

ORIGINAL ARTICLE

Improving environmental quality in an operating room: clinical outcomes and economic implications

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Key words

Operating room • Environmental monitoring • Outcomes of quality improvement

Summary

An experimental study was conducted in a hospital in Liguria (northern Italy) on two groups of patients with the same disease severity who were undergoing the same type of surgery (primary hemiarthroplasty). Our aim was to assess the results of a quality-improvement scheme implemented in the operating room. The quality-improvement protocol involved analyzing a set of parameters concerning the operating team's behavior and environmental conditions that could be attributed to the operating team itself. A program of training and sanitary education was carried out to rectify any improper behavior of the operating staff. Two hundred and six hip-joint replacement operations (primary hip hemiarthroplasty - ICD9-CM 81.51) all conducted in the same operating room were studied: 103 patients, i.e. operations per-

formed before the quality-improvement scheme and 103 patients, i.e. operations performed after the quality improvement scheme; all were comparable in terms of type of surgery and severity. The scheme resulted in an improvement in both behavioral and environmental parameters and an 80% reduction in the level of microbial air contamination ($p < 0.001$). Patient outcomes improved in terms of average postoperative hospitalization time, the occurrence and duration of fever ($>37.5^{\circ}\text{C}$) and microbiological contamination of surgical wounds.

From an economic point of view, facility efficiency increased by 28.57%, average hospitalization time decreased ($p < 0.001$) and a theoretical increase of € 1,441,373.58 a year in revenues was achieved.

Introduction

Surgical site infections (SSIs) are a major cause of morbidity and place an economic burden on hospitals worldwide [1]. Identifying and implementing evidence-based strategies designed to minimize SSI is therefore an important clinical goal. The rate of surgical wound infections is strongly influenced by operating room quality. An operating room 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 behavior of healthcare workers. A safe and salubrious operating room 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 [2].

Knobben et al. [3] observed that the combination of systemic and behavioral measures in the operating theater, such as wearing proper attire and limiting needless activity, led to a reduction in the incidence of intra-operative bacterial contamination and, consequently, of prolonged wound discharge and superficial SSI. 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.

Many studies have shown that various methods can be adopted in order to minimize postoperative infection; one of the most effective ways has proved to be the administration of prophylactic antibiotics within 1 hour of surgical incision and continuation of their use during the immediate postoperative period [4]. However, microorganisms that are resistant to antibiotic treatment have been increasingly involved in SSIs, which is one of the main reasons why patients still suffer adverse outcomes from postoperative infections. Indeed, the number of SSIs caused by methicillin-resistant *Staphylococcus* (*S.*) *aureus* (MRSA) has increased dramatically [5], and recent studies have shown that reduced susceptibility to vancomycin and other glycopeptides is emerging in various MRSA clones all over the world [6, 7].

In 2008, the World Health Organization (WHO) published guidelines recommending several practices to ensure the safety of surgical patients worldwide [8]. Haynes et al. subsequently found that introducing the WHO Surgical Safety Checklist into operating rooms in eight 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 [9].

A management philosophy which seeks continuous improvement in hospital processes, products and services

and, in this specific case, in the operating room, is required in order to guarantee healthy conditions both for in-patients undergoing surgery and for health care providers. At the same time, maximum efficiency and effectiveness of the resources utilized must be ensured. For these reasons, measures undertaken to improve quality concern the entire organization, staff and facilities of the hospital [10-13].

Hence, quality improvement schemes yield both social and economic benefits. Social benefits comprise lower rates of postoperative complications and improved comfort and safety both of patients undergoing surgery and of health care providers. Economic benefits stem from the cost reductions resulting from shorter hospitalization due to optimization of operating room and staff use. Moreover, a lower postoperative complication rate reduces the need for antibiotic therapy and also shortens hospitalization.

We conducted an experimental study in a hospital in Liguria (northern Italy) on a group of patients with the same severity of illness (same ASA score) for whom the same resources were utilized (same patient management categories). Our purpose was to assess the results of a quality improvement scheme involving the operating room. Here, we report the results of the scheme in terms of environmental microbiological features and clinical outcomes.

Materials and methods

The study was conducted in 2012.

