Original Article

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☑ Knowledge translation and advances in health and nursing practices

Checklist validation for use in safe heart surgery

Validação de checklist para utilização em cirurgia cardíaca segura

Validación de la lista de verificación para su uso en cirugía cardiaca segura

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ABSTRACT

Objective: Build and validate an instrument in checklist format for use in safe cardiac surgery.

Method: Methodological research carried out in the following stages: literature review; national construction of items and content validation by experts in two stages, at regional level 9 and with 41 judges. For data analysis, the agreement rate per constructed item was determined.

Results: The construction of version 1 resulted in 49 items, version 2 presented 46 items, and the final version 41 items distributed in Sign in (1 to 27), Time out (28 to 32) and Sign out (33 to 41). All items obtained agreement greater than 80%, considering validated.

Conclusion: The checklist was built and validated in terms of content, consisting of 41 items, and can be used in the area of cardiac surgery for the implementation of safe care for patients undergoing these procedures.

Keywords: Checklist. Thoracic surgery. Cardiac surgical procedures. Patient safety. Cardiovascular diseases.

RESUMO

Objetivo: Construir e validar um instrumento no formato checklist para utilização em cirurgia cardíaca segura.

Método: Pesquisa metodológica realizada nas seguintes etapas: revisão da literatura; construção dos itens e validação de conteúdo por especialistas em duas etapas, a nível regional com 9 e nacional com 14 juízes. Para análise dos dados, aplicou-se a taxa de concordância por item construído.

Resultados: A construção da versão 1 resultou em 49 itens, a versão 2 apresentou 46 itens, e a versão final 41 itens distribuídos em Sign in (1 a 27), Time out (28 a 32) e Sign out (33 a 41). Na versão final, todos os itens foram validados com concordância superior a 80%.

Conclusão: O checklist foi construído e validado quanto ao conteúdo, composto por 41 itens,e poderá ser utilizado na área de cirurgia cardíaca para a implementação de assistência segura aos pacientes submetidos a esses procedimentos.

Palavras-chave: Lista de checagem. Cirurgia torácica. Procedimentos cirúrgicos cardíacos. Segurança do paciente. Doenças cardiovasculares.

RESUMEN

Objetivo: Construya y valide un instrumento en formato de lista de verificación para su uso en cirugía cardíaca segura.

Método: Investigación metodológica realizada en las siguientes etapas: revisión de la literatura; construcción nacional de ítems y validación de contenido por expertos en dos etapas, a nivel regional 9 y con 41 jueces. Para el análisis de datos, se determinó la tasa de concordancia por ítem construido.

Resultados: La construcción de la versión 1 resultó en 49 ítems, la versión 2 presentó 46 ítems y la versión final 41 ítems distribuidos en Sign in (1 a 27), Time out (28 a 32) y Sign out (33 a 41). Todos los ítems obtuvieron una concordancia superior al 80%, considerados validados.

Conclusión: La lista de verificación fue construida y validada en cuanto al contenido, consta de 41 ítems y puede ser utilizada en el área de cirugía cardíaca para la implementación de cuidados seguros para pacientes sometidos a estos procedimientos.

Palabras clave: Lista de verificación. Cirugía torácica. Procedimientos quirúrgicos cardíacos. Seguridad del paciente. Enfermedades cardiovasculares.

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INTRODUCTION

Nearly six billion people worldwide do not have access to safe and timely cardiac surgical care when needed, even though cardiovascular disease (CVD) remains the leading cause of death in the world, with more than 17.5 million deaths every year and these are likely to increase by more than 20 million in the next decade[1]. The same occurs in Brazil, since CVD has been the leading cause of mortality since the 1960s, responsible for a substantial burden of such diseases[2].

Cardiac surgery is one of the most complex fields of medicine. It is a demanding specialty that involves high-risk procedures and various phases of care, which mobilizes the multidisciplinary team to improve this specialty[3]. A recent Dutch study has defined cardiac surgery as all open-heart surgery, with or without cardiopulmonary bypass, which can be elective and emergency, surgical procedures to treat coronary heart diseases, valve, aortic, and congenital diseases[4].

Studies revealed that errors in surgery are caused by ineffective communication, lack of knowledge, inattention, memory deficits, distractions, interruption in workflow, poor staff, unskillfullness, fatigue and system failures[5]. Thus, high workload associated with a multitasking profile creates an environment conducive to surgical errors, which requires the use of means and instruments that favor their prevention and boost patient safety[3].

The use of a checklist is a strategy aimed to promote the improvement of care for surgical patients, as it reduces complications, adverse events, and is also low-cost, being accessible for different realities, even where resources are limited[6]. It is an instrument for quick and objective checks, which is why they are recommended to be used by all professionals in the surgical team, as it enables safer care practices[7].

The identification of causes and the elaboration of plans, combined with the use of more specific checklists, can minimize or eliminate the risks of the development of adverse events, allowing the establishment of a system that guarantees patient safety. Although the instruments currently used include general risk factors, they often do not cover the specificities necessary for proper management in cardiac surgeries, because several specific resources are used, such as: cardiopulmonary bypass machine to bypass the heart, use of defibrillators to monitor intrathoracic impedance, temperature control to induce hypothermia and use of a solution for myocardial protection, among others[8].

