SURGICAL SAFETY CHECKLIST: ANALYSIS OF ITS ELABORATION AND IMPLEMENTATION IN TWO TERTIARY HOSPITALS

Protocolo de cirurgia segura: análise da produção e execução em dois hospitais terciários

Protocolo de cirugía segura: análisis de producción y ejecución en dos hospitales terciarios

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ABSTRACT: Objective: To analyze the process of elaboration and implementation of the surgical safety checklist in two tertiary hospitals in the city of Manaus. **Method:** This study was based on design thinking, focusing on the double diamond technique. It was conducted in two public hospitals in Manaus, from July 2018 to March 2019. The following stages were adopted for this research: investigation (observation and questionnaire) and intervention (synthesis, ideation, and delivery). **Results:** The first stage, consisting of 120 hours of observation, showed the non-fulfillment of the three phases of the process. After analyzing the answers to the 63 questionnaires, we confirmed the non-adherence to the checklist. Based on these findings, the synthesis phase focused on the use of the checklist; the ideation phase involved the proposal of solutions and the pilot testing; the delivery phase concluded the cycle by providing solutions to the hospitals. **Conclusion:** The analysis of the process of implementation of the checklist indicated non-compliance, suggesting risk to patient safety. After delivery and implementation, the tested solution may contribute to the effective execution of the checklist.

Keywords: Patient safety. Surgery department, hospital. Perioperative nursing.

RESUMO: Objetivo: Analisar o processo de produção e execução do protocolo de cirurgia segura em dois hospitais terciários do município de Manaus. **Método:** Pesquisa guiada pelo *design thinking*, com ênfase na técnica do duplo diamante, realizada em dois hospitais públicos no município de Manaus, de julho de 2018 a março de 2019. Foi feita nas etapas: investigativa (observação e questionário) e interventiva (síntese, ideação e entrega). **Resultados:** Na primeira etapa, com 120 horas de observação, constatou-se que as três fases do protocolo não foram cumpridas; analisando-se as repostas a 63 questionários, reforçou-se a não adesão ao *checklist*. Com base nesses achados, na etapa de síntese, elegeu-se como foco a aplicação do *checklist* do protocolo; na etapa de ideação, realizou-se a proposição de solução e a testagem-piloto; a etapa de entrega da solução aos hospitais encerrou o ciclo. **Conclusão:** A análise do processo de execução do protocolo indicou seu descumprimento, o que sugere o comprometimento da segurança do paciente. A solução testada poderá, após entrega e implementação, contribuir para a execução efetiva do protocolo.

Palavras-chave: Segurança do paciente. Centro cirúrgico hospitalar. Enfermagem perioperatória.

RESUMEN: Objetivo: Analizar el proceso de producción y ejecución del Protocolo de Cirugía Segura en dos hospitales terciarios de la ciudad de Manaus. **Método:** Investigación guiada por *Design Thinking,* con énfasis en la técnica *Double Diamond,* llevada a cabo en dos hospitales públicos de la ciudad de Manaus, desde julio de 2018 hasta marzo de 2019. Se realizó por etapas: de investigación (observación y cuestionario) e intervencionista (síntesis, ideación y entrega). **Resultados:** En la primera etapa, con 120 horas de observación, se encontró que las tres fases del protocolo no se cumplieron; En base a las respuestas a 63 cuestionarios, se reforzó la no adhesión a la lista de verificación. Con base en estos hallazgos, en la etapa de síntesis, la aplicación de la lista de verificación del protocolo fue elegida como el foco; en la etapa de ideación, se llevaron a cabo la propuesta de solución y la prueba piloto;

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Received: 04/16/2019 – Approved: 07/22/2020
https://doi.org/10.5327/Z1414-4425202000030002

La etapa de entrega de la solución a los hospitales finalizó el ciclo. **Conclusión:** El análisis del proceso de ejecución del protocolo indicó incumplimiento, lo que sugiere comprometer la seguridad del paciente. La solución probada puede, después de la entrega y la implementación, contribuir a la ejecución efectiva del protocolo.

