

ORIGINAL ARTICLE

CONSTRUCTION AND VALIDATION OF A CHECKLIST FOR OPERATING ROOM AS A PATIENT SAFETY DEVICE

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ABSTRACT

Objective: To construct and validate a checklist for the organization of operating rooms.

Method: Methodological study conducted from June to December 2018 in a private hospital in the state of Maranhão, Brazil. It consisted of the following steps: literature review for the construction of the checklist, elaboration of the instrument and content validation. Seventy-four (74) members of the surgical team made assessments to validate the content. Reliability test by Cronbach's alpha coefficient and degree of internal consistency ≥ 0.70 were used.

Results: An instrument with three items (functionality of fixed and mobile equipment/accessories in the operating room; surgery; anesthesia) and 33 sub-items was developed. Cronbach's alpha coefficient was 0.956.

Conclusion: The checklist has high reliability, good internal consistency and is suitable to the organization of the preparation of operating rooms. It contributes to a better management of incidents, safe surgical care and support for new studies.

DESCRIPTORS: Patient Safety; Surgery Centers; Operating Rooms; Checklist; Validation Study.

CONSTRUCCIÓN Y VALIDACIÓN DE UNA LISTA DE VERIFICACIÓN PARA EL QUIRÓFANO COMO DISPOSITIVO DE SEGURIDAD DEL PACIENTE

RESUMEN:

Objetivo: construir y validar la lista de verificación para organización de quirófanos. Método: estudio metodológico, desarrollado entre junio y diciembre de 2018, en un hospital privado del estado de Maranhão - Brasil. Se compuso de los siguientes pasos: revisión de la literatura para la construcción de la lista de verificación, elaboración de un instrumento y validación del contenido. El contenido fue validado por la evaluación de 74 componentes del equipo quirúrgico. Se utilizó la prueba de fiabilidad mediante el coeficiente Alfa de Cronbach y el grado de consistencia interna $\geq 0,70$. Resultados: se elaboró un instrumento con tres ítems (funcionalidad de los equipamientos/accesorios fijos y móviles en el quirófano; cirugía; anestesia) y 33 sub-ítems. El alfa de Cronbach total fue de 0,956. Conclusión: la lista de verificación presenta una alta fiabilidad, buena consistencia interna y adecuación a la organización en el montaje de los quirófanos. Contribuye a la gestión de incidentes, a la seguridad de la atención quirúrgica y a las subvenciones para nuevos estudios.

DESCRIPTORES: Seguridad del Paciente; Centros Quirúrgicos; Quirófanos; Lista de Verificación; Estudio de Validación.

INTRODUCTION

Patient Safety (SP) is a topic widely discussed among health professionals and by various agencies, institutions and sectors directly related to patient care. It is defined as the absence of damage or accidental injury during the delivery of health care⁽¹⁾. Therefore, in 2008, the World Health Organization launched a set of safety standards called "Safe Surgery Saves Lives" and in 2013, Brazil's Ministry of Health established the National Patient Safety Program (PNSP). Both actions seek to establish the promotion of patient safety, encouraging the adoption of surgical protocols that recommend the importance of using a surgery safety checklist, to ensure the delivery of safe care to patients⁽²⁻⁴⁾.

The Surgery Center (SC) concentrates a large number of complex and stressful tasks, which require extra attention⁽⁵⁾. The preparation of operating rooms is a considerable part of the assistance provided at the Surgery Center. Its purpose is to ensure functional conditions and the necessary procedures for a smooth and successful surgical anesthetic procedure and for patient safety, through aseptic techniques, forecasting and provision of materials, and the necessary and appropriate equipment to perform the surgery⁽⁶⁻⁷⁾.

In this context, the WHO recommends the elaboration of checklists for the various in-hospital services, as a way of stimulating the culture of Patient Safety (PS)⁽⁸⁾ and reducing errors⁽²⁾. It is a relevant practice recently inserted in the health care area⁽⁹⁾, aimed to ensure systematic observation, in order to overcome failures from forgetfulness, as well as some difficulties and doubts related to the surgical procedure, the material to be used, the resources needed to perform the surgery, assisting all professionals involved in the operative process⁽¹⁰⁾.