These specificities can be aligned with the complexity of cardiac surgical procedures, given the importance of the heart as a vital organ of the body and its influence on the patient's hemodynamic stability, surgical time, the presence of cardiopulmonary bypass, and graft-related factors[3–8]. The checklist is a flexible tool that can be formatted according to the complexity of the procedure[5].

While the impact of a safety checklist is clear, the essential inherent benefit is that it provides a specific tool to engage a team and ensure minimum standards are met, avoiding ambiguity and encouraging participation by all team members[8].

The American and European Association for Cardio-Thoracic Surgery (EACTS) considered the checklist a class I recommendation to be applied in all cardiac surgeries, as the benefits seem to be directly related to an improvement in team communication and situational awareness, shortly before starting the procedure[9].

Thus, a recent Dutch study suggests that the quality of the surgical safety checklist can be improved by adjusting it according to existing procedures and staff expectations through a bottom-up implementation strategy [10]. Therefore, this study aims to build and validate a checklist for use in safe cardiac surgery, meeting the real daily needs of the surgical team.

METHOD

This is a methodological research for checklist validation carried out in the following stages: integrative literature review, construction of items and content validation by regional and national experts. Thus, the recommendations of the theoretical procedures were followed with the use of criteria of clarity, relevance and relevance, and content validation to represent the dimension of the subject addressed[11].

To start stage 1, an integrative review, the research question was elaborated based on the PICO[12] strategy – with P corresponding to patient safety, I to the checklist and Co to safe cardiac surgery – with the objective of identifying in the literature which checklists are available for safe cardiac surgery.

The following databases were used: Medline via Pubmed, Cinahl, Scopus, Lilac and Web of Science. Chart 1 represents the search scheme in each database.

The process of selection of articles was independently carried out between July and November 2020 by two researchers. To organize the evidence found, Equator flowchart and the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (Prisma) checklist were used[13].

Importing to EndNoteon-line was performed and the occurrence of duplication was identified by the Find Duplicates option, and the articles that met the following inclusion criteria were then selected: studies in English, Portuguese and Spanish; articles with a qualitative and quantitative approach that answered the guiding question. Duplicate articles, theses,

Database	Strategy	Descriptor	Result
Medline via *Pubmed*	("Checklist"[Mesh]) AND ("Thoracic Surgery"[Mesh] OR "Thoracic Surgical Procedures"[Mesh])	Mesh	81
Cinahl	checklist AND thoracic surgery OR thoracic surgical procedures	Headings	78
Scopus	(Checklist AND Thoracic Surgery OR Thoracic Surgical Procedures)	Keyword	47
Lilacs	(lista de checagem) or "CHECKLIST" [Palavras] and segurança do paciente [Palavras] and (cirurgia cardiaca) or "CIRURGIA" [Palavras]	Decs	30
Web of Science	(checklist) AND TOPIC: (thoracic surgery)	Keyword	41

Chart 1 – Database search strategy. Maceio, Alagoas, Brazil, 2020
Source: Research data (2020).

dissertations and book chapters were excluded. No period delimitation was established because few articles met the inclusion criteria.

The following information was extracted from the articles: characterization of the study, including author, country and year of publication, surgical phase of use of the instrument, professionals involved, instrument format and items corresponding to each safety check, tabulated in Excel spreadsheet.

For stage 2, construction of the instrument, the items extracted from the integrative review articles, the World Health Organization (WHO) safe surgery checklist and the authors' experience were used. The structural model of the instrument was designed to maintain an objective and easy-to-apply structure, in which each item was composed of dichotomous responses aimed at solving the item. After creating the checklist, stage 3 began.

For composing the sample of judges/experts of stages 3 and 4, the criteria that indicate the number from six to 20[11], were met, with emphasis on the number being odd, in order to avoid possible ties[14]. The inclusion criteria for stage 3 involved professionals who work in the surgical anesthetic scenario of the categories: anesthesiology, surgeon or nurse and in more than one health service, with a specialty registered with their respective professions council.

Recruitment was performed using the snowball technique[15], the first version of the instrument was sent to 13 professionals in printed format or sent via e-mail to assess the criteria for clarity and relevance, with three anesthesiologists, four nurses and six cardiac surgeons. Professionals were asked to return the completed instrument within 15 days of receipt, with notes of particular issues observed in the region service. Nine (9) professionals returned the instrument within the estimated time.

In stage 4, content validation was carried out with professionals from all over Brazil, which was necessary because it involved the expertise of specialists at the national level, not being restricted to evaluation at the regional level. Thus, a search was carried out on the Lattes Platform, and 50 judges were eligible, including nurses, surgeons, professors, experts in the field of instrument validation, anesthesiologist and perfusionist.

For inclusion, a minimum score of five points was established[16]. The invitation to participate in the study was made by e-mail with the presentation of information about the research and the checklist version 2 to be evaluated based on the criteria of clarity, relevance, relevance, surgical stage and respondent professional. Judges who reported any reason that prevented participation in the study and those who did not return the completed instrument during the data collection period (15 days after the invitation) were excluded from the sample. Finally, 14 judges evaluated the instrument within the estimated period.

For data analysis in stages 3 and 4, the agreement rate method was adopted, using the following formula[17]:

$$\% \text{ agreement} = \frac{\text{Number of participants who agreed} \times 100}{\text{Total number of participants}}$$

This rate is interpreted considering that a result greater than or equal to 80% agreement means adequacy. When agreement is less than 80%, the item must be discussed and modified[11].