Palabras clave: Seguridad del paciente. Servicio de cirugía en hospital. Enfermería perioperatoria.

INTRODUCTION

The concern with patient safety in health facilities has globally increased. Research in this area started in 1974 and reached a significant milestone in 1999, after the Institute of Medicine report, *To Err is Human*, published results of a study conducted in hospitals of the United States of America (USA). The findings revealed that approximately 100 thousand people died from adverse events, that is, damage caused during care and not associated with the patient's disease[1].

The international mobilization to promote patient safety reached Brazil in 2001 when the Sentinel Hospital Project was created to increase and systematize the surveillance of products used in health services, ensuring better safety and quality for patients and professionals[2]. In 2008, the Pan American Health Organization (PAHO) established the Brazilian Network for Nursing and Patient Safety (*Rede Brasileira de Enfermagem e Segurança do Paciente* – REBRAENSP) to disseminate the patient safety culture to health facilities, workers, and families of patients[3].

The World Health Organization (WHO), with the aid of collaborators from several countries, developed a surgical safety checklist (SSC) for the perioperative period, guided by three principles: simplicity, broad applicability, and the possibility of impact measurement. Thus, it allows the teams to follow critical safety steps efficiently and minimize the most common avoidable risks endangering the lives and well-being of patients[3,4].

In 2009, the Ministry of Health, together with PAHO, published guidelines in Portuguese to implement measures for the patient safety project Safe Surgery Saves Lives. In a study carried out in 2009 and 2010, complications decreased by 36% and mortality by 47% in surgical patients after the establishment of safe surgery[4]. Patient safety is part of a care axis committed to providing a service free of harm and accidental injuries during the delivery of health care[4].

The SSC created by the WHO has been implemented in Brazilian hospitals to ensure the safety of surgical patients[4,5]. It is considered a tool that helps foster teamwork among those involved in the anesthesia-surgical procedure, promoting patient safety, in addition to favoring the training of professionals and a better understanding of the actions necessary for strengthening patient safety processes, that is, perceived risk as an effective way of establishing a practical change in preventive measures[5,6].

The nurse who works in a surgical context can identify problems and encourage the development of devices and technological solutions[7]. Possible errors, difficulties, and weaknesses that can jeopardize the safety of surgical patients must be solved with the proper and full use of instruments that provide strategies for safe and quality care[7].

Based on the exposed, we formulated the research question: how can the SSC implementation process be developed in two large general hospitals in the city of Manaus?

OBJECTIVE

To analyze the process of elaboration and implementation of the SSC in two hospitals in Manaus.

METHOD

This is a methodological study[8] based on the stages of design thinking, focused on the double diamond technique[9,10]. In the health field, the design thinking method has been successfully used and has contributed to solving problems in several areas, such as the humanization of services, attention to patient needs, and improvement to perioperative flow[10].

A model proposed for implementing design thinking is the double diamond technique, created by the British Design Council in 2004[11]. The development of the double diamond technique requires the completion of four stages: discovery (research), which seeks to understand the problem to be solved; definition (synthesis), which identifies the area of focus; development (ideation), which elaborates and tests potential

solutions to the problem; implementation (delivery), which provides solutions that work best[10,11].

Thus, this research has adapted the double diamond technique, carrying out the following stages: investigation (discovery – observation and administration of questionnaires), which took place between July and September 2018; intervention (synthesis, ideation with pilot testing, and delivery), between October 2018 and March 2019. Both stages were completed in two surgical centers of two large public hospitals in Manaus, Amazonas, Brazil; one of them is a state hospital, reference in orthopedic surgeries (Hospital A), and the other is a federal university hospital (Hospital B).

