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Safe surgery checklist: filling adherence, inconsistencies, and challenges.

Checklist de cirurgia segura: adesão ao preenchimento, inconsistências e desafios.

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A B S T R A C T

Objective: to identify adherence to the safe surgery checklist from its filling out in a general referral hospital in the interior of Minas Gerais state, as well as to verify factors associated with its use. **Methods:** this is a retrospective, documentary, cross-sectional study with a quantitative approach. Data collection was performed through a retrospective review of medical records of patients undergoing surgery within one year. Patients of all specialties, aged 18 years or older, and with hospitalization period equal to or greater than 24 hours were included. The probabilistic sample was composed of 423 cases. **Results:** the checklist was present in 95% of the medical records. However, only 67.4% of them were completely filled out. The presence of the checklist in the medical record was significantly associated with the anesthetic risk of the patient. There was no difference in the filling out percentage among the three checklist moments: before anesthetic induction (sign in), before surgical incision (time out or surgical pause), and before the patient leaves the operating room (sign out). There were also no significant differences regarding the filling out percentage of the surgeon's responsibility items. Considering the surgical procedure performed, inconsistencies were found in the laterality item. **Conclusion:** despite the high percentage of medical records with checklist, the presence of incompleteness and inconsistency may compromise the expected results in the safety of the surgical patient.

Keywords: Checklist. Patient Safety. Surgical Procedures. Operative.

INTRODUCTION

Surgical treatment is an essential therapeutic modality for health care, adding a progressive technological advance that provides cure for many diseases, besides reducing disabilities and the risk of deaths[1,2]. According to 2012 data from 194 World Health Organization (WHO) member countries, an estimated 312.9 million surgeries were performed annually, showing a 33.6% increase in the number of operations comparing with the previous estimated number referring to 2004[2].

Although surgical procedures provide great benefits to patients, safety failures may cause considerable damages, resulting in temporary or permanent disabilities and even deaths[1]. Literature indicates that the occurrence of damages associated with surgery is frequent and produces more serious consequences than those observed in clinical care[3,4]. International studies have demonstrated that the risk of having an adverse event (AE) is higher among patients who have undergone surgery when compared to patients with clinical hospitalization[5,6].

Some incidents represent unacceptable surgical complications, such as surgery performed on the wrong patient or site, unintended foreign body retention within a surgical site after the end of the procedure, and intraoperative or immediate postoperative death in patients previously classified as low-risk for complications and death[7].

In this context, it is important to consider the legal impacts that such incidents can have on the medical team, besides the physical, social, and emotional damages caused to patients.

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In addition, there is an increase in the length of hospital stay, which leads to the need for new diagnostic and therapeutic interventions and greatly increases treatment costs[8].

Growing concern about safety in health services led WHO to launch in 2004 the World Alliance for Patient Safety. As part of this Alliance, Safe Surgery Saves Lives[1] challenge was launched in 2008. In Brazil, the so-called National Patient Safety Program (PNSP), established by Ministry of Health, Ordinance n# 529/2013[9], and reinforced by Resolution of Collegiate Board (RDC) n# 36/2013[10], of National Health Surveillance Agency (ANVISA), established mandatory actions to promote patient safety, among them, those aimed at surgical safety. Brazilian College of Surgeons (CBC), in partnership with ANVISA and PanAmerican Health Organization (PAHO), contributed significantly to the dissemination of its Safe Surgery Manual, published in 2014.

To implement safety actions, WHO recommended the adoption of a safe surgery checklist with the objective of assisting surgical teams in systematically following critical safety steps. The instrument consists of 19 items divided into three moments: before anesthetic induction (sign in), before surgical incision (time out or surgical pause), and before the patient leaves the operating room (sign out)[1].

The use of this tool has been strongly recommended as effective intervention, with relatively easy and inexpensive application[1]. It involves the joint participation of patients, surgeons, anesthesiologists, and nursing staff. Studies conducted in developed countries have already proved that the checklist (CL) use reduces mortality and complication rates among surgical patients, besides reducing the number of errors due to miscommunications among team members[11-14].