Thus, the use of this surgical care and safety technology as part of the routine of the work process in the organization of the rooms allows the adoption of procedures recommended by surgical care protocols, with adequate checking of important items and search for the reliability of the performance of critical tasks in the intraoperative period (before anesthesia or sign in; before surgical incision or time out; before leaving the operating room or sign out)^(9,11). The referred technology also emphasizes the human, environmental and organizational aspects of communication, team performance and incident reduction, the risk of readmission, complications and hospital mortality⁽¹²⁾.

The success in the applicability of the checklist requires its adaptation to the workflow routine in the surgery center of each organization and the commitment of the professionals involved in the surgical process. That said, it is essential to have key team members in a supervisor role, that is, checklist coordinator⁽¹³⁾. Nurses are responsible for observing and checking the data. These professionals organize and manage the material resources and devices that make up a safe surgical environment, i.e. foreseeing and providing these items. They are the most qualified health professionals to supervise the whole process regarding the preparation of the operating room, in which they can intervene quickly in case of possible existing failures⁽¹⁴⁾. Also, the nursing technician is the direct contact person for pre, intra and post operative functions⁽¹⁵⁾.

However, to improve the rate of adherence to the use of the checklist and reduce failures in the checking of the items, an effective intervention with a multidisciplinary emphasis is required, and involvement of all members of the group who work in the operating rooms (surgeons, anesthesiologists, nursing staff)⁽¹³⁾. Since the nursing team comprises the largest number of professionals who provide care to patients and deal with continuous dynamic situations in several fields, such as patients' progress, management of human resources, management of technological aspects and stress itself⁽¹⁶⁾, it is essential to recognize the processes and weaknesses in the surgery center environment regarding the organization of the operating rooms.

However, studies related to the surgical context are still scarce⁽¹⁷⁾, and there is

scientific evidence that research on the use of checklists is poorly investigated in developing countries⁽⁹⁾. In this context, it is worth mentioning the importance of the preparation and checking of items in an operating room, through a checklist⁽¹⁸⁾. Thus, the present study aims to construct and validate a checklist for the organization of operating rooms.

METHOD

Methodological study consisting of the following steps: review of the literature for the construction of the checklist, preparation of the instrument and content validation. The study was carried out in a private hospital in São Luís, Maranhão - BR, between June and December 2018.

The first stage of the study was performed from June to September 2018, with search and selection in the following databases: Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), Scientific Electronic Library Online (SciELO), National Library of Medicine (PUBMED), Cochrane Library, Biblioteca Digital Brasileira de Teses e Dissertações (BDTD) of the Coordination for the Improvement of Higher Education Personnel (CAPES). Empregou-se termos genéricos identificados nos Descritores em Ciências da Saúde (DeCS) and in Medical Subject Headings (MeSH), in diferente combinations: "Lista de checagem" ("Checklist"), "Segurança do Paciente" ("Patient Safety"), "Salas Cirúrgicas" ("Operating Rooms"), "Estudos de Validação" ("Validation Studies"), "Período Intraoperatório" ("Intraoperative Period"). The universe of publications was expanded through the use of "AND" / "OR" Boolean connectors.

Based on particular situations observed in the daily routine of the health service (empirical elements), gaps were identified in the preparation of the operating room by the responsible team, which led to the following questions: how to ensure safety actions considered essential in the intraoperative care practice, with emphasis in organizing the assembly of operating rooms? How can safety actions considered essential in healthcare practice be ensured? intraoperative, with emphasis on the organization of the assembly of operating rooms? How can the professionals involved in this organizational process be assisted? These questions supported the elaboration, in checklist format, of the referred instrument on safety items in operating rooms.

The population consisted of 21 surgeons, six anesthesiologists, 19 nurses and 28 nursing technicians. The final sample consisted of 74 professionals of the surgical team. Professionals who had at least one year of professional experience and who performed their duties in the operating room were included. Professionals away from work activities during data collection were excluded from the study.

The theoretical framework was guided by the dimensions contained in the WHO surgical safety checklist and in the national guidelines of the PNSP: identification; b) practice of handwashing; c) prevention of pressure ulcers (PU); d) falls prevention; e) safety in drug prescription, use and administration, and; f) safe surgery protocols⁽¹⁹⁾. The norms recommended by the Brazilian Association of Nurses in Surgery center, Anesthetic Recovery and Material and Sterilization Center (SOBECC) were also adopted. They set standards for the practices recommended for preparation of the operating room, for a smooth surgical anesthetic procedure and patient safety (PS)⁽⁶⁻⁷⁾.