QUALITY-IMPROVEMENT PROTOCOL

The protocol was implemented over an 8-month period and included the following: (a) analysis of a set of parameters concerning the operating team's behavior (Tab. I); (b) evaluation of the airborne microbial load attributable to the operating staff; evaluation of microbiological features of surfaces and air from inlet ports of the ventilation system, upon completion of sanitation; (c) training and sanitary education to rectify inappropriate behaviors of the operating staff and to optimize plant and equipment maintenance and management by the technical staff. Conditions and behaviors (Tab. II) expected to improve the quality of the operating room environment were illustrated to the staff; particular emphasis was placed on clothing, operating room management, patient preparation and the various procedures used, through continuing medical education (CME) and the application of techniques focused on specific issues [14, 15].

ROOM QUALITY AND VENTILATION

The design of the operating suite provides adequate space for reception, anesthesia, surgery, recovery, and observation of patients. The air-conditioning system in the operating suite is equipped with high-efficiency particulate air (HEPA) filters, provides 24 air exchanges per hour by means of turbulent flow and is

Tab. I. Analysis of a set of parameters concerning the operating team's behavior.

1. During operations
 - How many people are in the operating room?
 - How many people not belonging to the operating staff are in the operating room?
2. In the operating room
 - How many people use gloves?
 - How many people replace their surgical mask after every operation?
 - How many people wear proper clothes?
 - How many people use universal precautions?
 - Opening of doors
3. Assessment of procedures and protocols for
 - hand-washing,
 - routine and terminal cleaning,
 - aseptic techniques,
 - sterilization,
 - infectious patients,
 - pre-operative and post-operative management of patients,
 - waste management

Tab. II. Behavioral and organizational interventions undertaken in the operating room.

1. Surgical staff
 - Opening of doors kept to minimum
 - Restricting access to the operating room of people not belonging to the surgical team.
 - Movement of people kept to minimum
 - No changing of personnel during operation
 - Proper wearing of body covering:
 - use of disposable non-woven fabric suits,
 - use of clothes covering the whole body.
 - surgical mask replaced after every operation
2. Implementation of protocols for:
 - Routine and final cleaning.
 - Pre-operative and post-operative management of patients.
 - Routine control of air-conditioning system.

checked regularly by the maintenance staff. The same type of filter was used throughout the study.

AIRBORNE AND SURFACE BACTERIAL LOAD

Airborne and surface bacterial loads were determined both before and after implementation of the quality-improvement scheme.

Microbial measurements were taken under rigorously aseptic conditions by means of a portable Surface Air System (SAS) SUPER 100 (PBI International®) impactor equipped with RODAC plates ($\varnothing = 55$ mm) containing γ -irradiated TSA (Tryptone Soy Agar) culture medium (Biotest Italia s.r.l.). In order to sample the air in the center of the room, the instrument was positioned in the immediate vicinity of the operating table, at a height of 1.5 m. During each procedure, a 1000 L volume of air was aspirated by means of a multi-aspiration modality; the impactor was switched on by remote control just as the skin was incised, and was switched off on completion of suturing [16]. To

determine the bacterial load of the airflow from the inlet ports of the ventilation system in at-rest conditions, the sampler was positioned in proximity to the flow-regulators. The total volume of air sampled was 1000 L. In order to prevent contamination, each plate was sealed after sampling and carried to the quality control laboratory in a biocarrier [17]. Plates were incubated at 37°C for 48 h before the total aerobic bacterial count was measured. Microbiological results are expressed as Colony Forming Units (CFU)/m³. Microbial sampling of surfaces was conducted by means of RODAC contact plates (Ø = 55 mm) containing Columbia blood agar culture medium (Biotest Italia s.r.l.). Sampling was carried out after sanitation of the operating room, as indicated by ISPEL and by the French guidelines [16, 18]. Plates were incubated at 37°C for 48 h before the total aerobic bacterial count was measured. Microbiological results are expressed as CFU/plates.

Subsequently, a search for *S. aureus* was undertaken. An 18-24 h culture of the test organisms was then prepared by inoculating a tube of Brain Heart Infusion Broth with a loopful of growth taken from pure culture, and a coagulase tube assay (Coagulase Plasma EDTA – Biolife Italiana S.r.l.s) was performed. The specificity of the reaction was checked by means of a control test carried out on each positive sample (*S. aureus* ATCC 25923).

