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## ADAPTATION AND VALIDATION OF A SURGICAL SAFETY CHECKLIST IN THE CESAREAN DELIVERY<sup>1</sup>

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### ABSTRACT

**Objective:** adapt and validate a surgical safety instrument in the cesarean delivery, based on an integrative review of the literature, and on the World Health Organization protocol and surgical safety checklist.

**Method:** methodological study, with triangulation of data, involving a total of 43 participants, being eight judges for the validation of content and apparent of the instrument, using the Delphi technique, and for the semantic validation, another 35 professionals from the surgical team of a public hospital in the Federal District, Brazil. The reliability coefficient was applied to the instrument.

**Results:** the instrument achieved general content validity index of 0.9 and inter-rater agreement of 1. The total coefficient of Cronbach's alpha was 0.86, and the mean score of the dimensions obtained high scores.

**Conclusion:** the instrument presented validity in the three criteria studied and reliability to be applied in future studies evaluating the surgical safety in cesarean deliveries.

**DESCRIPTORS:** Women's health. Patient safety. Checklist. Nursing surgical center. Cesarean section.

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## ADAPTAÇÃO E VALIDAÇÃO DE *CHECKLIST* DE SEGURANÇA CIRÚRGICA NA CESÁREA

### RESUMO

**Objetivo:** adaptar e validar um instrumento de segurança cirúrgica na cesárea, com base em revisão integrativa da literatura, e no protocolo e *checklist* de segurança cirúrgica da Organização Mundial da Saúde.

**Método:** estudo metodológico, com triangulação de dados, envolvendo um total de 43 participantes, sendo oito juízes para a validação de conteúdo e aparente do instrumento, utilizando-se a técnica Delphi, e para a validação semântica outros 35 profissionais da equipe cirúrgica de um hospital público do Distrito Federal, Brasil. Foi aplicado o coeficiente de confiabilidade ao instrumento.

**Resultados:** o instrumento alcançou índice de validade de conteúdo geral de 0,9 e concordância interavaliadores de 1. O coeficiente total do alfa de Cronbach foi de 0,86, e a média dos escores das dimensões obteve notas elevadas.

**Conclusão:** o instrumento apresentou validade nos três critérios estudados e confiabilidade para ser aplicado em futuros estudos que avaliem a segurança cirúrgica na cesárea.

**DESCRIPTORIOS:** Saúde da mulher. Segurança do paciente. Lista de checagem. Enfermagem de centro cirúrgico. Cesárea.

# ADAPTACIÓN Y VALIDACIÓN DEL *CHECKLIST* DE SEGURIDAD CIRÚRGICA EN LA CESÁREA

## RESUMEN

**Objetivo:** adaptar y validar un instrumento de seguridad quirúrgica en la cesárea, con base en la revisión integrativa de la literatura y en el protocolo y *checklist* de seguridad quirúrgica de la Organización Mundial de la Salud.

**Método:** estudio metodológico con triangulación de datos envolviendo un total de 43 participantes, siendo ocho jueces para la validación del contenido aparente del instrumento. Se utilizó la técnica Delphi y para la validación semántica se usaron otros 35 profesionales del equipo quirúrgico de un hospital público del Distrito Federal, Brasil. Se aplicó el coeficiente de confiabilidad en el instrumento.

**Resultados:** el instrumento alcanzó el índice de validez del contenido general de 0,9 y la concordancia de los interevaluadores fue de 1. El coeficiente total del alfa de Cronbach fue de 0,86 y el promedio de los resultados de las dimensiones obtuvo notas elevadas.

**Conclusión:** el instrumento presentó validez en los tres criterios estudiados y confiabilidad para ser aplicado en futuros estudios que evalúen la seguridad quirúrgica en la cesárea.