A preliminary version of the instrument was obtained, which contained three items and 32 sub-items: 1) Functionality of the fixed and mobile equipment/accessories of the operating room (17 sub-items); 2) Surgery (three sub-items); and 3) Anesthesia (12 sub-items). A subjective question was also included regarding the suggestions made by the experts that were considered relevant and were not addressed in the first version of the instrument.

Data collection concerns the content validation process of the checklist and is carried out in two stages, involving all components of the surgical team. The first collection took place in November 2018 and was maintained for 30 days; the second was conducted in December of the same year and ended on the 30th day. For the validation steps, a specific checklist of the research was used, elaborated according to the versions to be assessed and organized in three parts, as follows: I - Invitation to participate in the research by signing the Free and Informed Consent Form (TCLE); II - Sociodemographic data for the characterization of the participants; III – Judgment of the content of the checklist.

A Likert-type scale was used to measure the degree of relevance, with four response alternatives: 1 = Irrelevant; 2 = Not very relevant; 3 = Relevant and 4 = Totally relevant. Suggestions and justifications were requested for the sub-items classified with scores 1 and 2, for further analysis of their degree of relevance regarding the preparation of the operating room. With the Likert scale it was possible to measure the degree of agreement between the members of the surgical team based on the level of internal consistency, relevance and evaluation of the initial construct.

After data collection, each sub-item was analyzed separately; the value assigned to each position of the variables by degree of relevance made it possible to reformulate and validate the checklist for the final version (20). Thus, the instrument was restructured according to the suggestions of the members of the surgical team, and the final version had three items and 33 sub-items. Each item that reached a Cronbach's alpha coefficient equal to or greater than 70% internal consistency between the members of the surgical team was considered valid (21). The reliability of the questionnaire was applied and measured using Cronbach's alpha coefficient, considering the following values: > 0.90 - excellent; > 0.80 - good; > 0.70 - acceptable; > 0.60 - questionable; > 0.50 - poor and < 0.50 - unacceptable (19).

The study data were tabulated in a Microsoft Excel® 2010 spreadsheet and evaluated by the Statistical Package for the Social Sciences® version 20.0, and analyzed using descriptive statistics. The validity of the checklist was assessed and calculated using Cronbach's Alpha test for all items. The study was approved by the Research Ethics Committee of Universidade Ceuma, under Protocol No. 2,599,273.

RESULTS

Analysis of the reliability of the 32 items of the instrument was obtained with the measurement of internal consistency using Cronbach's alpha. The value obtained for the study participants was 0.956, considered reliable, as it can vary between zero and one, and the closer to one, the greater the reliability of the instrument. A value between 0.7 and 1.0 is considered ideal⁽¹⁰⁾. The Cronbach's alpha coefficient based on standardized items was 0.964 in 32 items.

Table 1 shows the degree of reliability for each explanatory variable of the three items (I-Functionality of fixed and mobile equipment/accessories in the operating room; II-Surgery; III-Anesthesia), in which all variables have positive weights, reaching the same level of significance, ranging from 0.954 to 0.957.

Table 1 - Description of Cronbach's Alpha value of the sub-items that make up the checklist for the organization of operating rooms. São Luís, MA, Brazil, 2018

Items and Sub-items	Cronbach's alpha	
I - Functionality of the operating room's fixed and mobile equipment/accessories		
Air conditioner	0,955	
Waste cans (normal/infectious)	0,955	
Rolling stool	0,957	
Electric scalpel with complete accessories	0,954	
Cool box	0,956	
Two-step staircase	0,956	
Extension cords	0,955	
Ceiling-mounted surgical light	0,954	
Printed material	0,956	
Sheet set	0,955	
Locked and tested operating table	0,954	
Instrument tables	0,954	
X-ray wall-mounted viewer	0,958	
Complete suction system	0,954	
Medical gas pipeline system	0,955	
Hamper stand	0,956	
Infusion stands	0,956	
II – Surgery		
Surgery information	0,954	
Surgical instruments	0,955	
Surgical kits/pharmacy	0,955	
III - Anesthesia		
Tested anesthesia machine	0,954	
Soda lime	0,954	
Capnograph	0,954	
Cuffometer	0,955	
Stethoscope	0,955	
Guidewire	0,954	
Comprehensive laryngoscope kit	0,954	
Tracheostomy kit	0,955	
Guedel cannula set	0,954	
Non-invasive masks for mechanical ventilation	0,954	
Complete and tested multi-parameter monitor	0,954	
Complete ventilation unit	0,954	
Carress that are (2010)		

Source: the authors (2018).