The colonies that proved positive on the coagulase test were subjected to an antibiogram in order to evaluate methicillin/oxacillin resistance, according to the Oxacillin Agar Screen Test of the National Committee for Clinical Laboratory Standards (NCCLS, 2002, 12th Informational Supplement).

PATIENTS

In order to obtain homogeneous and thus comparable data, the study recruited patients with the same disease severity (same ASA score) who were undergoing the same type of surgery.

We monitored 206 hip-joint replacement operations (ICD-9-CM 81.51) performed in the same operating room. These were divided into two groups: group 1 comprised 103 patients who underwent surgery before the beginning of the quality-improvement scheme; group 2 comprised 103 patients who underwent surgery after completion of the scheme.

Each patient from group 1 was matched with one patient from group 2. Both groups displayed comparable features: i.e. no concurrent diseases, age, sex, etc.. All patients in both groups followed the same protocol of prophylactic antibiotics: a single administration of 200 mg of Vancomycin combined with 400 mg of Pefloxacin 1 hour before surgery. All patients underwent surgery within 24 hours of hospitalization.

No joint sepsis or abnormal pain in the joint was noted in any of the patients.

The following parameters were considered for each patient:

- postoperative pyrexia above 37.5°C;

- administration, if any, of additional antibiotics;
- days of hospitalization.

STATISTICAL ANALYSIS

Statistical analysis was carried out by means STATA/SE9tm software (StataCorp LP, College Station, TX, USA). The results were analyzed in terms of descriptive statistics, and the relationships between data were examined by means of a t-test and Pearson's chi-squared test. A value of P less than 5% was considered significant. The rho Spearman rank correlation was used to assess the degree of association between the duration of pyrexia (>37.5°C) and hospitalization time.

ETHICS STATEMENT

We did not need ethics committee approval, as the study was carried out as part of routine control tests that we conduct in the operating rooms of the hospital. As is the case of all studies conducted in the hospital environment, the General Management of the hospital approved the study protocol. The General Management is responsible for ensuring the ethical aspects of all activities of the hospital. Furthermore, the entire study was organized in accordance with a protocol agreed upon with the operating room teams. On entering the hospital, all patients sign an informed consent form regarding treatments in the hospital and the conditions of those treatments. Finally, the research was carried out in full respect of the Italian law on privacy (Legislative Decree n. 196 of 30 June, 2003).

Results

The behavioral and organizational interventions undertaken in the operating room are presented in Table II. Table III reports the average values of the various parameters considered.

With regard to environmental monitoring, the median value of the airborne bacterial load detected during the first set of measurements was 15 CFU/m³; this value decreased to 3 CFU/m³ (80% drop) in the second set of measurements (t-test = -13.5060, p < 0.001). The microbial load of the airflow through the inlet ports proved to be < 1 CFU/m³ both first and second set of measurements. The median surface bacterial load decreased from 2 CFU/plate to 0 CFU/plate.

Analysis of the surfaces sampled before the quality-improvement scheme revealed contamination by 3 CFU of *S. aureus*, one strain of which proved to be MRSA; after implementation of the quality-improvement scheme, no *S. aureus* was found.

With regard to complications of patients, a 31.91% reduction in pyrexia (above 37.5°C) was recorded post-operatively. The number of patients with fever fell from 94/103 (91.26%) before implementation of the quality-improvement scheme to 64/103 (62.14%) after implementation. This difference proved statistically significant ($X^2 = 24.4462$, p = 0.0000), with an Odds Ratio of 6.36 (95% Confidence Interval [CI]: 2.77-15.86). The

Tab. III. Average values of the various parameters considered and percentage change after implementation of the quality improvement scheme.

	A	B	C
Total microbial contamination — air (CFU/m³)			
operating room - median (Q1-Q3) [§]	15 (10-20)	3 (0-5)	-80
air-conditioning plant	< 1	< 1	
Total microbial contamination — surfaces (CFU/plate)			
operating room - median (Q1-Q3) [§]	2 (2-4)	0 (0-1)	-100
<i>Staphylococcus aureus</i> surface (n.)	3	0	-100
MRSA contamination — surface (n.)	1	0	-100
Pyrexia above 37.5°C[§]			
duration of pyrexia (days) above 37.5°C (mean+S.D) [§]	6.84±3.15	3.16±1.05	-48.54
additional antibiotic therapy [§]	32.98%	17.19%	-47.88
days of hospitalization (mean + SD) [§]	7.99 ± 3.24	4.92 ± 0.96	-28.57
Greater revenue(Euro) due to more operations		€ 1,441,373.58	