**DESCRIPTORES:** Salud de la mujer. Seguridad del paciente. Lista de chequeo. Enfermería de centro quirúrgico. Cesárea.

## INTRODUCTION

It is estimated that approximately 2% of the obstetric patients experience some serious adverse event (AE) during labor and/or delivery, which contributes to maternal and neonatal morbidity and mortality. Considering about three million births a year in Brazil, this may represent around 60,000 women suffering from some AE each year.<sup>1-2</sup>

An AE consists of damage resulting from a therapy used, and it can be avoidable or not.<sup>3</sup> In the case of the cesarean delivery, the risks of various complications that may be fatal or that can permanently affect health, such as hemorrhage, infection and problems in anesthesia are increased. They can also produce severe pelvic adhesions, even with harmful consequences for future pregnancies. Pain is also an important factor after surgery, and it requires a long recovery period and more days of hospital stay.<sup>4-5</sup>

In this field of scientific knowledge that is being built, several initiatives have been implemented and have been assisting in the prevention of AEs, such as conducting research involving the application of checklists aimed at improving the work process.<sup>6</sup>

The World Health Organization (WHO) released in 2008 international guidelines for actions to promote and ensure the safety of surgical patients. A checklist was conducted in several services, and its results pointed to a reduction of the AEs, proving to be effective in improving the care provided.<sup>7-8</sup> In Brazil, the WHO surgical safety protocol and the surgical safety checklist were released in 2009.<sup>9</sup>

The implementation of an adapted WHO checklist in a Brazilian hospital admission unit brought significant benefits that resulted in the adherence of the guideline to establish the use of a checklist as a mandatory routine for elective gy-

necological and urological surgeries. For this end, awareness-raising actions were carried out with the surgical center staff, through educational meetings, seeking to prepare them for their application.<sup>10</sup>

In 2015, the safe childbirth checklist was released by WHO following a study conducted in 2010 involving nine countries, demonstrating significant improvements in obstetric care. The safe childbirth checklist allows the investigation of other aspects that cover the routine childbirth and cesarean delivery care.<sup>11-12</sup> Thus, it does not replace the safe surgery checklist, since it does not contain items related to the intraoperative period. It can be stated that both checklists complement each other and, together, reinforce the maternal and neonatal security.

In this perspective, adopting checklists and protocols that promote safety in surgical care can bring benefits to professionals and patients, as well as fully involve the health team. The results of studies analyzed in an integrative review indicated significant changes in the area of communication between the professionals of the surgical team, besides reducing incidents in obstetric care.<sup>13</sup>

The development of standardized actions, such as the creation of the protocol and the WHO surgical safety checklist, is a fundamental step, because it is extremely simple and effective. However, the peculiarities inherent in each locality mean that approaches to patient safety must be adapted.<sup>14</sup>

Considering the recommendation of the use of the surgical safety protocol and the adaptation of the WHO surgical safety checklist in view of the need of the different realities of the health services in the country and in the world, it is worth highlighting the interest in adapting it to the cesarean section, since it is one of the most performed surgeries worldwide, especially in Brazil, where the rates are around 52%, representing a greater exposure of women to the risks inherent to the surgery.<sup>15</sup>

In view of the above, the following guiding question emerged: what is the validity and reliability of an instrument adapted to the checklist format to be used in surgical safety in cesarean delivery?

In search of the answer to this questioning, the aim of this research was to adapt and validate an instrument of surgical safety in the cesarean delivery based on an integrative review of the literature, and on the protocol and checklist of surgical safety of the World Health Organization.