A total of 63 professionals participated in the study (14 nurses, 15 surgeons, 13 anesthesiologists, 14 nursing technicians, and 7 surgical technologists). The sample was defined by convenience. The inclusion criteria were: working in one of the two surgical centers and having at least one year of experience in surgical activities.

Data collection was based on non-participant observation (shadowing), supported by the SSC, and an adapted questionnaire[11]. The observation in the two hospitals was performed by the first researcher, after the surgical team agreed and consented to participate, and occurred concomitantly in both facilities (Hospital A in the morning and Hospital B in the afternoon). During the intervals between observations (the end of one surgery and the start of the next), the researcher talked with the professionals about the goals of the study and provided the questionnaire to be filled, which aimed at verifying the knowledge, benefits, difficulties, and suggestions mentioned by the professionals for the implementations of the SSC. The completion of the questionnaire by the surgical team took place at the premises of the surgical center, at times previously scheduled with the participants according to their availability, with subsequent return to the researcher.

Data were analyzed through quantitative descriptive statistics, based on mean and percentage. We performed the distribution of absolute (n) and relative (%) frequencies of the data listed (attributes or nominal data) and the descriptive statistics of quantitative data (specific magnitudes or variables). Data were organized in Microsoft® Excel 2013 and assessed in the Statistical Package for the Social Sciences (SPSS), version 21.

The study complied with ethical aspects at all stages, in agreement with Resolution no. 466/2012 of the National Health Council. The Research Ethics Committee of Universidade Federal do Amazonas (REC/UFAM) approved this project under the Certificate of Presentation for Ethical Consideration (*Certificado de Apresentação para Apreciação Ética* – CAAE) no. 92500817.9.0000.5020. This article is part of the Master's thesis entitled *Programa de cirurgia segura: proposta para consolidar a implementação em dois hospitais públicos terciários em Manaus* (Safe surgery checklist: proposal to consolidate its implementation in two tertiary public hospitals in Manaus).

RESULTS

The investigation stage involved 120 hours of observation, 60 in each hospital, in their respective surgical blocks (SB). The mean number of surgeries observed daily in both hospitals was 20, totaling 200 surgical procedures followed in 10 days in each hospital. These observations focused mainly on the beginning and the end of surgeries.

Regarding the moment before induction of anesthesia (sign in), the surgical site was not marked in 197 procedures (98.5%) in both hospitals, as recommended by the SSC, except for plastic surgery patients. In three procedures (1.5%) of the latter type, the patients were examined by the surgeon or resident physician to confirm the side of the surgery and perform the marking. In these three cases, the marking of the surgical site was not done correctly. With respect to the moment before surgical incision (time out), the nurse was not present during the safety pause in both hospitals. No procedure implemented the time out or had the identification of the surgical team verbally confirmed by each member as to their name and function before surgical incision, as recommended by the SSC.

The observation of the time out allowed identifying items that did not comply with the established by the SSC, such as:

- absence of the nurse at the moment of time out since they were busy with other administrative activities;
- circulating nurse could not verbally run through the checklist because they were performing several tasks in the operating room (OR);
- lack of verbal confirmation of the checklist because no professional was specifically assigned to the task.

Concerning the moment before the patient leaves the OR (sign out), 150 procedures (75%) had instruments, needles, and sponges counted. In the observation period, no surgery reported whether the equipment worked properly during the procedure. About this aspect, 75 procedures (37.5%) had technical failures in the monitoring and reading of parameters, such as pulse oximetry, heart rate, and non-invasive blood

pressure, and the equipment had to be replaced. We noted that equipment such as monitors and anesthesia machines were not tested before the surgical procedures and even had expired calibration or no information as to the last calibration or check by the clinical engineering team.

The second part of the investigation stage consisted of administering the questionnaires, which started with the profile data of the interviewees (Table 1). Among the participants, 30 worked in Hospital A and 33 in Hospital B.