In Brazil, as in other developing countries, there is little evidence on the CL use. In general, studies indicate low adherence to the instrument, especially when assessing the quality/completeness of the checking items[15-18].

Knowing the adherence to the instrument is important to identify how this tool has been used in surgical care, indicating CL potentialities and weaknesses that can be managed for producing the expected impact on surgical patient safety. Thus, this study aimed to identify adherence to the safe surgery CL from its filling out in a general referral hospital in the interior of Minas Gerais state, as well as to verify factors associated with its use.

METHODS

This is a retrospective, documentary, cross-sectional, and quantitative study carried out through the review of a probabilistic sample of medical records of patients undergoing surgery in 2015. CL adherence was estimated considering the presence of the instrument in the patient's medical record and the completeness of the checking items.

The study scenario was a large philanthropic general hospital located in a municipality in the interior of Minas Gerais state, with an estimated population of 516,247 inhabitants in 2010. The CL was implemented in the institution in the first half of 2013, thanks to the initiative of Patient Safety Center (NSP). The instrument is an adaptation of WHO's standard CL. After its construction and training of the team, the CL was included as a mandatory document in the medical records of all patients undergoing surgical procedure, regardless of specialty.

The study population consisted of all patients who underwent surgical procedures in 2015. Those aged 18 years or older and with hospitalization period equal to or greater than 24 hours were included. To calculate the sample size we considered an estimation of a population with a prevalence of 0,50, which corresponds to the worst situation, 95% confidence level, and absolute precision of at least five percentage points. Thus, the sample used was of 423 medical records of surgical patients.

For the selection of patients, we used simple random sampling from an electronic database provided by the institution, covering all patients undergoing surgical procedure in 2015. In addition, the sample was stratified per month in order to minimize possible fluctuation effects of the monthly number of surgeries, as well as to allow that all months were represented in the sample.

The CL presence in each selected medical record was verified, as well as the filling out of each item of the instrument. Besides, additional data were collected in order to characterize the sample (patient identification data and information on hospitalization and the anesthetic-surgical procedure performed). It is important to note that the CL form was not available in the electronic medical record, being necessary to request the printed document for each selected medical record.

To estimate CL adherence, we considered as outcomes the presence of the instrument in the medical record and the complete checking of all items that make up the instrument. The independent variables were listed, considering data availability in the medical records and information found in studies on the theme in question, as follows: a) patient and hospitalization characteristics; b) related to the surgical procedure; c) regarding CL filling out.

The initial analysis included a description of study variables through descriptive statistics and exploratory data analysis. Bivariate analysis investigated the association of outcomes with independent variables using Pearson's chi-square test at a significance level of 5%. The magnitude of the association between the outcomes and the independent variables that presented statistical significance ($p<0.20$) in the bivariate analysis was verified by estimating the parameters of simple logistic regression models, using the backward feature of Statistical Package for the Social Sciences (SPSS version 20.0 for Windows).

The research project was approved by the Research Ethics Committee of Federal University of Juiz de Fora (UFJF) under Resolution n# 2.046.497.

RESULTS

There was a predominance of females (56.7%) and of the age group classified as adult (65.7%). Regarding the type of care, it was found that most patients were attended by *Sistema Único de Saúde*/SUS (56%), the Brazilian public health care system. Among these patients, 56.7% were attended on an emergency basis. Most of the surgical procedures occurred in the afternoon shift (40.9%) and lasted up to one hour (42.3%). The characteristics related to patients, hospitalization, and surgical procedure are shown in table 1.

The CL presence was verified in 95% of the medical records. However, the existence of the instrument with all checking items filled out was found in only 67.4% of the records. Nevertheless, more than 88% of the CL had at least 15 of the 19 items checked. Considering the completeness of the moments that make up the CL, there was little difference among them, being the third moment (84.9%) slightly more filled out than the others (both 84.2%).