Data related to the experts' suggestions about relevant equipment that should be added to the instrument is shown in Table 2. Twenty-one (21) respondents (28.4%) said blanket warmers (n=8; 38.1%) were the most important surgical equipment to be added to the checklist.

Table 2 - Items suggested by the surgical team members in the construction and content validation of the checklist for the organization of the operating rooms. São Luís, MA, Brazil, 2018

Suggested items	n	%
Surgical equipment added		
Did not answer	53	71,6
Answered	21	28,4
Surgical equipment added (n=21)*		
Blanket warmer	8	38,1
Portable vacuum cleaner	3	14,3
Videoendoscopy tower system	2	9,5
Microscope	2	9,5
Photophore	2	9,5
Emergency trolley	2	9,5
Thermohygrometer	2	9,5
Auxiliary oxygen flowmeter	1	4,8
Operating room storage cabinet	1	4,8
Flexible anesthetic frame	1	4,8
Operating table fixation strap	1	4,8
Spinal board	1	4,8
Devices for moving the ceiling-mounted surgical light	1	4,8
Autotransfusion system	1	4,8
Warming mattress	1	4,8
Lead-lined wall	1	4,8
Mesa violão	1	4,8

^{*}Regarding the 21 participants who answered questions about important equipment Source: the authors (2018).

Regarding the distribution of responses on the degree of relevance of the functionality of fixed and mobile equipment/accessories in the operating room, half of the respondents (n=37; 50%) pointed out that the two-step ladder was irrelevant/not very relevant in the surgical environment. The professionals (n=33; 44.6%) also classified the X-ray wall-mounted viewer as irrelevant/not very relevant (Figure 1).

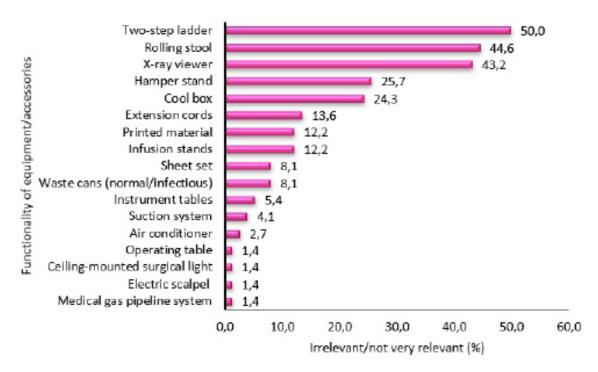


Figure 1 - Data on the degree of relevance of the item functionality of fixed and mobile equipment/ accessories of the checklist for the organization of operating rooms. São Luís, MA, Brazil, 2018

DISCUSSION

Based on our findings, internal consistency and construct validation were assessed. The items positively assessed were obtained, and regarding the reliability of the instrument, a Cronbach's Alpha coefficient of 0.956 was obtained for the 32 items. Therefore, the checklist for the Operating Room in the preparation of operating rooms was considered valid and reliable, and can be used to promote adjustments in work processes and contribute to the reduction of incidents and the continuous improvement of the quality and safety of patient care⁽¹¹⁾.

This result corroborates studies on validation of checklists that emphasize the importance of reliability measured by the agreement of the experts' answers and a high Cronbach's alpha coefficient^(6-7,10-11,18,21-22). Therefore, reliability is a major factor for the credibility of a validated instrument⁽¹⁰⁾. Studies have shown that the answers obtained with the elaboration and administration of checklists or a checklist of surgical safety are significant, since they favor systematization of data, improvement in the standards of care, reduction in the number of cases of infections and deaths, recognition of avoidable risk situations, in addition to facilitating the process of communication, interaction and commitment between team members and system users^(1,6-7). However, the technological complexity of the equipment used in surgical procedures and their relationship with health professionals and services cannot be disregarded, as well as the need for permanent updating of the care team⁽¹¹⁾.

Through the elaboration of this checklist, the members of the surgical team were able to assess each safety item in the preparation of the operating room. Although it is a routine procedure in the surgery center, it may impact patient safety if it is not performed safely⁽²¹⁾. The Surgery Center is composed of a group of professionals from different occupations, with different objectives and training, but who are supposed to be able to work as a team and value this. However, the operating room can be a high-risk scenario, with weaknesses regarding the skills of interpersonal relationships, and the culture of the surgical team can

be inflexible and reluctant to change^{s(7,18,21)}.