Regarding the second part of the questionnaire, Table 2 shows the percentage of answers to questions 1 to 3, with total data from both hospitals. We underline that the number of participants differs in the second and third questions because 3 of the 63 professionals who comprised the sample reported not knowing the SSC.

About the use of the SSC, the end of the questionnaire asked the professionals to pinpoint its main benefits and the difficulties in its implementation. Table 3 shows the answers collected in both hospitals studied.

The intervention phases (synthesis, ideation with pilot testing, and delivery) occurred after analyzing the previous stage (investigation). In the synthesis phase, a report was drafted, and the checklist was elected as the aspect of focus for subsequent steps. The choice of focus is confirmed by the results of the previous stage, which indicated, among other aspects, that the checklist either arrived filled in the patient's medical records, with the stages stamped, or was filled at the end of the anesthesia-surgical procedure, when each professional completed and stamped their part. This scenario reveals the non-compliance with the protocol recommended by the WHO, according to which the SSC must be completed by a single professional.

The results also emphatically showed the resistance of the entire surgical team in running through the checklist, especially when the surgical procedures took place consecutively, one after the other. Furthermore, in all cases observed, surgeons also demonstrated resistance in verbally presenting the team. As to the existence of a standard, we found no specific rules established for the completion of the checklist in the hospitals.

The ideation phase proposed a solution to the full implementation of the SSC and the pilot testing. A model with five steps, called Five-Step Model, was elaborated as follows:

Table 2. Answers to the SSC questionnaire from hospital professionals.

Questions	Yes n (%)	No n (%)
1. Do you know the WHO SSC? (n=63)	60 (95.2)	3 (4.7)
2. Is the SSC used in all surgeries of this hospital? (n=60)	27 (45.0)	33 (55.0)
3. Do you use the SSC? (n=60)	35 (58.3)	25 (41.6)

SSC: surgical safety checklist; WHO: World Health Organization.

Table 1. Profile of the professionals participating in this study (n=63).

Variable	Profession				
	Nurse	Surgeon	Anesthesiologist	Nursing technician	Surgical technologist
Mean age (years)	34.7	35.5	42.3	39.4	29.3
Mean length of service (years)	6.7	5.5	11.7	10.8	3.5
	n (%)	n (%)	n (%)	n (%)	n (%)
Sex					
Male	6 (43.7)	12 (80.0)	7 (53.3)	4 (37.5)	2 (33.3)
Female	8 (56.3)	3 (20.0)	6 (46.7)	10 (62.5)	5 (66.7)
Degree					
Specialist	14 (87.5)	14 (93.3)	13 (86.6)	0 (0.0)	0 (0.0)
High school	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	7 (100)
Master's	2 (12.5)	1 (6.7)	2 (13.4)	0 (0.0)	0 (0.0)
Residence	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Technician	0 (0.0)	0 (0.0)	0 (0.0)	14 (100)	0 (00.0)

Table 3. Benefits and difficulties of implementing the SSC as indicated by the professionals (n=60).

	Answers	
	n	%
Benefits		
Makes procedures safer	31	51.6
Improves the service	21	35.0
Reduces medical errors	30	50.0
Promotes effective communication	21	35.0
Benefits the health facility	23	38.3
Prevents the use of defective equipment	15	25.0
Difficulties		
Another bureaucratic role	17	28.3
The time out takes too long and delays the service	13	21.6
Lack of knowledge about the SSC by the health team	39	65.0

SSC: surgical safety checklist.

