# Patient safety in the operating room and documentary quality related to infection and hospitalization

Segurança do paciente no centro cirúrgico e qualidade documental relacionadas à infecção cirúrgica e à hospitalização

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#### **Keywords**

Patient safety; Checklist; Operating room nursing; Nursing records; Surgical wound infection; Hospitalization

#### **Descritores**

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## **Abstract**

**Objective:** To describe the documentary quality of two records related to patient safety in the operating room and to identify differences between information related to infection and hospitalization.

**Methods**: Comparative study based on two cross sections, conducted with 3,033 patients who had been hospitalized for more than 24 hours in an Orthopedics and Traumatology Center. Sociodemographic and clinical data, as well as information provided in forms were compared. Postoperative infection was identified as an adverse event.

**Results:** There was a significant correlation between hospitalization days and the total number of diagnoses collected (Pearson=0.328; p<0.001). When diagnoses and infections were grouped together, a significant value was found between closed fractures and infection (p=0.001).

**Conclusion:** Differences in the degree of completion were observed between the two records. There were no differences between adverse events.

## Resumo

**Objetivo:** Descrever a qualidade documental de dois registros relacionados à segurança de pacientes no centro cirúrgico e estabelecer as diferenças nas informações relacionadas à infecção cirúrgica e à permanência hospitalar.

**Métodos**: Estudo comparativo baseado em dois cortes transversais, realizado com 3.033 pacientes internados há mais de 24 horas, advindos de Cirurgia Ortopédica e Traumatologia. Foram comparados dados sociodemográficos, clínicos e de preenchimento. Mediu-se a infecção pós-cirúrgica como um efeito adverso. **Resultados**: Houve correlação significativa entre os dias de hospitalização e o número total de diagnósticos coletados (*Pearson*=0,328; p<0,001). Quando se agruparam os diagnósticos e a infecção, notou-se um valor significativo entre as fraturas fechadas e a infecção (p=0,001).

**Conclusão**: Foram observadas diferenças no grau de preenchimento entre os dois registros. Não houveram diferenças no evento adverso.

Conflicts of interest: there are no conflicts of interest to declare.

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## Introduction

The operating room is one of the environments with the highest number of adverse events<sup>(1,2)</sup> of hospitalization. It is a multifactorial cause resulting from the complexity of procedures, the interaction of multidisciplinary teams and work under pressure. In most related studies, it was proved that the operating room is more likely to pose risks, but most of them can be avoided.<sup>(3,4)</sup> The presence of adverse events in a surgical intervention is estimated at 37.6%.<sup>(3)</sup>

One of the objectives of The World Alliance for Patient Safety, in its second campaign, Safe Surgery Saves Lives, was to strengthen surgery safety practices as defined by the World Health Organization. (5) The program addressed important safety matters such as inadequate safety anesthetic practices, surgical infections that may be avoided and lack of communication between members of the surgical team.

In this world campaign, the Alliance implemented the Surgical Safety Checklist in June 2008. This initiative aimed to identify the basic rules of surgical care that can be applied universally. The implementation of the Surgical Safety Checklist results in team work, in greater participation and communication, in a sense of responsibility of all members of the surgery team and in a change in personal attitude. (6,7) The verification systems are in fact a routine practice in fields such as the aeronautical, aviation and nuclear industries. (8)

In centers where the Surgical Safety Checklist was used, there was a decrease in the rate of greater complications in patients, from 11% to 7%, and the rate of hospital mortality after main surgeries decreased from 1.5% to 0.8%.<sup>(9)</sup>

In order to correctly fill the Surgical Safety Checklist, only one person should be in charge of using and filling it in during a surgery. The World Health Organization proposed that the "checklist coordinator" be a nurse.

Although it seems simple from an administrative point of view, the process of implementation of the Surgery Safety Checklist is complex, due to two

circumstances that must be considered for efficient results: professionals' resistance to change<sup>(10)</sup> and the adaptation of the list to the needs of the environment and the particularity of the place where it is to be used.<sup>(11,12)</sup>

The objectives of this study were to describe the documentary quality of two records related to patient safety in the operating room and to identify differences between information related to infection and hospitalization.

## **Methods**

This is a comparative study, based on two cross sections related to 2009 and 2010, supported by data recorded at the Orthopedics and Traumatology surgery center of Hospital Santa Cruz de Liencres de Cantabria, Spain, conducted with 3,033 patients who had been hospitalized for more than 24 hours. All records from the studied years that met the inclusion criteria were included. Its duration was 2 years (from 2009 to 2010).

The calculation of the sample size was performed using the EPIDAT 3.1. In order to compare the rates of surgery infection between both groups of patients, an assumption of the proportion was made within Group 1, with Free Forms, at 4%; and an expected minimum decrease of 2% within Group 2, with Surgery Safety Checklist, with a 95% confidence interval and 80% of potential.