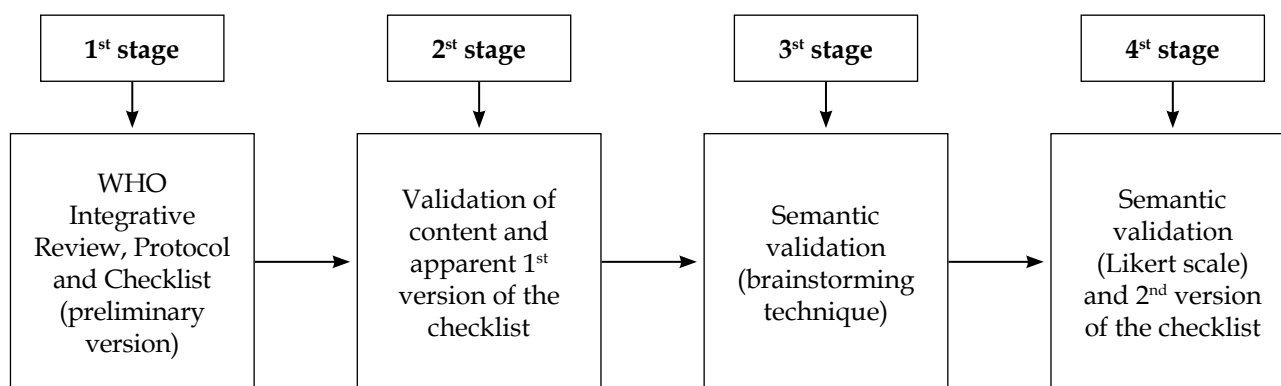
## METHOD

The methodological study was adopted to adapt and validate the surgical safety instrument

in the cesarean delivery. This type of research is dedicated to investigate through instruments and techniques of treatment of reality or to discuss theoretical-practical approaches.<sup>16</sup>

A total of 43 subjects participated in the study, being eight judges for the validation of content and apparent of the instrument, using the Delphi technique, and for the semantic validation, another 35 professionals of the surgical team of a public hospital of the Federal District, Brazil, being the sample defined according to the psychometric technique.<sup>17</sup> The research was carried out from December 2014 to March 2015.

According to figure 1, four stages were followed to obtain the instrument validation.



**Figure 1 - Stages of the checklist validation for the cesarean delivery**

In the first stage, the instrument was adapted based on the performance of an integrative review of the literature in which seven electronic databases were consulted from October to December 2014: The US National Library of Medicine, Cumulative Index to Nursing and Allied Health Literature, Latin American and Caribbean Health Sciences Literature, Medical Literature Analysis and Retrieval System Online, Cochrane Library, Database in Nursing and Scientific Electronic Library Online,<sup>13</sup> linking the guidelines present in the WHO protocol and checklist translated to Brazil. A preliminary version was reached in which the dimensions contained in the WHO surgical safety checklist, that is, before the anesthetic induction, were maintained before the surgical incision and before the patient left the operating room, represented respectively by the letters A, B and C.<sup>8</sup>

In the second stage, the instrument was delivered to eight judges for analysis, whose number was defined according to the principles of

the psychometric technique.<sup>17</sup> For the selection of judges, the following inclusion criteria were applied: professionals with *lato sensu* and *stricto sensu* post-graduation, sorted through the search of their curriculums in the Lattes Platform of the National Council of Scientific and Technological Development (CNPq), who had relevant experience and/or teaching and/or research experience in the areas of mother and child, anesthesiology and/or patient safety, and at least two years of experience in the work area, excluding professionals who did not meet these criteria.

The content and apparent validation of the instrument was performed using the Delphi technique, which analyzes and discusses the evaluation of experts on a specific topic. The Delphi technique requires accounting the results according to a group of judges, there is no ideal number for the composition of the group and this varies according to the phenomenon studied and the criteria defined by the researcher for the selection of these specialists.<sup>18</sup>

The judges evaluated each item of the instrument in order to obtain a consensus with the appropriately organized collective assessment. The questionnaire involved established criteria and it was sent to the specialists through electronic mail or applied in person. The structured questionnaire with the adapted items and the instructions for completion and return circulated through the group of judges until the consensus was reached.<sup>19</sup>

For the content analysis, eight criteria were adopted: 1) objectivity: item allows specific response; 2) clarity: the item must be intelligible to all the strata of the target population; 3) accuracy: the evaluation item must be distinct from the others; 4) variety: the items vary so as not to cause monotony; 5) simplicity: the item expresses a single idea; 6) relevance: it should be described in a relevant way; 7) credibility: it is formulated in a way that does not appear to be unreasonable; and 8) behavioral: the item allows clear and precise action.<sup>17</sup>

Then, the items were distributed on a Likert scale with 24 items judged according to the following classification: number 4 was representative, number 3 required small revision to be representative, number 2 needed major revision to be representative and item number 1 was not representative. A content validity index of 0.8 was adopted as a criterion for the permanence of the item. Some items had their writing adjusted when suggested by judges/experts.<sup>17,20</sup>