This study was approved by the Research Ethics Committee (CAAE: 15410219.6.0000.5013), according to Resolution 466/2012, which regulates research with human beings.

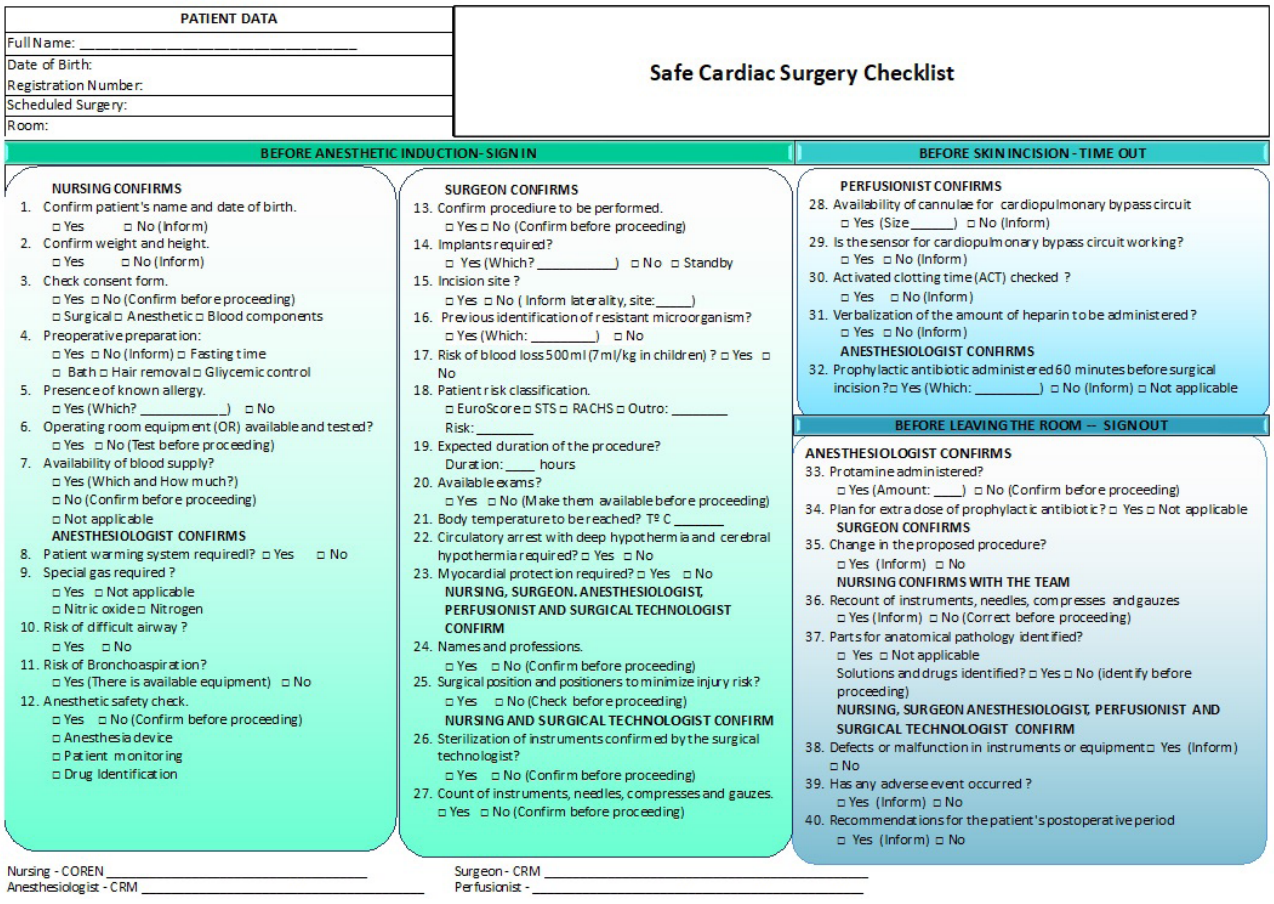
RESULTS

Chart 2 presents evidence-based information. Chart 3 presents the result of content validation by the practice judges at the regional level. Figure 1 shows version 3, after validation by the judges at the national level.

In the first version of the checklist built for cardiac surgery, consisting of three surgical moments, 49 items were constructed with an indication of the respondent and the dichotomous answer guiding the answer for each item. At the Sign in phase (before anesthetic induction) 19 items were created. In the Time out phase (before skin incision) items 20 to 42 were created and in the Sign out phase (before the patient leaves the operating room) seven items were created, 43 to 49.

As for the results of the content validation of version 1, it should be emphasized that all judges have expertise in cardiac surgery, participating directly in the surgical anesthetic act, most are men (55.6%), aged between 20 and 40 years (66.7%), time elapsed since graduation 10 and 20 years (44.5%), with medical profession (66.7%) in the field of anesthesiology and 33.3% were nurses.

In Chart 3, the results of the construction are presented in the first column, followed by the changes made based on the analysis of the judges at the regional level and the third column shows the item in the second version of the checklist. The changes between versions 1 and 2 were adjusted to clarify the content, resulting in three questions excluded, five rewritten, 11 repositioned in the professional category respondent, and six rewritten/repositioned. This resulted in version 2 of the checklist with 46 items.