This is the reality of the surgical site where this study was conducted: it is necessary that health professionals and managers effectively recognize changes in patient care, in which the quality and safety of actions are closely related to people and work processes⁽⁹⁾.

According to the literature, lack of knowledge about safety in the Surgery center (SC) can cause irreversible damage and countless losses to patients. Therefore, it is necessary to constantly develop strategies for the qualification of professionals in health institutions, with the purpose of implementing a safety culture that faces the barriers and collective involvement regarding the necessary adaptations in the work environment⁽¹⁷⁾. Health professionals should perceive this tool as a strategy that will reduce the rates of adverse events in the operating rooms, and not merely as one additional form to be filled out⁽¹⁴⁾.

Thus, the professionals involved in this process must understand that, in addition to the emphasis on teamwork, there is a need for effective and efficient communication, recognition of their limitations, and learning from errors, which can be characterized as an incident of an intentional or unintentional nature⁽¹¹⁾. The importance of using a checklist for the preparation of the operating room is highlighted here, as it allows health professionals to check the availability and functionality of the equipment before performing surgical procedures, especially in surgeries that demand greater complexity to reduce possible weaknesses in the intraoperative period⁽¹⁸⁾.

Regarding the need for other surgical equipment, blanket warmer was the item most reported by the participants. The equipment is used after anesthetic induction to maintain normothermia, as perioperative hypothermia may occur in this phase. A study carried out in a hospital network in Portugal found that blanket warmers were the most used heating systems (87%) followed by fluid heating systems, with visible temperature control (51.9%) (23). A study conducted in the state of Sergipe, also in a private hospital, found that blanket warmers was the equipment most cited by the participants as a preventive measure for the control of hypothermia. Because they are available in all rooms of the surgery centers of the hospitals, blanket warmers have become standard equipment for controlling the temperature of patients. However, there is still no consensus in the literature on the best method of active intraoperative warming⁽²⁴⁾.

Although the members of the surgical team reported that the two-step ladder was the least relevant equipment in the preparation of the operating room, this sub-item was included in the instrument to guarantee a Patient Safety Culture (PSC), in order to prevent falls from patients in that site. The National Patient Safety Program (PNSP) aims to implement measures that include assessment of risks for hospitalized patients, in order to reduce the occurrence of falls and ensure a safe hospital environment⁽²⁵⁾. Despite the constant development of new technologies based on scientific evidence related to equipment and products specific for the surgery center, the acquisition of these materials must consider the reality of each institution⁽¹⁵⁾.

Hospital organizational and cultural factors can constitute barriers to the implementation of a checklist. The mere implementation is not enough. Other measures must be introduced, such as standards and training measures for the teams that participate in the process⁽²⁵⁾. Considering the applicability of the checklist proposed in this study and the different care contexts, health institutions may use it as a model and adapt it according to their real needs. However, transforming a checklist into an essential technology for improving the Culture of Patient Safety (CPS) in the surgical environment is a challenge⁽¹⁶⁾.

Surgical checklists contribute to a good cost-benefit relationship in health services and to positive changes in the context of care quality. Nursing has a prominent role in this regard, and the nursing team participates directly in the surgical checklist in the intraoperative moment. Nursing professionals are duly qualified for this function and must be accompanied and supervised by a nurse, who collaborates effectively in the management of the quantity and quality of supplies and equipment, in the composition

of technical commissions responsible for the selection and testing of these materials, and issuing opinions in public, private and philanthropic agencies⁽¹⁵⁾.

Through this instrument, information and guidelines that minimize errors and adverse events could be disseminated, with the purpose of promoting adaptations in health care and corrective measures targeted to the organizational process of the preparation of the operating room. The present study has the following limitations: lack of prior research studies on the topic and the fact that it was conducted in a single institution.

CONCLUSION

This investigation validated an instrument based on the transformation of the work process regarding the organization of operating rooms, with high reliability and good internal consistency. The study demonstrates the need to implement technological innovations capable of improving routine care practices, in this case, the preparation of the operating room.

The investigation contributes to providing a safe environment for surgical anesthetic procedures, in order to reduce the occurrence of adverse events to patients during surgery. If they occur, they generate high individual, social, economic costs, among others, both for individuals and their families, and for the health system.

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