The independent variables were: age on the day of intervention, gender, length of stay and primary and secondary diagnosis. The studied variables related to documentary quality were the rates of completion of all items of both records. As results variables, we studied: postoperative complications, surgery infection, comorbidity and length of stay.

For grouping diagnoses, according to the international classification of diseases, in its ninth revision, clinical modification (ICD-9), a division was made into six categories, based on primary diagnosis and prognosis of severity: arthrosis, closed frac-

tures, inflammation/infections, neoplasms, malformations and other pathologies.

A descriptive analysis was performed for both groups of patients, in which a comparison was made between the variables age, gender, diagnosis of intervention and degree of completion of each record, by means of frequency percentage.

Quantitative variables were analyzed with measures of central tendency, and qualitative variables were calculated with frequency percentages. In order to analyze the association between infection and the group to which the patient belonged, a chisquare test was performed.

Afterwards, univariate and multivariate analyses were performed in order to associate the infection variable with the other variables studied. The analysis was performed by means of the Statistical Package for the Social Sciences, using a basis created for this purpose.

The development of the study complied with national and international ethical guidelines for research involving human subjects.

## **Results**

Out of 6,300 patients surveyed, 3,033 records met the inclusion criteria and were studied. In 2009, within Group 1 (Free Form), 1,733 records were included, whereas Group 2 (Surgery Safety Checklist) had 1,300 records in 2010.

The mean age of patients on the day of intervention in 2009 (Group 1) was 60 years old, and in 2010 (Group 2), it was 59 years old. As for gender, 56.2% were women and 43.8% were men, with a similar distribution for both groups of patients.

The length of stay in both cases was 5 days, with no significant difference (p=0.589).

Of the total diagnoses studied, arthrosis had an incidence of 43.9% of the total of patients, thus being the most frequent.

Concerning information on the checklist, at the first step, the Entry Stage, the forecast of critical events was revised by an anesthetist, reaching 57.9%. The surgeon revised severe

or unexpected cases, duration and the expected blood loss, and a rate of 36.1% was found; the nurses revised the confirmation of sterility and checked whether there were questions or problems related to material and/or equipment, reaching 89.1%.

Complementary information had the following results: antibiotic prophylaxis administered in the last 60 minutes remained at 52.9%; the item availability for interventions of radiological images that are essential for intervention achieved 60.7%, and the lack of precedence of the type of intervention, 16.4%.

The adequate site of operation, in cases of laterality or multiple structures or levels, was indicated by the surgeon in 99% of patients.

In the next step, Time Out, in which all the safety protocols were considered before induction of anesthesia so as to ensure safety of the procedure, the nurse confirmed orally the patient's identity in 99.2% of cases, the site of operation in 98.8%, the type of intervention was written down in 96.1% of cases and informed consent was reported in 91.4%.

At the third and last stage, Sign Out, before the patient left the surgery unit, the nurse confirmed orally the exact surgical intervention that was performed in 79.1% of cases. In addition, before the patient's departure, the instrument nurse confirmed orally the exact counting of the material and needles in 77.9% of cases, and gauze compresses in 18.4% of cases. There was no counting of the remaining material in 11% of cases, and in 69.7% of cases regarding gauze compresses.

As for signatures of the Surgery Safety Checklist by all team members, the results were: 42.3% of anesthetists, 97.6% of nurses and 21.2% of surgeons.

Postoperative infection before the first 72 hours was reported in 1% of cases in both years, which has no statistical significance (p=0.844).

The length of stay resulting from the intervention was similar in both groups, with no statistical significance. The mean of hospitalization days, after intervention on those who had signs of surgery in-

tures, inflammation/infections, neoplasms, malformations and other pathologies.

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fection, had no statistical significance between both groups, as shown in table 1.

Regarding information related to the patient's diagnosis, the records of the Surgery Safety Checklist group were greater in number when compared to the Free Form group. Through the Surgery Safety Checklist, 562 patients were reported with one or two diagnoses and 490 with three or more.

A significant correlation between hospitalization days and the total number of diagnoses was found (Pearson=0.328; p<0.001).

**Table 1.** Age, length of stay and days with postoperative infection in 2009 and 2010

Year	Mean age	p-value	Mean stay	p-value	Mean days of infection	p-value
2009	60.65		5.5		3.2	
2010	59.08	0.038	5.1	0.080	12.2	0.128

In the relationship between postoperative infection and hospital stay, there was a significant difference (Table 2). Likewise, when diagnoses of intervention and surgery infection were grouped, a significant difference was also found between closed fractures and infection (p=0.001).