Table 1. *Information related to patients and to the characteristics of hospitalization and surgery.*

Variables	n (423)	%
Patient characteristics		
Age		
Adult (18-59 years)	278	65.7
Elderly (60 years or over)	145	34.3
Gender		
Female	240	56.7
Male	183	43.3
Race		
White	306	72.3
Black	36	8.5
Yellow	02	0.5
Brown or indigenous	79	18.7
Hospitalization characteristics		
Type of care		
SUS	237	56.0
Health insurance/Private	186	44.0
Type of hospitalization		
Elective	183	43.3
Emergency	240	56.7
Length of hospital stay		
1-3 days	227	53.7
4-7 days	72	17.0
More than 7 days	124	29.3
Characteristics of surgical procedure		
Specialty		
Gynecology and Obstetrics	103	24.4
Orthopedics and Traumatology	100	23.7
General	85	20.2
Cardiothoracic and Vascular	57	13.5
Others	78	18.2
Shift		
Morning	160	37.8
Afternoon	173	40.9
Night	90	21.3
Duration		
Up to 30 minutes	26	6.1
31-60 minutes	153	36.2
61-120 minutes	146	34.5
121-240 minutes	81	19.1
More than 240 minutes	17	4.1

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Variables	n (423)	%
Type of Anesthesia		
Local	18	4.3
Regional	239	56.5
General	166	39.2
Type of procedure		
Elective	303	71.6
Urgency/Emergency	120	28.4
Classification regarding the potential for surgical wound contamination		
Clean	194	45.9
Potentially contaminated	172	40.7
Contaminated	31	7.3
Infected	26	6.1

In the first moment, the least checked item was "risk of bleeding" (87.7%), which is one of the things to be confirmed with the anesthesiologist. In the second moment, the least checked item was "identification of the patient, surgery, and surgical site" (85.8%), which should be carried out by all members of the surgical team (surgeon, anesthesiologist, and nursing staff). In the third moment, the least checked item was "identified surgical specimens" (84.6%), which *a priori* is confirmed by nursing staff. Data related to CL filling out in the analysed medical records are described in table 2.

When consistency between checked items and surgical procedure performed was observed, inconsistencies were found in 15.4% of the analysed instruments. The most frequent findings included inconsistencies related to the checking of laterality item: surgeries involving laterality without indicating the correct side (5.2%) and surgeries that did not involve laterality with the correct side item checked (4.5%). Besides, there were also some cases of patients with drug allergy registered in the medical records, but who in the CL had the allergy item checked as "No".

The bivariate analysis revealed the existence of some variables which showed significant associations with the CL-presence outcome in the medical record. Regarding type of care, there was a significant association (p=0.01) of the outcome with patients attended by SUS and also those attended by health insurance or privately. Considering surgical specialty, a significant association (p=0.007) was also found between the specialties studied and the outcome. According to the American Society Anesthesiology (ASA) classification, the anesthetic risk of patients was associated (p=0.001) with the presence of CL in the medical record. Finally, the length of hospital stay also showed a significant association (p=0.036) with the outcome in question (Table 3). The same independent variables were tested for the CL-completeness outcome, which considered the existence of the instrument in the medical record with all safety items checked. For this outcome, the bivariate analysis did not show significant associations (p<0.05), as shown in table 3. Therefore, the multivariate analysis for the CL-completeness outcome was not performed.

Table 2. *Data related to the safe surgery CL filling out in the analysed medical records.*

Adherence indicators	n (423)	%
Presence of CL in the medical record	402	95.0
100% filled-out CL	285	67.4
Average checked items		
0-7	23	5.4
8-14	25	5.8
15-18	90	21.4
19 itens	285	67.4
First moment		
Complete filling out	356	84.2
Patient confirmed identification, site, procedure, and consent	394	93.1
Proposed procedure	393	92.9
Signed informed consent form	395	93.4
Fasting	396	93.6
Laterality	380	89.8
Checked anesthesia equipment	382	90.3
Monitoring	382	90.3
Allergy	382	90.3
Patent airway	380	89.8
Risk of major bleeding	371	87.7
Second moment		
Complete filling out	356	84.2
Surgical team introduced	365	86.3
Team confirmed patient, surgery, surgical site	363	85.8
Available equipments, materials, and instruments	371	87.7
Prophylactic antibiotic	391	92.4
Needed exams available	395	93.4
Correct positioning on the surgical table	367	86.8
Third moment		
Complete filling out	359	84.9
Surgical procedure performed	390	92.2
Counting of instruments, gauzes, and compresses	390	92.2
Identified surgical tools	358	84.6

