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Analysis of the registration and content of surgical safety checklists

Análise do registro e conteúdo de checklists para cirurgia segura Análisis del registro y contenido de checklists para una cirugía segura

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ABSTRACT

Objective: To analyze and relate the registration of information and content of checklists with the objectives of the Safe Surgery Saves Lives Program. Methods: Documentary study with 257 checklists from orthopedic surgeries performed between 2011 and 2012 in a Brazilian hospital. The 12,629 items related to surgical safety were entered into an Excel spreadsheet and were analyzed using the Statistical Package for the Social Sciences. Results: 99.8% of the checklist items were checked and the content of the records showed, through documental checks, no guarantee of safety elements relative to the correct surgical site (objective 1), blood loss (objective 4), allergic reaction (objective 5) retention of instruments/compresses (objective 7), identification of surgical specimens (objective 8) and communication (objective 9). Conclusion: The high adherence to completing the checklists allowed potential surgical risks arising from unconfirmed safety actions to be identified, requiring actions seeking to qualify the care.

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

RESUMO

Objetivo: Analisar e relacionar o registro de informações e conteúdo dos *checklists* com os objetivos do Programa Cirurgias Seguras Salvam Vidas. **Métodos**: Pesquisa documental com 257 *checklists* de cirurgias ortopédicas realizadas de 2011 a 2012 em hospital brasileiro. Os 12.629 itens relativos à segurança cirúrgica alimentaram planilha do programa Excel e foram analisados com auxílio do programa *Statistical Package for the Social Sciences*. **Resultados**: 99,8% dos itens do *checklist* foram verificados e o teor dos registros evidenciam não garantia, por meio da checagem documental, de elementos de segurança relativos ao local cirúrgico certo (objetivo 1), perdas sanguíneas (objetivo 4), reação alérgica (objetivo 5), retenção de instrumentais/compressas (objetivo 7), identificação de espécimes cirúrgicos (objetivo 8) e comunicação (objetivo 9). **Conclusão**: A alta adesão ao preenchimento do *checklist* permitiu identificar potenciais riscos cirúrgicos decorrentes de ações de segurança não confirmadas, exigindo ações em busca da qualificação da assistência.

Palavras-chave: Lista de Checagem; Segurança do Paciente; Procedimentos Cirúrgicos Operatórios.

RESUMEN

Objetivo: Analizar y relacionar el registro de informaciones y contenido de *checklists*, con los objetivos del Programa Cirugías Seguras Salvan Vidas. **Métodos:** Investigación documental con 257 *checklists* de cirugías ortopédicas realizadas en 2011 y 2012, en hospital brasileño. Los 12.629 ítems de seguridad quirúrgica fueron inseridos en una hoja de cálculo del Programa Excel y analizados en el Programa *Statistical Package for the Social Sciences*. **Resultados:** El 99,8% de los ítems fueron verificados, pero el contenido de los registros demuestra no garantías, por medio de la comprobación, de elementos de seguridad acerca del local quirúrgico correcto (objetivo 1), perdidas de sangre (objetivo 4), reacción alérgica (objetivo 5), retención de instrumentales/gasas (objetivo 7), identificación de muestras quirúrgicas (objetivo 8) y comunicación (objetivo 9). **Conclusión:** La adhesión al completar el *checklist* ha permitido identificar potenciales riesgos quirúrgicos resultantes de acciones de seguridad no confirmadas, exigiendo acciones para la calificación de la asistencia.

Palabras-clave: Lista de Verificación; Seguridad del Paciente; Procedimientos Quirúrgicos Operativos.

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INTRODUCTION

Deaths by errors or complications from the assistance in health care have contributed to the beginning of a worldwide movement in order to promote patient safety, defined as the reduction to the minimum of the acceptable risk associated to health care¹.

In the context of care to the surgical patient, global estimate showed that half of postoperative complications were avoidable², highlighting the potential level to prevent damages. In this context, in 2009, the World Health Organization (WHO) launched the program "Safe Surgeries Save Lives", which is part of the second Global Patient Safety Challenge. The program includes 10 key objectives presented in Chart 1¹.

As a strategy to achieve the proposed objectives, the WHO recommends health institutions to use a Checklist to be filled in at three stages or moments: before anesthetic induction, before the surgery and before the patient leaves the operating room.