The inter-rater agreement was calculated to assess the extent of confidence of the judges who judged the instrument. An agreement of at least 80% among the experts can serve as a parameter on the relevance of the item to what it theoretically refers to.<sup>17,21</sup>

For apparent validity, the judges judged whether the items were appropriate for reaching the goal. This is a subjective process judged by a judge or group of judges. It does not consist of sophisticated technique, and it refers to the fact that the measurement instrument appears to be valid, that is, it indicates whether the items in the instrument seem to measure what is intended. It is a necessary characteristic, because if the instrument seems silly or inadequate, lack of validity may compromise the entire study.<sup>17,20-23</sup>

In the third and fourth stages, the semantic evaluation of the instrument was carried out. The instrument once validated by the judges was presented and discussed among the components of the surgical team and had as mediator the responsible researcher.

There are several efficient ways of performing the analysis of the instrument, such as applying the instrument to a sample of approximately 30 people of the target population and then discussing with them the doubts that the items raise. However, a technique that has been most effective in evaluating an item comprehension is to check them with small groups of people (3 or 4) in a brainstorming session.<sup>17</sup>

In this research, the decision was to use both techniques, with the purpose of inferring greater precision to the result. At first, a qualitative approach was used, through the brainstorming technique with five members of the surgical team, namely: an obstetrician, an anesthesiologist, the nurse in charge of the sector, an assistant nurse, and a nursing technician. Therefore, the inclusion criterion for participation in the brainstorming technique consisted of professionals of all categories who are part of the surgical team of the obstetric center and who provided direct care to the patient, excluding all other professionals and students.

In a brainstorming session, a facilitator guides and engages a group to generate ideas and present a list of possible solutions to a given problem or challenge.<sup>17,24</sup>

In the fourth stage, in the second moment, in order to consolidate and reiterate the results of the brainstorming technique, another semantic evaluation was used, through a quantitative approach with a Likert scale, whose rankings ranged from 1 to 5 with graded order of the following concepts assigned: 1 for "Not important"; 2 for "Little important"; 3 for "Fairly important"; 4 for "Extremely important"; and 5 for "Indispensable".

This scale was applied to 30 professionals who were part of the surgical team, among physicians, nurses and nursing technicians. Professionals who did not work in the surgical team of the investigated service and students were excluded. The consensus level from 70% among professionals was considered for the sum of the Likert scale scores for "extremely important" and "indispensable". Some studies recommend consensus from 50% to 80%.<sup>19</sup>

The data treatment was based on descriptive statistical analysis, with triangulation of qualitative and quantitative data. For the numerical data the programs Statistical Package for the Social Science version 22 and Microsoft Excel 2010 were used; using sum, mean, percentage and standard deviation. Subsequently, the reliability of the research instrument/checklist was estimated using the Cronbach's total alpha coefficient. This coefficient is considered significant when its value varies from 0.7 to 0.9.<sup>22</sup>

The national and international standards of research ethics involving human beings were met. The research project was approved with the opinion No. 901.713 of the Ethics Research Committee of the Foundation for Education and Research of Health Sciences of the Federal District, with CAAE 38102614.3.0000.5553.

## RESULTS

The results of the first stage of the study corresponded to the adaptation of the instrument based on the protocol and surgical safety checklist of the WHO, which were translated to Brazil, and to the conduction of an integrative review of the literature. In this review, of the 463 articles surveyed, 11 were selected, analyzed and categorized, which, in summary, demonstrated the scarcity of publications with a high level of evidence, indicating the need for further studies, especially by nurses.<sup>13</sup>

Afterwards, the adapted instrument was presented to the judges who participated in the second stage, corresponding to the content and apparent validation of the instrument. Still in this stage, the results regarding the characterization of the judges showed that all of them worked in the area of teaching and/or care, in the area of teaching and/or research, in the areas of maternal and child,

anesthesiology and/or patient safety, and had at least two years of professional experience. Among them, one was an obstetrician, one anesthesiologist, three nurses with a PhD, and three nurses with a master's degree. Their mean age was 47 years old ( $\pm 8.1$ ) and the mean time of experience in the area of performance was 15 years ( $\pm 7.4$ ).