PATIENT DATA

Full Name: _____
Date of Birth:
Registration Number:
Scheduled Surgery:
Room:

Safe Cardiac Surgery Checklist

BEFORE ANESTHETIC INDUCTION - SIGN IN

NURSING CONFIRMS

1. Confirm patient's name and date of birth.
   □ Yes □ No (Inform)
2. Confirm weight and height.
   □ Yes □ No (Inform)
3. Check consent form.
   □ Yes □ No (Confirm before proceeding)
   □ Surgical □ Anesthetic □ Blood components
4. Preoperative preparation:
   □ Yes □ No (Inform) □ Fasting time
   □ Bath □ Hair removal □ Gliycemic control
5. Presence of known allergy.
   □ Yes (Which? _____) □ No
6. Operating room equipment (OR) available and tested?
   □ Yes □ No (Test before proceeding)
7. Availability of blood supply?
   □ Yes (Which and How much?)
   □ No (Confirm before proceeding)
   □ Not applicable

ANESTHESIOLOGIST CONFIRMS

8. Patient warming system required? □ Yes □ No
9. Special gas required ?
   □ Yes □ Not applicable
   □ Nitric oxide □ Nitrogen
10. Risk of difficult airway ?
    □ Yes □ No
11. Risk of Bronchoaspiration?
    □ Yes (There is available equipment) □ No
12. Anesthetic safety check.
    □ Yes □ No (Confirm before proceeding)
    □ Anesthesia device
    □ Patient monitoring
    □ Drug Identification

SURGEON CONFIRMS

13. Confirm procediure to be performed.
    □ Yes □ No (Confirm before proceeding)
14. Implants required?
    □ Yes (Which? _____) □ No □ Standby
15. Incision site ?
    □ Yes □ No (Inform laterality, site: _____)
16. Previous identification of resistant microorganism?
    □ Yes (Which: _____) □ No
17. Risk of blood loss 500 ml (7 ml/kg in children) ? □ Yes □ No
18. Patient risk classification.
    □ EuroScore □ STS □ RACHS □ Outro: _____
    Risk: _____
19. Expected duration of the procedure?
    Duration: ____ hours
20. Available exams?
    □ Yes □ No (Make them available before proceeding)
21. Body temperature to be reached? Tº C _____
22. Circulatory arrest with deep hypothermia and cerebral hypothermia required? □ Yes □ No
23. Myocardial protection required? □ Yes □ No

NURSING, SURGEON. ANESTHESIOLOGIST, PERFUSIONIST AND SURGICAL TECHNOLOGIST CONFIRM

24. Names and professions.
    □ Yes □ No (Confirm before proceeding)
25. Surgical position and positioners to minimize injury risk?
    □ Yes □ No (Check before proceeding)

NURSING AND SURGICAL TECHNOLOGIST CONFIRM

26. Sterilization of instruments confirmed by the surgical technologist?
    □ Yes □ No (Confirm before proceeding)
27. Count of instruments, needles, compresses and gauzes.
    □ Yes □ No (Confirm before proceeding)

BEFORE SKIN INCISION - TIME OUT

PERFUSIONIST CONFIRMS

28. Availability of cannulae for cardiopulmonary bypass circuit
    □ Yes (Size_____) □ No (Inform)
29. Is the sensor for cardiopulmonary bypass circuit working?
    □ Yes □ No (Inform)
30. Activated clotting time (ACT) checked ?
    □ Yes □ No (Inform)
31. Verbalization of the amount of heparin to be administered?
    □ Yes □ No (Inform)

ANESTHESIOLOGIST CONFIRMS

32. Prophylactic antibiotic administered 60 minutes before surgical incision? □ Yes (Which: _____) □ No (Inform) □ Not applicable

BEFORE LEAVING THE ROOM – SIGN OUT

ANESTHESIOLOGIST CONFIRMS

33. Protamine administered?
    □ Yes (Amount: ____) □ No (Confirm before proceeding)
34. Plan for extra dose of prophylactic antibiotic? □ Yes □ Not applicable

SURGEON CONFIRMS

35. Change in the proposed procedure?
    □ Yes (Inform) □ No

NURSING CONFIRMS WITH THE TEAM

36. Recount of instruments, needles, compresses and gauzes
    □ Yes (Inform) □ No (Correct before proceeding)
37. Parts for anatomical pathology identified?
    □ Yes □ Not applicable
    Solutions and drugs identified? □ Yes □ No (identify before proceeding)

NURSING, SURGEON ANESTHESIOLOGIST, PERFUSIONIST AND SURGICAL TECHNOLOGIST CONFIRM

38. Defects or malfunction in instruments or equipment □ Yes (Inform) □ No
39. Has any adverse event occurred ?
    □ Yes (Inform) □ No
40. Recommendations for the patient's postoperative period
    □ Yes (Inform) □ No

Nursing - COREN _____
Anesthesiologist - CRM _____
Surgeon - CRM _____
Perfusionist - _____

Figure 1 – Version 3 and end of the safe cardiac surgery checklist. Maceio, Alagoas, Brazil, 2021
Source: Research data, 2021.