The multivariate analysis for the CL-presence outcome in the medical record aimed to identify the magnitude of the association of the independent variables with this outcome, controlled by the other factors. For the CL-presence outcome in the medical record, the "anesthetic risk" variable maintained a significant inverse association. Following ASA classification (P1= healthy person; P2= presence of mild systemic disease(s) and absence of expressive functional limitation; P3= presence of moderate to severe systemic disease(s) with functional limitation; P4= presence of severe systemic disease with constant risk of death; P5= dying patient with no hope of survival without surgery;

Table 3. *Bivariate analysis of the association of CL-presence and -completeness outcomes with the independent variables analysed.*

Variables	CL presence		CL completeness	
	X^2	*p-value*	X^2	*p-value*
Type of hospitalization	0.240	0.624	1.968	0.161
Type of care	5.572	0.018*	3.290	0.070
Surgical specialty	12.746	0.007*	2.662	0.616
Anesthetic risk (ASA)	15.882	0.001*	3.166	0.366
Surgery shift	0.073	0.964	1.778	0.411
Surgery duration	4.341	0.466	4.220	0.589
Anesthesia type	1.713	0.425	0.494	0.781
Surgery classification regarding urgency	0.000	0.983	2.484	0.155
Surgery classification regarding contamination potential	4.275	0.155	0.535	0.911
Length of hospital stay	6.657	0.036	1.880	0.391

** Variables which showed significant association with the outcome.*

P6= patient with declared brain death, organ donor), it was found that patients classified as P3, when compared to patients classified as P1, had a 72.3% reduction (OR: 0.28; 95%CI: 0.10-0.78) in the chance of having CL in their medical records (Table 4). The other variables were not significant in the logistic regression model when analysing their joint influences. In the sample, no patient was classified as P5 or P6.

Table 4. *Multivariable analysis for the CL-presence outcome in the medical record of surgical patients.*

Variables	Crude analysis		*Adjusted analysis*	
	OR*	95% CI	OR*	95% CI
Type of care				
SUS	1.00	–	1.00	–
Health insurance/Private	3.52	1.17-10.64	2.82	0.92-8.76
Specialty				
General Surgery	1.00	–	1.00	–
Gynecology and Obstetrics	1.85	0.31-11.33	1.90	0.31-11.93
Orthopedics and Traumatology	1.19	0.22-6.03	1.00	0.19-5.23
Cardiothoracic and Vascular	0.20*	0.05-0.76	0.35	0.07-1.81
Others	0.68	0.15-3.13	0.63	0.13-3.06
Anesthetic risk (ASA)**				
P1	1.00	–	1.00	–
P2	2.19	0.56-8.60	2.19	0.56-8.62
P3	0.24*	0.09-0.66	0.28*	0.10-0.78
P4	0.25	0.03-2.29	0.25	0.26-2.39
Surgery classification regarding contamination potential				
Clean	1.00	–	1.00	–
Potentially contaminated	2.00	0.69-5.90	1.35	0.40-4.52
Contaminated	0.88	0.19-4.14	0.48	0.09-2.59
Infected	0.47	0.12-1.78	0.34	0.08-1.42
Length of hospital stay				
1-3 days	1.00	–	1.00	–
4-7 days	0.47	0.13-1.69	0.50	0.10-2.40
More than 7 days	0.28*	0.10- 0.78	0.63	0.13-2.87

** Variables which showed significant association in multivariable analysis; ** ASA: American Society of Anestesiology.*

DISCUSSION

In the context of concern for patient safety in healthcare organizations, the safe surgery CL emerges as a tool with the potential to coordinate surgical care, promote team unity, stimulate the development of a safety culture, and contribute to reducing complications[19]. The importance of CL adherence is based on the complexity of the surgical environment, where professionals are subject to fallibility of memory and attention, especially in routine issues, which can be easily overlooked[20].