For the third stage, five other healthcare professionals participated in the semantic analysis, through the technique of brainstorming, with mean age of 38.4 years old ( $\pm 6.6$ ) and mean of nine years of professional experience ( $\pm 6$ ). In the fourth stage, other 30 healthcare professionals also participated in the semantic analysis through the use of the Likert scale, of which 10 were doctors (33.3%), 10 nursing technicians (33.3%) and 10 nurses (33.3%), with a mean age of 42 years old ( $\pm 8.1$ ) and mean age of experience of 12 years ( $\pm 5.3$ ). The professional experience of the participants of the semantic analysis of the two groups was contemplated in the maternal-infant and/or anesthesiology areas, totaling a sample of 43 participants for all the stages of the study.

The instrument validated by the judges presented in table 1 shows the results of the Content Validity Index (CVI), by item. The overall index score was 0.96.

**Table 1 - First version of the instrument. Results of the Content Validity Index (CVI) by item. Brasília, FD, Brazil, 2015**

| Item | Dimensions A, B and C*  | CVI  |
|------|---|------|
| A1   | The identity of the patient, the procedure and the surgical site were confirmed.  | 1    |
| A2   | The patient's consent for the cesarean section and anesthesia were confirmed.   | 1    |
| A3   | All the equipment has been checked and are in proper working order, including the electric scalpel.                                     | 0.92 |
| A4   | The connection of the multiparametric monitor, including the pulse oximeter, was tested on the patient to verify its functioning.       | 1    |
| A5   | It was investigated whether the patient has any known allergies.  | 1    |
| A6   | The anesthesiologist checked if there is a difficult airway and risk of aspiration. If so, he requested equipment/assistance available. | 0.85 |
| A7   | The intravenous access has been checked for its adequate and functioning condition.   | 0.98 |
| A8   | It was checked if there was a risk of blood loss >500 mL. If so, the planning for blood components and derivatives is checked.          | 1    |
| B9   | All the team members introduce themselves by name and role.   | 0.98 |
| B10  | The team verbally confirms the patient's identification, surgical site and procedure.   | 1    |
| B11  | The obstetrician foresees critical steps, possible critical events and blood loss. If so, verbally revise the planning performed.       | 0.88 |
| B12  | Have any anesthetic complications been predicted by the anesthesiologist? If so, verbally revise the planning performed.                | 1    |

| Item | Dimensions A, B and C*  | CVI  |
|------|---|------|
| B13  | The nursing team revises the materials needed, to check if they are all present.  | 1    |
| B14  | It is checked by the nursing team if all the materials are within the sterilization period (including the indicator results).             | 0.92 |
| B15  | Issues related to equipment or any concerns that need to be addressed were raised by the nursing team.                                    | 0.85 |
| B16  | The placement of the scalpel plate was performed and communicated to the team.  | 0.98 |
| B17  | The nursing counts the gauze, checks the number of instruments and needles before the incision.   | 0.98 |
| B18  | The antimicrobial prophylaxis was performed 1 hour before the cesarean section delivery.  | 1    |
| B19  | The intravenous anti-HIV chemoprophylaxis for seropositive pregnant women was performed.  | 0.96 |
| C20  | The registry of the procedure performed by the obstetrician, anesthesiologist and nursing was verbally confirmed.                         | 1    |
| C21  | The team confirmed orally whether the surgical instrument and needle count was the same as the beginning of the cesarean section.         | 1    |
| C22  | The gauze count was reported to see if it matches the onset of cesarean section delivery.   | 0.98 |
| C23  | The nursing professional verbally confirms the correct labeling of any pathological sample when obtained during the procedure.            | 1    |
| C24  | The surgical team reviews essential concerns for the postpartum recovery of the patient, such as pain, hydration, dressing, among others. | 1    |

\* A: before the anesthetic induction; B: before the surgical incision; C: before the patient leaves the operating room.