Article/ code	Country	Professionals involved	Information contained in the study
Surgical time out checklist with debriefing and multidisciplinary feedback improves venous thromboembolism prophylaxis in thoracic surgery: a prospective audit.	United Kingdom (UK)(18)	Anesthesiologist Surgeon	Checklist for reducing venous thromboembolism (VTE) prophylaxis errors described in the "Time out" phase.
Lessons from aviation – the role of checklists in minimally invasive cardiac surgery.	Canada[19]	Perfusionist Surgeon Anesthesiologist	Stages involving insertion of cannulas for procedures in minimally invasive cardiac surgery, with 22 checks sequenced, described in the "Time out" phase.
Checklists and Safety in Pediatric Cardiac Surgery.	United States of America (USA)[20]	Circulating nurse Anesthesiologist Surgeon Surgical technologist	Checklist developed for a pediatric cardiac program with checks submitted to professionals, maintaining the Sign in, Time out and Sign out phases.
Developing a Cardiopulmonay Bypass Separation Checklist:Consensus Via a Modified Delphi Technique.	Texas, United States of America (USA)[21]	Anesthesiologist Surgeon Perfusionist	Checklist for preparing for cardiopulmonary bypass separation, with nine items to check, described in the "Timeout" phase.
Improved Compliance and Comprehension of a Surgical Safety Checklist With Customized Versus Standard Training: A Randomized Trial.	India[22]	Nurse Surgeon Anesthesiologist Perfusionist	Surgical safety checklist composed of 44 items, divided into five phases. Nurse pre-op verification checklist, Before Anesthesia Begins, Before Skin Incision(2), Before Sternal Closure.
When a checklist is not enough: How to improve them and what else is needed.	Boston, Mass United States of America (USA(23)	Surgeon Nurse	Preoperative checklist, with a simple eight-question feedback model, described in the "Time out" phase.
The use of checklist as a method to reduce human error on cardiac operating rooms.	Richmond, Virginia, United States of America (USA)[24]	Perfusionist Surgeon Nurse Anesthesiologist Perfusionist	Subdivided into charts1 and 2, chart 1 describes a checklist to be used by the infusion and chart 2 describes checks by each professional with the inclusion of debriefing at the end of the checklist.
Briefing and debriefing in the cardiac operating room. Analysis of impact on theatre team attitude and patient safety.	United Kingdom (UK)(25)	Anesthesiologist Surgeon Circulating nurse Perfusionist	Checklist with dichotomous answers divided into a general stage with four items, briefing with eleven items and debriefing with six items.

Chart 2 – Integrative review articles with information from the study checklists. Maceio, Alagoas, Brazil, 2020
Source: Research data, 2020.

Items Version 1	Validity of the item	Items Version 2
Item 1 – Patient name checked using two identifiers ☐ Yes ☐ No (Inform)	Rewritten	Confirm patient's name, date of birth, weight and height ☐ Yes ☐ No (Inform)
Item 2 – Confirmation of the procedure to be performed ☐ Yes ☐ No (Confirm before proceeding)	Valid	Confirmation of the procedure to be performed ☐ Yes ☐ No (Confirm before proceeding)
Item 3 – Delimited surgical site ☐ Yes ☐ No (Confirm) ☐ Not applicable	Excluded	Excluded
Item 4 – Checked consent form (Surgical, Anesthetic and blood components) ☐ Yes ☐ No (Confirm before proceeding)	Valid	Checked consent form (Surgical, Anesthetic and blood components) ☐ Yes ☐ No (Confirm before proceeding)
Item 5 – Preoperative preparation: fasting time, bath and hair removal ☐ Yes ☐ No (Inform)	Valid, not supported rewritten	Preoperative preparation: fasting time, bath and hair removal ☐ Yes ☐ No (Inform)
Item 6 – Presence of known allergy ☐ Yes (Inform) ☐ No	Valid, not supported rewritten	Presence of known allergy ☐ Yes (Which? _____) ☐ No
Item 7 – Assembly of the operating room (OR) according to the scheduled procedure? ☐ Yes ☐ No (Correct before proceeding)	Valid	Assembly of the operating room (OR) according to the scheduled procedure? ☐ Yes ☐ No (Correct before proceeding)
Item 8 – Surgical materials with correct identification of sterilization ☐ Yes ☐ No (To correct before proceeding)	Valid	Surgical materials with correct identification of sterilization ☐ Yes ☐ No (To correct before proceeding)
Item 9 – Operating room (OR) equipment available and tested? ☐ Yes ☐ No (Test before proceeding)	Valid	Operating room (OR) equipment available and tested? ☐ Yes ☐ No (Test before proceeding)
Item 10 –Implants required? ☐ Yes ☐ No ☐ Standby	Rewritten	Implants required? ☐ Yes (Which? _____) ☐ No ☐ Stand by
Item 11- In case of organ transplantation, check donor/recipient ABO compatibility ☐ Yes ☐ No (Confirm before proceeding) ☐ Not applicable	Rewritten	Donor/Recipient ABO Compatibility Check ☐ Yes ☐ No (Confirm before proceeding) ☐ Not applicable
Item 12 – Availability of blood supply? ☐ Yes (Which and How much) ☐ No (Confirm before proceeding) ☐ Not applicable	Valid	Availability of blood supply? ☐ Yes (Which and How much) ☐ No (Confirm before proceeding) ☐ Not applicable
Item 13 –Heating system required? ☐ Yes ☐ No	Rewritten/ Repositioned	Patient warming system required? ☐ Yes ☐ No

Chart 3 – Construction, changes recommended by the judges and second version of the checklist. Maceió, Alagoas, Brazil, 2021