**Table 2.** Results of the relationship between age, stay and infection

Variables	Infection	No infection	p-value
Mean days of stay	12	5.32	0.002
Age	62.58	59.92	0.41

For multivariate analysis, models of multivariate logistic regression were fitted with the variable response to infection proportion and explanatory variables (gender, age, stay and grouped diagnoses). Results obtained are presented in table 3.

## **Discussion**

Although the objectives of this study were to describe the characteristics of the use of the Surgery Safety Checklist and the Free Form and to determine their differences in postoperative complications, surgery infection and stay, the records did not contain information related to adverse events, this being one of the main limitations encountered.

**Table 3.** Results of the fitted model

Variables	p-value
Free Form - Surgery Safety Checklist	0.635
Gender	0.754
Age	0.411
Length of stay	< 0.001
Grouped D1*	0.256
Grouped D1* (1)	0.012
Grouped D1* (2)	0.997
Grouped D1* (3)	0.998
Grouped D1* (4)	0.933
Grouped D1* (5)	0.811
Constant	< 0.001

\*Grouped D1 - Primary diagnosis related to intervention

Until 2009, a compulsory form was used to record the intraoperative and care safety measures, in an original version with three copies, called Free Form, which was specific to surgery. It is an independent document that completes the others that are part of the clinical record.

In 2010, the studied hospital implemented the Surgery Safety Checklist, which divides the surgical procedure into three stages, each one corresponding to a period of time in the normal course of the process: before, during and after the intervention, when the surgeon, the anesthetist and the nurse perform their duties. In both cases, the nurse is in charge of filling in the forms.

Patient safety has been discussed in different countries and regions at different times. (3,13) However, since the World Health Organization asserted its importance, strategies related to patient safety (5,15) have been improved.

The Surgery Safety Checklist was implemented in most European Union countries and is used in a large number of surgical specialties. The results obtained for the degree of completion in our study were not different than those published since the strategy of surgery safety was officially released. (16)

The implementation of measures that require changes in attitude and processes is complex, and the application of the Surgery Safety Checklist is no exception. The recommendations of the World Health Organization regarding the filling in or the modification of the list were followed, in order to adapt it to the local practice at Hospital Santa Cruz de Liencres, and to reach consensus regarding its filling in. In most hospitals where it was imple-

mented, the checklist was changed and adapted to the needs of each specialty and to the management of the organization<sup>(17)</sup>, which is different in each country, and this opens up the scope for studies related to the validity of records among countries.

As in other studies<sup>(18)</sup>, one of the items that was less frequently filled in was the presentation of the members of the surgery team and their roles. This can be explained by the process of implementation and methodology used in training and awareness of the Surgery Safety Checklist or by the lack of culture of this way of filling in records.

The percentage of confirmation of patients' details (identity, site of operation, procedure and consent) is similar to those informed by other surgical units.<sup>(19)</sup>

The application of the Surgical Safety Checklist allowed for the detection of events that altered the normal course of the surgery, without affecting the patient. There are many publications stating that the effect on morbidity and perioperative mortality and the culture of safety at the surgical unit is improved with the Surgery Safety Checklist. (20,21) However, this information was not reported in our study.

It is worth mentioning the differences between the degree of completion among the nursing staff and the other groups, which is certainly associated with the culture of filling in that existed before with the previous record (free and instrumentalist). Rates of completion of 90% and 100% were obtained, whereas for the rest of the team, rates of 42.3% were obtained for anesthetists and 21.2% for surgeons. In addition, in most published studies, coordination was performed by the nursing team, who was also responsible for filling in, (22) and took charge of it as another routine surgery task.

When comparing the number of Surgery Safety Checklists of different hospital units at a global level, between 80 and 90%<sup>(17,19,23)</sup> of cases the rates of completion were similar to those of the Orthopedics and Traumatology surgery center of Liencres.

After a deeper analysis of the results of this study, it was possible to find that not all items of the Surgery Safety Checklist were filled in, in which the second stage (Time Out) was the one

with the highest degree of completion among the consulted studies.

Patterns of completion of the Free Form should be between 80% and 90%, as it is a compulsory procedure carried out by the nurse, besides being a document that is part of the clinical record. When we observe the pattern of the variable of completion in the Surgery Safety Checklist, the most complete and with the highest number of signatures is the one completed by the nurse in relation to the rest of the team. (16)

## Conclusion

Both the Free Form and the Surgery Safety Checklist fulfilled the expectations of the management and participation of health professionals in clinical safety. The need to improve the filling in of some items of the second record was evident, as well as the need to focus efforts on encouraging its completion. It was not possible to associate adverse events on patients with the use of each document.

### **Collaborations**

Torres B, Macia L, Nolasco A, Lopez MJ and Pina F contributed to the project conception, research development, interpretation of data, writing and critical review and final approval of the published version.

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