Legend

A = case (before environment improvement); B = control (after environment improvement); C = percentage variation

[§] = p ≤ 0.001

SD = Standard Deviation

duration of pyrexia (> 37.5°C) was longer in the patients belonging to group 1 (6.84 ± 3.15 days) than in the subjects belonging to group 2 (3.16 ± 1.05 days) (t = 8.1251, p = 0.0000). Some of the patients with pyrexia received additional antibiotics: 31/94 (32.98%) of group 1 versus 11/64 (17.19%) of group 2. The difference was statistically significant (X² = 4.8651, p = 0.020) with an Odds Ratio of 2.37 (95% CI: 1.03-5.72).

The average duration of hospitalization significantly decreased from 7.99 ± 3.24 days (group 1) to 4.92 ± 0.96 days (group 2) (t-test = 9.1998, p = 0.0000); a significant correlation (rho = 0.7730) emerged between the duration of pyrexia (> 37.5°C) and the time of postoperative hospitalization (p < 0.0000).

Finally, considering that in 2012, 596 operations were performed in this operating room, which is used exclusively for hip-joint replacement operations (ICD-9-CM 81.51) and also that, according to Italian law [19], the reimbursement is made by means of Diagnosis-related group (DRG n. 544) and the unit cost of hip-joint replacement operations amounts to € 8,565, we examined the functional and economic implications of the changes that were brought about. Owing to the reduction (3.07 days) obtained in the average duration of hospitalization, 828 more days became available for hospitalization. If we consider the average duration of hospitalization among group-2 patients, i.e. 4.92 days, 168 more operations could potentially be performed in this operating room. Thus, the waiting list (currently more than 2,000 people) could also be shortened, thereby producing clear social advantages.

Discussion and conclusions

A high degree of variability in air microbial contamination has been observed in some studies among operating suites and operating rooms, suggesting that factors which strongly affect the quality of air (e.g. number of

people in the operating room, their movements, door-opening rate) may not be well controlled [3, 20-23].

Whyte et al. showed [24] that the incidence of joint sepsis progressively declines as air contamination is reduced, and that this trend is more marked below the value of 10 CFU/m³. Specific regulations concerning this issue have already been enforced in many countries [25, 26].

At the beginning of our study, the air bacterial load was fairly satisfactory (median 15 CFU/m³). Nevertheless, though the technological and structural features of the operating room remained unchanged, measures to improve staff behavior yielded a net improvement in clinical outcomes: This improvement was paralleled by the very low levels of air bacterial load (3 CFU/m³) obtained. Another our study confirms this result. [27].

With regard to surface bacterial load, an improvement was obtained after the implementation of sanitation protocols that included the use of hydrogen peroxide. Indeed, it has been shown that proper sanitation with hydrogen peroxide, which, even at low doses, reduces the bacterial load on surfaces by 50% [28], can eliminate *S. aureus*. Hence, clinical outcomes also improved, as indicated by the shorter duration of pyrexia (48.54% reduction) and hospitalization (28.57% reduction).

The presence of *S. aureus*, particularly MRSA, in the environment of the operating room reveals the importance of reducing the microbial load during surgery at high risk of SSI and highlights the fact that antibiotic prophylaxis, which is obviously necessary, should always be accompanied by good practice on the part of the operating staff.

Improved performance is mainly achieved through greater efficiency, rather than through the allocation of greater resources. Therefore, in addition to lowering the unit cost of the resources employed (overheads, structures, staff etc.), the hospital also receives more funds. The estimated increase in the number of operations that can be performed by the hospital means that revenues could be increased by € 1,441,373.58 a year (€ 8,565

X 168 extra hip-joint replacements that could be performed).

Moreover, shortening the waiting list would result in fewer patients going to hospitals outside their region. The Regional Healthcare System pays 20% more for a DRG performed in an extra-regional hospital (100%) than for the same DRG carried out in a hospital within the Regional Healthcare System (80%).

These data show the economic advantages deriving from a quality improvement scheme. However, the social and human benefits obtained should also be taken into account: namely, less discomfort for patients due to a shorter period away from home, higher quality of hospitalization as a result of fewer complications, and less time spent waiting for an operation that will improve the patient's quality of life.

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