Items Version 1	Validity of the item	Items Version 2
Item 14 – Risk of difficult airway or Bronchoaspiration? ☐ Yes (There is available equipment) ☐ No	Valid	Risk of difficult airway or Bronchoaspiration? ☐ Yes (There is available equipment) ☐ No
Item 15 – ASA rating ☐ Yes ☐ No (Confirm before proceeding)	Valid	ASA rating ☐ Yes ☐ No (Confirm before proceeding)
Item 16 – Anesthetic safety check: Anesthesia device, Patient monitoring, Tube position, Drug identification ☐ Yes ☐ No (Confirm before proceeding)	Rewritten	Anesthetic safety check: Anesthesia device Patient monitoring and Drug identification ☐ Yes ☐ No (Confirm before proceeding)
Item 17 – Expected anesthetic risks for the patient? ☐ Yes (Inform) ☐ No	Excluded	Excluded
Item 18 – Midline incision? ☐ Yes ☐ No (Inform laterality) Site: _____	Valid, not supported, rewritten	Midline incision? ☐ Yes ☐ No (Inform laterality) Site: _____
Item 19 – Identification of MRSA (methicillin-resistant *Staphylococcus aureus*) ☐ Yes (Inform) ☐ No	Valid, not supported rewritten	Identification of MRSA (methicillin-resistant *Staphylococcus aureus*) ☐ Yes (Inform) ☐ No
Item 20 – Names and professions ☐ Yes ☐ No (Confirm before proceeding)	Repositioned	Names and Professions ☐ Yes ☐ No (Confirm before proceeding)
Item 21 – Patient name, weight, height and procedure ☐ Yes ☐ No (Confirm before proceeding)	Excluded; Weight and height included in item 1	Excluded
Item 22 – Surgical position and positioners to minimize risk associated to patient positioning ☐ Yes ☐ No (Check before proceeding)	Repositioned	Surgical position and positioners to minimize risk associated to patient positioning ☐ Yes ☐ No (Check before proceeding)
Item 23 – Any hazards identified? ☐ Yes (Inform) ☐ No	Rewritten / repositioned	Any unsafe situation before starting the procedure? ☐ Yes (Inform) ☐ No
Item 24 – Duration of the procedure Time: _____	Repositioned	Duration of the procedure Time: _____
Item 25 – Preventive measures against surgical site infection ☐ Yes ☐ No (Prepare before proceeding)	Valid	Preventive measures against surgical site infection ☐ Yes ☐ No (Prepare before proceeding)
Item 26 – Predictable critical moments during the procedure ☐ Yes (Clarify before proceeding) ☐ No	Repositioned	Predictable critical moments during the procedure? ☐ Yes (Clarify before proceeding) ☐ No

Chart 3 – Cont.

Items Version 1	Validity of the item	Items Version 2
Item 27 – Imaging exams viewed? ☐ Yes ☐ No (Make available before proceeding)	Rewritten / repositioned	Exams viewed? ☐ Yes ☐ No (View before proceeding)
Item 28 – Risk of blood loss >500ml (7ml/kg in children) ☐ Yes ☐ No	Repositioned	Risk of blood loss > 500ml (7ml/kg in children) ☐ Yes ☐ No
Item 29 – Patient risk classification Risk: _____	Repositioned	Patient risk classification Risk: _____
Item 30 – Sterilization of instruments confirmed by the surgical technologist? ☐ Yes ☐ No (Confirm before proceeding)	Repositioned	Sterilization of instruments confirmed by the surgical technologist? ☐ Yes ☐ No (Confirm before proceeding)
Item 31 – Count of instruments, needles, compresses and gauzes ☐ Yes ☐ No (Confirm before proceeding)	Valid, not supported repositioning	Count of instruments, needles, compresses and gauzes ☐ Yes ☐ No (Confirm before proceeding)
Item 32 – Availability of cannulae? ☐ Yes (Size _____) ☐ No (Inform)	Valid, not Supported repositioning	Availability of cannulae? ☐ Yes (Size _____) ☐ No (Inform)
Item 33 – Temperature to be reached? TºC _____	Rewritten / repositioned	Body temperature to be reached? TºC _____
Item 34 – Deep hypothermic circulatory arrest or head with ice required? ☐ Yes ☐ No	Rewritten / repositioned	Circulatory arrest with deep hypothermia and cerebral Hypothermia required? ☐ Yes ☐ No
Item 35 – Myocardial protection solution required? ☐ Yes ☐ No	Repositioned and Word solution removed	Myocardial Protection Solution required? ☐ Yes ☐ No
Item 36 – Is the air sensor working? ☐ Yes ☐ No (Inform)	Repositioned	Is the air sensor working? ☐ Yes ☐ No (Inform)
Item 37 –Activated Clotting Time (ACT) checked? ☐ Yes ☐ No (Inform)	Repositioned	Activated clotting time (ACT) checked? ☐ Yes ☐ No (Inform)
Item 38 – Verbalization of the amount of heparin to be administered? ☐ Yes ☐ No (Inform)	Valid	Verbalization of the amount of heparin to be administered? ☐ Yes ☐ No (inform)
Item 39 – Amount of heparin to be administered ☐ Yes ☐ No (Confirm before proceeding)	Rewritten / repositioned	Heparin administered? ☐ Yes (Amount: _____) ☐ No (Confirm before proceeding)

Chart 3 – Cont.

