoring SSIs surveillance.

Regarding the microbiological monitoring it can be demonstrated that turbulent airflow with absolute HEPA filter is very efficiently.

Regarding the microbiological monitoring, the results demonstrate that it is possible to reach a high level of sterility in ORs using turbulent airflow systems, more economic and comfortable than the laminar one. This consideration of a high asepsis level can be extruded to the particulate pollution, that the verified to be conform to ISO4 classes in condition *at rest* and to ISO6 in *activity*.

The elaboration of termic stress monitoring data to define optimum microclimatic environmental conditions during an orthopaedic surgery is in progress.

The absence of SSIs case during two month of active surveillance was attributed to good functionality turbulent airflow system, good manufacturing practice of the operating staff and velocity with which the operating staff performed a surgery. Besides the operating staff followed conscientiously all guidelines that defined the prevention of NI to guarantee a high grade of environmental sterility.

The experimentation, still working, of automatic computer collecting data using RFID technology will be an important instrument for SSIs surveillance and for NI surveillance too. It will be provide in real-time any kind of sanitary information that are necessary to operating staff so reducing morbidity and mortality rates. Reducing morbidity and mortality it will be possible to pull down health-care costs to the reduction the patient stay (LOS) time and the drugs costs.

The main step attended for the future deals with the effort to correlate the different variables (particulate and CFU concentration, ventilation systems parameters, environmental parameters and so on) with the aim to investigate the genesis of the microbiological pollution phenomena and the corresponding qualitative and quantitative trend.

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