It is observed that all the 24 items of the first version had high CVI. Suggestions for changes in the description of some items, as well as the introduction of "yes", "no" and "not applicable" options were met, obtaining the secondary version with 26 items. Such modifications can be visualized by comparing tables 1, 2 and 3, as well as in the description of the results. When presenting the first version

of the checklist for the group of participants in the brainstorming technique (3<sup>rd</sup> stage), all the members judged the instrument and items to be clear and relevant, and suggested minor modifications in the description of the items. Likewise, the respondents of the Likert scale, according to results that present the consensus level of the sum of the scores 4 and 5, are shown in table 2.

**Table 2 - Results of the semantic analysis performed with the health professionals, by percentage of responses, according to the Likert scale. Brasília, FD, Brazil, 2015**

| Item | 1<br>Not<br>important |   | 2<br>Little<br>important |      | 3<br>Fairly<br>important |      | 4<br>Extremely<br>important |      | 5<br>Indispensable |      |
|------|-----------------------|---|--------------------------|------|--------------------------|------|-----------------------------|------|--------------------|------|
|      | n*                    | % | n*                       | %    | n*                       | %    | n*                          | %    | n*                 | %    |
|      | A1                    | - | -                        | -    | -                        | -    | -                           | 7    | 23.3               | 23   |
| A2   | -                     | - | -                        | -    | 4                        | 13.3 | 7                           | 23.3 | 19                 | 63.3 |
| A3   | -                     | - | -                        | -    | 7                        | 23.3 | 7                           | 23.3 | 16                 | 53.3 |
| A4   | -                     | - | 1                        | 3.33 | 6                        | 20.0 | 3                           | 10.0 | 20                 | 66.6 |
| A5   | -                     | - | -                        | -    | 1                        | 3.3  | 5                           | 16.7 | 24                 | 80.0 |
| A6   | -                     | - | -                        | -    | -                        | -    | 4                           | 13.3 | 26                 | 86.6 |
| A7   | -                     | - | -                        | -    | 1                        | 3.3  | 3                           | 10.0 | 26                 | 86.6 |
| A8   | -                     | - | -                        | -    | -                        | -    | 4                           | 13.3 | 26                 | 86.6 |
| A9   | -                     | - | -                        | -    | 3                        | 10.0 | 3                           | 10.0 | 24                 | 80.0 |
| A10  | -                     | - | -                        | -    | -                        | -    | 5                           | 16.7 | 25                 | 83.3 |

| Item | 1<br>Not<br>important |      | 2<br>Little<br>important |       | 3<br>Fairly<br>important |      | 4<br>Extremely<br>important |      | 5<br>Indispensable |      |
|------|-----------------------|------|--------------------------|-------|--------------------------|------|-----------------------------|------|--------------------|------|
|      | n*                    | %    | n*                       | %     | n*                       | %    | n*                          | %    | n*                 | %    |
|      | A11                   | -    | -                        | -     | -                        | 1    | 3.3                         | 5    | 16.7               | 24   |
| B12  | 1                     | 3.33 | -                        | -     | 6                        | 20.0 | 10                          | 33.3 | 13                 | 43.3 |
| B13  | -                     | -    | 3                        | 10.00 | 2                        | 6.6  | 9                           | 30.0 | 16                 | 53.3 |
| B14  | -                     | -    | -                        | -     | 3                        | 10.0 | 9                           | 30.0 | 18                 | 60.0 |
| B15  | -                     | -    | -                        | -     | 2                        | 6.6  | 6                           | 20.0 | 22                 | 73.3 |
| B16  | -                     | -    | -                        | -     | 3                        | 10.0 | 8                           | 26.7 | 19                 | 63.3 |
| B17  | -                     | -    | -                        | -     | 2                        | 6.6  | 10                          | 33.3 | 18                 | 60.0 |
| B18  | -                     | -    | -                        | -     | 2                        | 6.6  | 8                           | 26.7 | 20                 | 66.6 |
| B19  | -                     | -    | 1                        | 3.33  | -                        | -    | 5                           | 16.7 | 24                 | 80.0 |
| B20  | -                     | -    | 1                        | 3.33  | 4                        | 13.3 | 7                           | 23.3 | 18                 | 60.0 |
| C21  | -                     | -    | -                        | -     | -                        | -    | 3                           | 10.0 | 27                 | 90.0 |
| C22  | 1                     | 3.33 | 2                        | 6.67  | -                        | -    | 10                          | 33.3 | 17                 | 56.6 |
| C23  | -                     | -    | -                        | -     | 1                        | 3.3  | 7                           | 23.3 | 22                 | 73.3 |
| C24  | -                     | -    | -                        | -     | 2                        | 6.6  | 5                           | 16.7 | 23                 | 76.6 |
| C25  | -                     | -    | -                        | -     | 1                        | 3.3  | 5                           | 16.7 | 24                 | 80.0 |
| C26  | -                     | -    | -                        | -     | -                        | -    | 9                           | 30.0 | 21                 | 70.0 |