The results found here showed that the CL was present in the vast majority of the medical records (95%), suggesting that the surgical team endeavored to use it. Even though the completely filled-out instrument was found in only 67.4% of the medical records, the incomplete instruments had a high percentage of filling out. International studies conducted in England and Canada have also found a high percentage of adherence, with values of 96.7% and 92%, respectively[21,22].

The incompleteness of the instruments has been a constant result in national and international studies on CL adherence[13,17,23,24]. In the first Brazilian study which has estimated adherence to the instrument, the CL has been found in 60.8% of the records, with complete filling out in only 3.5% of them[18]. In more recent research, the CL has been found in 90.72% of the medical records. However, none of the instruments has had complete filling out[23]. In all studies, the authors have concluded that the effectiveness of CL on patient safety has crucially depended on the completeness of the instrument.

Another relevant finding here refers to the small difference between the percentage of filling out of each surgical moment. While other studies have found differences[17,18,21], in this one, the percentage remained similar. The results suggested that the verification of safety items occurred during the period in which the patient was in the operating room, which could contribute to the achievement of good safety practices.

At the study site, the responsibility for conducting the safety CL lies with the room circulating nurse, with the active participation of the anesthesiologist in the first moment and surgeon in the second moment. Thus, some checking items are the responsibility of specific professionals. In this study, as there was no significant difference in the filling out percentages of the items, the results suggested that surgeons, as well as other team members, were committed to the filling out adherence to the instrument.

When the consistency of the checked items was analysed considering the surgical procedure performed, some CLs presented inconsistencies in the filling, especially in relation to the confirmation of laterality item. Besides, we found medical records of patients with allergy recorded in the preoperative, but which was not confirmed in the surgical safety CL. Checking laterality is the responsibility of the surgeon, while the existence of allergy is confirmed by the anesthesiologist. Checking laterality and the existence of a known allergy is essential to avoid potentially serious events that cause permanent disabilities or deaths[1].

In a survey which has analysed the responses of 502 orthopedic surgeons to a safe surgery CL questionnaire, it has been found that 40.8% of professionals have confirmed that they had already seen at least one surgery accomplished in the wrong patient or at the wrong site.

In addition, 25.6% of them have considered that communication failure among surgical team members has been the determining factor for the occurrence of the event[25].

The existence of inconsistencies in safety checking suggests inadequate guidance on CL, its importance, and purpose, besides weaknesses in interaction and communication among the professionals involved and little valorization of the tool. Thus, inconsistencies should be carefully evaluated and become the object of future interventions[17].

The experiences related to the use of the safe surgery CL have evidenced many problems in application and execution fidelity, such as absence of the multidisciplinary team in the checking, non-verbalized checking of its safety items, and resistance to its use by professionals[26]. In this sense, it is essential that the surgical team be involved with the use of the instrument and know the purpose and importance of each checking item, avoiding inconsistencies in filling out and limitations in obtaining pieces of information that should be requested during the safety checking[17].

Regarding factors associated with adherence, in the bivariate analysis, some variables in this study showed significant association with the CL-presence outcome in the medical record. However, most of them lost relevance in the multivariable model, remaining only the "anesthetic risk" variable. It is relevant to mention that some studies have found significant association with some variables studied here: surgery duration, showing better adherence in longer surgeries[17,18]; length of hospital stay, showing better adherence in prolonged hospitalizations; and classification of the procedure according to urgency, with better use of the instrument in elective surgeries[23].

In this study, the "anesthetic risk" variable was associated with CL-presence in the medical record, indicating that patients with moderate to severe systemic diseases (P3) were less likely to have the CL in the medical record when compared to healthy patients (P1). This result demonstrates an important weakness in the CL use, since patients at higher risk of complications and death have been deprived of a safety checking, which would be essential to anticipate unexpected situations and provide adequate planning, avoiding worsening of the patient's condition.