Items Version 1	Validity of the item	Items Version 2
Item 40 – Prophylactic antibiotic administered 60 minutes before surgical incision? ☐ Yes ☐ No (Inform) ☐ Not applicable	Valid, included "Which"	Prophylactic antibiotic administered 60 minutes before surgical incision? ☐ Yes (Which: _____) ☐ No (Inform) ☐ Not applicable
Item 41 – Plan for extra dose of prophylactic antibiotic? ☐ Yes ☐ Not applicable	Valid	Plan for extra dose of prophylactic antibiotic? ☐ Yes ☐ Not applicable
Item 42 –Special gas required? (nitric oxide, nitrogen, carbon dioxide) ☐ Yes ☐ Not applicable	Repositioned	Special gas required? (nitric oxide, nitrogen, carbon dioxide) ☐ Yes ☐ Not applicable
Item 43 – Procedure name change ☐ Yes (Inform) ☐ No	Valid	Procedure name change ☐ Yes (Inform) ☐ No
Item 44 – Recount of instruments, needles, compresses and gauzes ☐ Yes (Inform) ☐ No (Correct before proceeding)	Valid	Recount of instruments, needles, compresses and gauzes ☐ Yes (Inform) ☐ No (Correct before proceeding)
Item 45 – Biopsies identified? ☐ Yes ☐ Not applicable	Valid	Biopsies identified? ☐ Yes ☐ Not applicable
Item 46 – Any equipment issues that need to be resolved? ☐ Yes (Inform) ☐ No	Valid	Any equipment issues that need to be resolved? ☐ Yes (Inform) ☐ No
Item 47 – Sera and drugs identified? ☐ Yes ☐ No (Identify before proceeding)	Rewritten	Solutions and drugs identified? ☐ Yes ☐ No (Identify before proceeding)
Item 48 – Evidence of an adverse event? ☐ Yes (Inform) ☐ No	Valid	Evidence of an adverse event? ☐ Yes (Inform) ☐ No
Item 49 – Recommendations for the patient's postoperative period ☐ Yes (Inform) ☐ No	Valid	Recommendations for the patient's postoperative period ☐ Yes (Inform) ☐ No

Chart 3 – Cont.
Source: Research data, 2021.

After adjustments were made to the three phases of the checklist, version 2 was submitted to the judges at the national level for the second stage of content validation. Considering the agreement rate of this second validation moment, Table 1 shows the percentage of each item in the respective criteria evaluated. Items with a percentage above 80% were validated and those with a lower percentage were discussed, rewritten, eliminated or readjusted, as suggested by the experts. We chose to present this category as a percentage because it had a greater perception of validation.

In the list of items, 19 were rewritten, 12 were maintained, 7 were excluded, 3 were repositioned and 5 were rewritten and repositioned in the professional category respondent. In this second validation stage, 57% of the judges reached a maximum score of 20 points according to the criteria[16], 64.3% were women, 35.7% were over 60 years old, 50% had graduated more than 30 years ago,, 42.9% were nurses, and 71.4% of the judges had a doctorate.

This process led to the formalization of version 3, which is the version validated by the study. The general average

percentage of the categories was 86% for clarity, 93% for pertinence, 93% for relevance, 85.71% for the indicated surgical phase and 85.71% for the respondent, confirming the feasibility of the instrument constructed and validated.

Figure 1 shows the final version of the safe cardiac surgery checklist divided into three phases, Sign in – before anesthetic induction, which corresponds to items 1 to 27; Time out – before skin incision, items 28 to 32; and Sign out – before leaving the room, which corresponds to items 33 to 41, with the identification of the items submitted to the nursing professionals, anesthesiologist, surgeon, surgical technologist and perfusionist.

Table 1 – Agreement rate of the safe cardiac surgery checklist version, by instrument item and validity criterion. Maceio, Alagoas, Brazil, 2021

Item	Clarity	Pertinence	Relevance	Surgical phase	Respondent
1	100%	100%	100%	92.85%	92.85%
2	92.85%	100%	100%	85.71%	78.57
3	92.85%	100%	100%	92.85%	85.71%
4	85.71%	100%	92.85%	92.85%	85.71%
5	92.85%	100%	100%	92.85%	85.71%
6	78.57	71.42%	85.71%	85.71%	64.28%
7	71.42%	92.85%	92.85 %	85.71%	78.57%
8	92.85%	100%	100%	92.85%	85.71%
9	100%	100%	100%	92.85%	85.71%
10	64.28%	92.85%	92.85%	92.85%	92.85%
11	100%	100%	100%	92.85%	92.85%
12	85.71%	92.85%	92.85%	85.71%	85.71%
13	85.71%	100%	92.85%	92.85%	92.85%
14	92.85%	92.85%	100%	85.71%	78.57%
15	92.85%	71.49%	71.49%	85.71%	78.57%
16	85.71%	92.85%	100%	92.85%	78.57%
17	85.71%	92.85%	92.85%	78.57%	85.71%
18	71.49%	85.71%	85.71%	85.71%	78.57%
19	92.85%	100%	100%	92.85%	92.85%
20	50%	85.71%	92.85%	85.71%	85.71%
21	78.57%	92.85%	100%	92.85%	92.85%

Table 1 – Cont.