The instrument aims at checking the items that could compromise patient safety¹, regardless of the team's memory fallibility. It strengthens the scan memory and encourages the discipline of high performance³; its application have showed a decrease from 11% to 7% of surgical complications and 1.5 to 0.8% of deaths associated to surgical procedures⁴. In Brazil, the Ministry of Health instituted in 2013, the Safe Surgery Protocol, which calls for the systematic use of the Checklist⁵, and constitutes the National Program for Patient Safety⁶.

As part of institutional actions to promote quality of care, and following the WHO recommendations¹, in 2010 a university hospital in the south of Brazil implemented the Checklist, initially in orthopedic surgeries, and adapted it to the reality of the institution. This instrument is distinguished from the model proposed by the WHO¹ for it includes a verification step during the patient reception at the surgical center, making it a total of four stages.

Orthopedic surgeries involve multiple and bilateral structures, such as arms and legs, fingers, ribs and vertebrae, and present higher risk of surgical error. Those can be preventable

through the surgical site demarcation prior to surgery⁷. A study carried out in 2012 with 502 Brazilian orthopedists showed that 65.3% of them reported partial or total unawareness of the WHO Program; 72.1% said they had not received training for the application of the Safe Surgery Protocol, although 63.5% did the site demarcation prior surgery. Only 37.1% of the participants recognized that the protocol is important for the safety of the patient.

From the principle that situational diagnoses contribute to the process of improvement actions¹, this study aimed at analyzing the information record and the content of the Checklists, and relate their results with the objectives of the WHO Safe Surgeries Save Lives program¹.

METHODS

Quantitative approach, documental, held in 2013, at the central operating room of a university hospital in the south of Brazil. Orthopedic surgeries were pioneers as for the use of the Safe Surgery Checklist, which justifies its choice for this research.

Inclusion criteria in this study comprise documents characterized as Checklists related to orthopedic surgeries performed from January 2011 to June 2012, in that surgical center and available in the hospital file. In this period there were three different models at use as checklists in accordance with the modifications made by the institution to the originally adopted model. There was no exclusion criteria, since all checklists, partially or totally filled in were considered.

The variable considered (record of checklist items) refers to the filling, or not, of the instrument items, patient identification, booking of the surgical site, blood supply, allergic patient identification, documentation and communication, among others. Each item to be checked allowed the registration of the answer yes, no and in some cases, not applicable, and indicated the completion of a single alternative.

For data collection a spreadsheet was created in the Microsoft Excel® 2007 version program containing all items to be checked of the three models adopted in the period of this research,

Chart 1. Objectives of the program "Safe Surgeries Save Lives". World Health Organization, 2009

- 1. The team will operate on the correct patient at the right surgical site.
- 2. The team will use methods known to prevent harm from anesthetic administration, while protecting the patient from pain.
- 3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
- 4. The team will recognize and effectively be prepared for risk of major blood loss.
- 5. The team will avoid inducing an allergic or adverse drug reaction known to be a significant risk to the patient.
- 6. The team will consistently use methods to minimize the risk of surgical site infection.
- 7. The team will prevent inadvertent retention of sponges or instruments in surgical wounds.
- 8. The team will secure and accurately identify all surgical specimens.
- 9. The team will effectively communicate and exchange critical patient information for the safe conduct of the operation.
- 10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results.

and the responses were recorded through number codes established by the researchers. Invalid response was applied when filling was unreadable, double or blurred. Data were checked by double typing and the discrepancies were corrected; the analysis was done using descriptive statistics, using the computer program Statistical Package for Social Sciences, the blue version 20.0. The results, presented in relative and absolute frequencies, were organized according to the steps of checking and associated with the corresponding objectives of the WHO program¹.

This study was approved under registration CEP/SD 1102.027.11.04 and met the principles of the Ethics Committee.

RESULTS

257 filed checklists were consulted; among the 12,629 items checked, 8.5% (n = 1,071) were not answered. Among the 11,558 (91.5%) responded items, 99.8% (n = 11,537) were understandable and 0.2% (n = 21) were not understandable. The results were related to the objectives of the WHO¹ program and are presented in accordance to each checking step tables. In table 1, data of the first step of the check list is presented and is related to the reception of the patient to the operating room.

Table 2 presents data from the checking stage carried out before anesthetic induction, with the patient in the operating room.