In the study scenario, the main barrier reported to the CL use was resistance by surgeons, especially residents, to verbally confirm the safety items under their responsibility. This situation may be related to the context of CL implementation in the institution which did not involve surgeons' participation in the training moments. Only PNSP members participated in the process, assuming the responsibility of disseminating information regarding the use of the tool to residents and surgeons, which was not systematically performed. A review on CL adherence has revealed that the use of the tool is more effective when physicians are actively involved in the implantation process, assuming leadership roles together with the surgical team[27].

It is important to highlight that the CL use itself is not an isolated solution capable of promoting safe surgical care. For the tool be a transformation tool in surgical care, it is recommended to invest in the development of strategies to promote patient safety culture, involving patients, managers, and health professionals, not just surgeons[11]. In addition, it is essential to periodically evaluate CL adherence and provide feedback to surgical teams about the indicators of the instrument's effectiveness in reducing complications[18,28].

Regarding the limitations of this study, it is noteworthy that the results reflect the context of the CL use in a single hospital, considering all its singularities. Therefore, comparisons with other realities should be performed with caution. In addition, data collection was performed through a retrospective observation of already filled-out instruments, with no direct observation of their applications. It is understood that the filling out checking itself does not guarantee the effective CL use, according to WHO recommendations regarding verbal item checking with the participation of the patient and members of the surgical team.

Our study made it possible to know the use of the safe surgery CL in a large general hospital, providing the identification of problems and factors associated with the use of this tool. The instrument was found in most medical records, but the results revealed weaknesses in the checking expressed by the existence of incompleteness and inconsistencies. In addition, patients at higher risk of complications and deaths were less likely to have the CL in the medical records. This reality may influence the achievement of positive results for safety in surgical care.

It is evident the need to implement actions to develop/enhance patient safety culture in the institution, also involving surgeons. Such actions should go through the training and qualification of the surgical team in order to stimulate recognition of the importance of using the CL properly. In addition, it is essential to insert contents related to patient safety in medical education, sensitizing students about the relevance of safety actions in surgical practice.

Future investigations should be performed with the objective of verifying the CL use in the reality of the operating room, contributing to elucidate the adherence of professionals to verbal checking, and not just to the filling out of items. In addition, studies should also be developed with the objectives of identifying other factors related to the adherence to the instrument and measuring the effect of the CL use on damage occurrence associated with surgery.

R E S U M O

Objetivo: *identificar a adesão ao checklist de cirurgia segura, a partir do seu preenchimento, em um hospital geral de referência do interior do Estado de Minas Gerais, bem como, verificar os fatores associados à sua utilização.* **Métodos:** *trata-se de estudo transversal, documental, retrospectivo de abordagem quantitativa. A coleta de dados foi realizada por meio da revisão retrospectiva de prontuários de uma amostra de pacientes operados no período de um ano. Foram incluídos os atendimentos de pacientes cirúrgicos de todas as especialidades, com idade de 18 anos ou mais, e período de internação igual ou maior do que 24 horas. A amostra probabilística foi de 423 casos.* **Resultados:** *o checklist estava presente em 95% dos prontuários. Porém, apenas 67,4% deles estavam com preenchimento completo. A presença do checklist no prontuário apresentou associação significativa com o risco anestésico do paciente. Não houve diferença no percentual de preenchimento entre os três momentos do checklist: antes da indução anestésica (sign in), antes da incisão cirúrgica (time out ou parada cirúrgica) e antes do paciente deixar a sala de cirurgia (sign out). Também não foram encontradas diferenças significativas em relação ao percentual de preenchimento dos itens de responsabilidade do cirurgião. Considerando o procedimento cirúrgico realizado, foram encontradas incoerências no item lateralidade.* **Conclusão:** *apesar do elevado percentual de prontuários com checklist, a presença de incompletude e incoerência pode comprometer os resultados esperados na segurança do paciente cirúrgico.*

Descritores: *Lista de Checagem. Segurança do Paciente. Procedimentos Cirúrgicos Operatórios..*

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