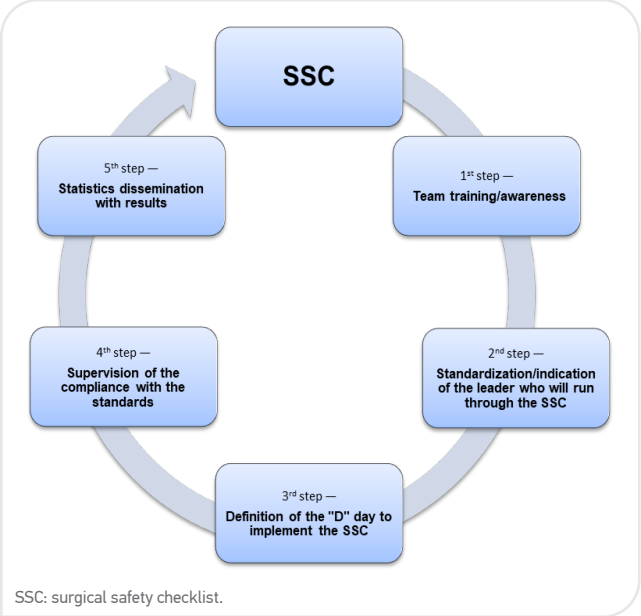

Figure 1. Five-step model proposed to implement the SSC.

- 1st step: training and raising awareness of the surgical team;
- 2nd step: standardization/indication of the leader who will run through the SSC;
- 3rd step: definition of the "D" day to implement the SSC;
- 4th step: supervision of the compliance with the standards;
- 5th point: statistics dissemination with results (Figure 1).

In January 2019, meetings were held in both hospitals to draw support for the pilot testing of the model, with the participation of the director-general, medical director, director of education and research, coordination of medical and nursing residency, coordination of the patient safety center, nursing and SB manager. They agreed on the full adherence to the model and its pilot testing.

Next, the model was tested in both SBs in February and March 2019. In the end, after new daily observation in the two hospitals (for 10 days) and dialog with hospital managers to gather their opinions, we noted an increase in the awareness of the surgical team and more effective use of the SSC. However, in some procedures, the SSC still was not verbally confirmed, and the professionals involved continued to resist its implementation, which shows the need for a medium-term, direct, and ongoing intervention from hospital managers.

DISCUSSION

In the observation period, the results of the first stage (investigation), which assessed the state of the practice as to the procedures that should be performed before induction of anesthesia, such as marking the surgical site, showed that they were not correctly carried out in the two hospitals investigated. According to the SSC, the identification/marking of the surgical site should be performed by the surgeon responsible for the procedure before sending the patient to the OR. The protocol recommends that the patient be awake and aware, if possible, to confirm the site of the procedure. The site where the surgery will be performed should be marked in the patient's body with a marking pen. "The health facility must define processes by writing to deal with exceptions, such as documented patient refusal, so as to ensure surgical safety"[12].

Study shows that about 1 in every 50 thousand surgeries in the USA is performed in the wrong site or the wrong patient, which corresponds to 1,500-2,500 incidents per year. After implementing the SSC in hospital units, "the deaths caused by surgical complications in the wrong site and the wrong patient decreased by almost half (from 1.5% to 0.8%)"[13].

Concerning the time out, that is, the moment before the surgical incision or safety pause, the checklist was not verbally confirmed because no professional was specifically assigned to the task. The same situation was reported in studies

conducted in a university hospital and a general hospital, as during the time out phase, none of the surgeries included the introduction of the surgical team before the procedure, patient identification, and marking of the surgery site[13,14].

At the end of the procedure (sign out), before the patient leaves the OR, the instruments, sponges, and needles must be counted, the surgical specimen must be identified for anatomopathological study, and equipment problems that require servicing must be reported[4]. The observation in both hospitals revealed that the instruments were not counted in the surgeries, even when the surgical technologist was present.

In a study on the inadvertent intracavitary retention of objects, 90% corresponded to textiles, 5.21% to surgical instruments, and 2.84% to needles. Among the reasons reported for this occurrence, the lack of counting was associated with 25% of cases. The most disseminated preventive measure is routinely counting these materials, which is not standardized in many surgical centers[15].