Table 3 shows the checking of the elements before the surgical incision, also called surgical step or time out.

In table 4 items related to the fourth and the final verification step before the patient leaves the operating room are presented.

DISCUSSION

In this study 91.5% of the items of the checklists were filled in, 0.2% were invalid, such result is similar to other studies^{8,9} and evidence the challenge of the adherence to practices of checking and registering elements that are essential to the safety of the surgical patient.

The lack of completion of the records directs to actions that include reorientation and team motivation, identification and understanding of factors that hinder the full verification, as well as elucidation and discussion of ethical and legal aspects that involve professional performance. The checking items aim at preventing adverse events and ensuring the safety of the surgical patient. They are based on the objectives pre-established by the WHO¹, which guide the discussion of the results presented in this research.

Considering the first objective¹, which refers to guaranteeing that surgeries are performed on the correct patient at the anatomic site, the results presented emphasize the importance of the conference of patient identification, since it ranged from 89.1% to 98%. Identifying the patient is an essential task to ensure that assistance is given to the correct person through the possibility of switching patients¹⁰. In this context, the Patient Identification protocol is recommended by the Brazilian Health Ministry for all institutions that provide health care⁵. Besides the patient identification, the surgery at the correct surgical site is essential once surgeries on correct patients, but wrong surgical site¹ are evidenced by the WHO as one of the challenges to be faced.

Table 1. Completion of items related to the reception of the patients to the operating room and to the corresponding objectives of the WHO program "Safe Surgeries Save Lives". Curitiba, from 2011 to 2012

Item (Objective)	Yes n (%)	No n (%)	Not applicable n (%)	Invalid n (%)	Not answered n (%)	Total* n (%)
Identified patient (Objective 1)	229 (89.1%)	13 (5.1%)	-	1 (0.4%)	14 (5.4%)	257 (100%)
Pre-anesthetic evaluation (Objectives 2, 10)	226 (88%)	15 (5.8%)	-	-	16 (6.2%)	257 (100%)
Surgical Consent (Objectives 9, 10)	245 (95.3%)	3 (1.2%)	-	-	9 (3.5%)	257 (100%)
Anesthetic consent (Objectives 9, 10)	152 (66.1%)	55 (23.9%)	-	-	23 (10%)	230 (100%)
Nursing evaluation (Objectives 9, 10)	68 (89.5%)	6 (7.9%)	-	-	2 (2.6%)	76 (100%)
Surgical site set (Objective 1)	166 (64.6%)	21 (8.2%)	49 (19%)	-	21 (8.2%)	257 (100%)
Fasting (Objective 3)	247 (96.1%)	2 (0.8%)	-	-	8 (3.1%)	257 (100%)

^{*} Total of instruments that comprised the item.

Table 2. Completion of items related to the step before induction of anesthesia and corresponding objectives of the Surgery Program Secure Saves Lives WHO. Curitiba, from 2011 to 2012

Item (Objetive)	Yes n (%)	No n (%)	Not applicable n (%)	Invalid n (%)	Not answered n (%)	Total* n (%)
Confirmed identity (Objective 1)	252 (98%)	-	-	1 (0.4%)	4 (1.6%)	257 (100%)
Surgical site set (Objective 1)	200 (77.8%)	15 (5.9%)	35 (13.6%)	-	7 (2.7%)	257 (100%)
Blood reserve (Objective 4)	133 (51.8%)	98 (38.1%)	3 (1.2%)	-	23 (8.9%)	257 (100%)

^{*} Total of instruments that comprised the item.

Table 3. Completion of items related to the step before surgical incision and corresponding objectives of the WHO program Safe Surgeries Save Lives. Curitiba, from 2011 to 2012

Item (Objetive)	Yes n (%)	No n (%)	Not applicable n (%)	Invalido n (%)	Not answered n (%)	Total* n (%)
Staff is introduced by their names and functions (Objective 9)	13 (48.2%)	8 (29.6%)	0	1 (3.7%)	5 (18.5%)	27 (100%)
Confirms identity and patient with identification (Objective 1)	243 (94.1%)	5 (1.9%)	0	0	10 (3.9%)	258 (100%)
Surgical site set (Objective 1)	198 (77%)	13 (5.1%)	38 (14.8%)	0	8 (3.1%)	257 (100%)
Allergic patient (Objective 5)	17 (9.4%)	147 (81.2%)	0	1 (0.6%)	16 (8.8%)	181 (100%)
Antibiotic prophylaxis (Objective 6)	219 (85.2%)	10 (3.9%)	0	0	28 (10.9%)	257 (100%)

^{*} Total of instruments that comprised the item.