Item	Clarity	Pertinence	Relevance	Surgical phase	Respondent
22	42.85%	85.71%	92.85%	85.71%	71.42%
23	50%	78.57%	71.42%	71.42%	64.28%
24	64.28%	92.85%	100%	92.85%	78.57%
25	85.71%	85.71%	85.71%	85.71%	85.71%
26	85.71%	92.85%	100%	92.85%	78.57%
27	100%	92.85%	92.85%	92.85%	85.71%
28	92.85%	85.71%	92.85%	85.71%	85.71%
29	78.57%	85.71%	92.85%	78.57%	85.71%
30	64.28%	71.42%	64.28%	71.42%	78.57%
31	78.57%	100%	100%	71.42%	85.71%
32	85.71%	92.85%	92.85%	85.71%	92.85%
33	71.42%	85.71%	100%	85.71%	92.85%
34	78.57%	92.85%	85.71%	78.57%	78.57%
35	85.71%	92.85%	92.85%	78.57%	85.71%
36	92.85%	92.85%	85.71%	85.71%	92.85%
37	92.85%	92.85%	85.71%	64.28%	85.71%
38	92.85%	100%	92.85%	85.71%	85.71%
39	85.71%	85.71%	85.71%	78.57%	78.57%
40	85.71%	100%	100%	85.71%	78.57%
41	92.85%	92.85%	100%	85.71%	85.71%
42	92.85%	92.85%	100%	85.71%	85.71%
43	85.71%	92.85%	85.71%	85.71%	78,57%
44	85.71%	85.71%	92.85%	85.71%	85.71%
45	85.71%	92.85%	92.85%	78.57%	71.42%
46	92.85%	100%	100%	92.85%	85.71%

Source: Research data, 2021.

DISCUSSION

Validation of the safe surgery checklist of this study sought to address the specific needs of cardiac surgery. During each of the stages, we attempted to include evidence from the literature, the suggestions of experts and the experiences of the authors to obtain a tool that helps the nursing team and the medical-surgical team to ensure that the procedure is safe, producing a checklist with key safety posts and facilitating its use in daily life, in line with its purpose.

A similar study on a checklist for assistance in cardiac surgery, over a period of five years, is the Incor Checklist – Five steps to safe surgery. The model includes five sequential phases: Briefing, Sign In, Time out, Sign out and Debriefing[26]. Regarding the analysis of the surgical phases, it was found that in the Sign in phase of the present study there is a greater quantity of items; in the second and third phases, Time out and Sign out respectively, a smaller quantity of items is associated when compared to the Incor Checklist model.

Another difference between these studies is that the Incor Checklist has Briefing and Debriefing and the checklist for assistance in safe cardiac surgery has dichotomous answers, which refer to the items, and the indication of the respondents. Thus, it can be concluded that in this study the judges found that most items should be checked before skin incision, which made the Sign in phase longer than the other phases.

In cardiac surgery, little has been published about new possibilities for surgical checklists. Most studies related to instrument validation are performed in non-cardiac surgeries. A large study carried out in seven Dutch hospitals was recently published, in which the implementation of a checklist for cardiac surgery was associated with a 43% reduction in mortality up to 120 days postoperatively[4]. In Brazil, a retrospective cohort study made it possible to identify that a checklist for cardiac surgery was associated with a 62% decrease in mortality[26].

There is still no data available on the impact of this proposed checklist in reducing mortality, and this should be the subject of further studies. Therefore, the surgical team must continue to improve the level of understanding about more effective formats, based on evidence for safer care for cardiac-surgical patients, providing risk-free and harm-free care.

While the impact of the security checklist is clear, the essential inherent benefit is that it provides a specific tool to engage a team and ensure minimum standards are met, avoid ambiguity, and encourage participation by all team members[27,28].

The challenge of building this instrument was to select the priority actions among many that this specialty requires, making it essential that these actions express adequate management and checks, in order to provide safe surgical care. The reasons why the most diverse errors related to patient safety persist should also be considered, since surgical safety checklists were implemented more than a decade ago as a preventive measure.

Despite the limitations to the construction and validation of this instrument for assistance in cardiac surgery, the objective of validating a checklist in cardiac surgery to meet the real daily needs of the team was fulfilled. It is a starting point for the safety of specialized cardiac care aimed to offer specific elements of checking, and its execution is essential for patient safety.

A limitation of the study was the difficulty in accessing recent articles that address the proposed theme and contain information on validation of other instruments used in cardiac surgery, improvement in processes and results for patients, as well as non-application of the instrument in a pilot trial of surgery as one of the final content validation stages. Another limiting factor was the characterization of the judges (stages 3 and 4), as it was not possible to identify the region and workplace of these professionals in the submission form.

CONCLUSION

The development of this study made it possible to validate a checklist for safety in cardiac surgery, in a three-phase format, identifying by whom the verification items should be referred. It is a tool that can be used by the surgical team for safer care for patients undergoing cardiac procedures.

The checklist for safe cardiac surgery, with questions addressed to the respondent (professional), consists of 41 items and proved to be a valid instrument. It is a promising tool capable of mitigating the occurrence of adverse events if implemented and used properly.

Finally, the validated checklist should also be compared with other cardiac surgery checklists for ease of use, execution time, and staff adherence, as well as for its performance on outcome indicators related to adverse events in cardiac surgery.

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