The observation allowed us to reflect on the resistance of professionals to implementing the SSC as a regular practice. Studies indicate that the implementation of the SSC is being stimulated in Brazil. Nevertheless, new routines are not always positively received at first, with resistance by surgical team members, in special surgeons and anesthesiologists, particularly when the effectiveness of the results, although crucial, is not easily demonstrated in the short term[16,17].

With respect to the interviews conducted in the hospitals studied, which involved all 63 (100%) professionals, we found that most of them knew about the existence of the SSC, and only 3 (7%) were had no knowledge of it. Considering that the SSC was implemented, on average, two years before in both hospitals, all professionals should know about it.

This finding corroborates a study that identified many surgeons and surgical residents who did not know the SSC proposed by the WHO and other doctors who, despite having it as a personal application, did not use it[18]. The study also pointed out that, among the nursing team, few members did not know the SSC[18].

Among the advantages of implementing the SSC acknowledged and indicated by the professionals in this study, making the procedure safer was the most cited, followed by reducing medical errors and benefiting the health facility. Considering the exposed, the professionals involved have, in theory, shown trust in the SSC, as they recognized that using it can reduce adverse events, providing more safety to the surgical patient.

As to the difficulties listed by the professionals for the implementation of the SSC, the most frequent answer was the addition of another bureaucratic role to be performed, and also the fact that the time out takes too long and delays the service. The participants also mentioned the team's lack of knowledge about the program. This report confirms the resistance of the target public interviewed to the verbal reading of the checklist, disregarding its role as a tool designed to reduce inherent risks related to the performance of anesthesia-surgical procedures, but shows that they recognize the need for improving knowledge about the SSC among the team.

In a study on adherence to the SSC, 32 publications about the theme identified that "the viability of the surgical safety checklist has become promising in several Brazilian hospitals, although the involvement of the surgical team concerning adherence is still low"[19]. The research indicated the need for a coordinator to facilitate the completion of the checklist, suggesting the nurse as the SB coordinator since they can use this tool as a way of measuring and assessing the care provided to surgical patients[19].

An investigation conducted in the USA on the implementation of the SSC in hospitals concluded that its success is associated with a better perception by the professionals regarding its use, mutual respect among the surgical team, leadership, coordination, and team communication. The study also confirmed that the professionals involved noted an improvement in perioperative safety after the implementation of the SSC[20].

The SSC implementation process is apparently simple but can become complex due to the need for overcoming the team's resistance to change, as they will have their routines in the work environment modified. Also, this change increases with the complexity of the location where the SSC should be implemented[18-20].

With respect to the intervention, after synthesis of the previous stage, we noticed the need for implementing an innovative model for improving the SSC performance, identified after some conflicts, especially the non-acceptance/resistance and the lack of implementation of the full SSC in the hospitals under study. The aim was to contribute some interventions that could reduce such conflicts. In doing so, besides applying the proposed model, we established new practical resources for improving the effectiveness of the SSC, since neither hospital had tools to help implement and execute the program. With the operationalization of the model, we expect a better adherence to the SSC, increasing the quality

of care provided to the surgical patient and helping reduce occasional adverse events and, consequently, hospital costs.

Studies show the importance of the nurse's role in carrying out the SSC, be it by their skill in managing the multidisciplinary team or by their wealth of knowledge, which can benefit health professionals and patients, contributing to improving surgical safety[5-7].

The limitations of the study include its performance in only two hospitals of the health care system in Manaus. Another limitation is the non-validation of the model proposed in the study by experts in the field, which will be done in subsequent work.

CONCLUSION

The analysis of the process of elaboration and implementation of the SSC indicated non-compliance with the phases of the checklist, suggesting risk to patient safety. The role of the nurse in the surgical context consists of identifying problems and encouraging the proposal of solutions for quality and risk-free care. The results pointed to the need for intrahospital solutions involving all professionals to increase adherence to the SSC. Thus, after its implementation in two hospitals, we believe that the model proposed and tested during this study may contribute to the more effective execution of the SSC.

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