Table 4. Completion of items related to the stage before the patient leaves the operating room and corresponding objectives of the WHO program Safe Surgeries Save Lives. Curitiba, from 2011 to 2012

Item (Objetive)	Yes n (%)	No n (%)	Not applicable n (%)	Invalid n (%)	Not answered n (%)	Total* n (%)
Anesthetic file (Objective 10)	235 (91.4%)	1 (0.4%)	-	-	21 (8.2%)	257 (100%)
Surgical description (Objective 10)	217 (84.4%)	2 (0.8%)	-	-	38 (14.8%)	257 (100%)
Instrumental counting (Objective 7)	199 (77.4%)	19 (7.4%)	4 (1.6%)	1 (0.4%)	34 (13.2%)	257 (100%)
Counting of compresses (Objective 7)	190 (73.9%)	16 (6.2%)	31 (12.1%)	-	20 (7.8%)	257 (100%)
Counting of gauzes (Objective 7)	123 (47.9%)	37 (14.4%)	44 (17.1%)	-	53 (20.6%)	257 (100%)
Identified samples (Objective 8)	35 (13.6%)	71 (27.6%)	120 (46.7%)	-	31 (12.1%)	257 (100%)

^{*} Total of instruments that comprised the item.

This study showed that less than 80% of surgical sites were set, allowing adverse events. In a study carried out in Sweden only 25% (n = 24) of the observed surgeries had their site previously set by the staff 11 . The identity of the patient was confirmed in 83% of the opportunities. It is noted that where the surgical specialties involve double handedness, such as orthopedics, the possibility of error is even higher.

The confirmation of the patient's identity is also associated with safety in medication administration, including pain killers. It is evidenced then that the use of methods in preventing the damage in this context, is one of the check items that concern to the pre-anesthetic evaluation, gives opportunity to unfavorable conditions for surgery to be identified beforehand; the surgery should not be performed if there is any disagreement^{1,12}. In this sense, the results of the survey show that in 88% of the procedures the evaluation was carried out; and validates a study that highlighted the importance of this evaluation and demonstrated the low incidence of anesthetic complications after their systematic adoption¹².

Another safety feature is the verification of the preoperative fasting, linked to the objective 3 which calls for the preparation of staff for air loss or respiratory function. Fasting wasn't confirmed in all surgeries (96.1%) although it is a key element to ensure

gastric emptying, avoiding aspiration, complications due to occlusion of airway¹.

The reserve of blood and intravenous access, with fluid planning, are items related to the objective 4 - the preparation of the team for the risk of major blood loss¹. The national protocol for Safe Surgery calls for a previous discussion by the team on risk of critical events during the procedure, and recommends a review of surgical planning, with inclusion of checking the condition of equipment and prediction of fluid replacement and blood components reserves⁵. The survey data show that in 51.8% of the procedures there was reserve of blood. Researchers emphasize the importance of blood transfusion in order to maintain hemoglobin levels, blood volume and favorable clotting factors for a safe surgical procedure¹³, This item must be contemplated before the operation when the risk of blood loss is greater than 500 ml in adults, or 1 ml per kilogram of body weight for children¹.

Given the objective 5 - the team will avoid the induction of adverse reaction to drugs or allergic reaction known as a risk to the patient, the results of this research express checking of 90.6%, similar frequency to another Brazilian study in 2012 that showed that the conference of allergies in 94% of cases. It implies that the items better filled in at checklist are the ones

related to risk of death. Therefore, the previous knowledge of this condition results in promoting security, prevention of complications and reduced risk of death¹.

Another study highlighted that nearly half of the adverse events in hospitalized patients was preventable, most of them related to surgery and use of medications¹⁴. Thus, investigating the status of the clinical conditions and the allergic status of the patients, through the proper evaluation and surgical planning, is an effective measure for the safety of the patient. As a member of the institutional checklist, the nursing assessment, performed preoperatively includes such research, and was performed in 89.5% of the procedures.

In order to minimize the risks of infection of the surgical site, corresponding to the objective 6, the team should confirm the use of antibiotic prophylaxis in the 60-minute period before the surgical incision⁵; This time coincides with the largest therapeutic level of the antibiotic at the time of tissue exposure to microorganisms^{1,5}. This study showed the antibiotic prophylaxis was confirmed in 85.2% of the surgeries. It should be noted, also, the importance of established protocols to be applied and known by the teams, since improper use can induce resistance of microorganisms, rather than provide protection¹.

The objective 7 refers to checking items before the patient leave the operating room, to make sure that all materials used were not retained in the operative field, avoiding damages to patients. The institutional checklist includes counting the surgical instruments and needles, bandages and gauze; however, checking ranged from 47.9 to 77.4%, which corroborates to a study conducted at the same institution, in which there was no significant application of checking those items¹⁵. The inadvertent retention of materials results in hospitalization, surgery, hospital expenses and even death, stressing the importance of counting the materials, as well as the adoption of additional measures, such as taking x-rays when the count is uncertain^{1,16}.

Regarding security and identification of surgical specimens by the team, the objective 8 of the WHO program, the study noted that 27.6% of the samples were identified and in 12.1% of the instruments this item wasn't answered. The use of a system of requisition of tests and identification of samples contribute to the reduction of error in samples, adverse events and damages to patients, which may incur a misdiagnosis and delays in treatment^{1,17}.

In addressing the issue of effective team communication and the exchange of information for operational security (objective 9), it was observed in this research a low application to the related items. The presentation of the time immediately before the surgical incision, along with the review of the surgical plan and of the possible complications (time out), occurred only in 48.2% of the procedures, similar to the Swedish study which showed that in 58% of the procedures the staff was introduced by name and the function 11. This measure

provides greater familiarity among professionals, sense of personal empowerment and knowledge of the attributes of each member; at an unexpected situation it allows greater flexibility in the intervention^{1,11}.

The tenth and final goal of the WHO program¹ states that hospitals and public health systems should establish routine surveillance of the surgical capacity, volume and results. Documents such as the nursing preoperative evaluation and the pre-anesthetic, anesthetic and surgical description consist an important source of information related to the patient's welfare and the quality of the services provided. These items were confirmed at 89.5%; 88%; 84.4% and 91.4%, respectively, requiring a greater movement to its filling, since they also consist of documents used in auditing and investigation of aggravation and post-operative death.

The written records contribute to the quality of care and correspond to evaluation indicators, and in the present context, is an indicator of process and result¹⁸. In health care institutions in Brazil, the Patient Safety Center is responsible for the analysis of records of incidents⁶. Documents related to hospital care constitute the record of relevant information in the chain of investigation of events, including surgical procedures, infections, surgical errors and occupational exposure to biological material. Thus, the records subsidize evaluation, revealing the conditions under which health services are provided and direct them to the safer practices.

The limitations of this study are related to the approach of the local reality and the specific surgical specialty. However, considering that the initiatives of the WHO and the Brazilian Health Ministry may still be considered recent, the results presented, along with other national studies, can contribute to better understand the Brazilian reality in the investigated theme.

CONCLUSIONS

The results of the research allowed us to learn about the frequency of completion and the contents of checklists related to surgical safety in orthopedics. There was a high frequency of items answered reflecting the adoption by the team to the completion of the instrument, applying knowledge of the institutional program. However, the lack of completion of the records shows that safe actions, according to the documents, have been neglected by the surgical team.

The contents of the documents analyzed show that the surgical team failed to ensure, by means of documentary checks, several objectives established by the WHO, notably the security features for the correct surgical site (objective 1), preparation for major blood loss (objective 4), allergic reaction prevention (objective 5) and retention of instruments or swabs (objective 7), and identification of surgical specimens (objective 8), as well as effective communication between staff (objective 9).

The results can support the planning of institutional corrective actions in order to check and record all items of the checklist and thus contribute to the full implementation and excellence of the "Safe Surgeries Save Lives" program in the institution and, most importantly, to develop a professional practice focused on the patient. This study will be able to guide activities aimed at promoting the culture of safety and awareness of health professionals, leaders and managers and patient safety in the operating room; as well as serve as a parameter in relation to completing the checklist for further investigations.

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