\*N: number of assignments according to the Likert scale.

After the semantic analysis, the secondary or binary scale, as shown in table 3. final version of the instrument is inserted with a

**Table 3 - Secondary version of the instrument. Brasília, FD, Brazil, 2015**

| Item | Dimensions A, B and C*  | Scale† |   |
|------|---|--------|---|
| A1   | Patient confirmed identity (identification bracelet and medical record).  | 1      | 2 |
| A2   | Patient confirmed procedure.  | 1      | 2 |
| A3   | Patient confirmed surgical site.  | 1      | 2 |
| A4   | The Informed Consent Terms (childbirth and anesthesia) were signed by the patient.  | 1      | 2 |
| A5   | The equipment: gas sources, anesthesia equipment, multi-parameter monitor, electric scalpel, aspirator and focus were checked, tested and/or replaced.  | 1      | 2 |
| A6   | Medications and materials have been verified, checked and/or replaced.  | 1      | 2 |
| A7   | The anesthesia safety check was completed.  | 1      | 2 |
| A8   | Does the patient have a known allergy? <input type="checkbox"/> No <input type="checkbox"/> Yes. If so, which?  | 1      | 2 |
| A9   | Did the anesthesiologist assess whether there is a difficult airway/risk of aspiration? <input type="checkbox"/> No <input type="checkbox"/> Yes and has he requested equipment/assistance available? | 1      | 2 |
| A10  | Verified suitable venous access.  | 1      | 2 |
| A11  | Is there a significant risk of blood loss? <input type="checkbox"/> No <input type="checkbox"/> Yes, and planning for fluids and/or blood components and/or derivatives.                              | 1      | 2 |

| Item | Dimensions A, B and C*  | Scale† |   |
|------|---|--------|---|
| B12  | All the team members introduce themselves by name and role.   | 1      | 2 |
| B13  | Obstetricians, anesthesiologists and nursing staff confirm verbally: identification, surgical site and procedure.   | 1      | 2 |
| B14  | Obstetricians check for critical steps and cesarean delivery duration.  | 1      | 2 |
| B15  | The anesthesiology team checks if there is any specific concern regarding the patient.  | 1      | 2 |
| B16  | The nursing team reviews whether materials, instruments and gauze are present and within the sterilization period, including the indicator result.  | 1      | 2 |
| B17  | Are there any equipment-related issues or concerns?<br><input type="checkbox"/> No <input type="checkbox"/> Yes. If so, which?  | 1      | 2 |
| B18  | Was the scalpel plate placed and communicated to the team? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> NA   | 1      | 2 |
| B19  | The nursing counts the gauze, checks the number of instruments and needles before the incision.   | 1      | 2 |
| B20  | The antimicrobial prophylaxis was performed 1 hour before the cesarean section delivery.  | 1      | 2 |
| C21  | The mother and newborn identification wristbands were placed and checked according to the service standard.   | 1      | 2 |
| C22  | The professional of the surgical team confirms verbally what was the surgical procedure performed.  | 1      | 2 |
| C23  | The nurse practitioner or obstetrician verifies whether or not the numbers for surgical instruments, gauze, and needles are correct.  | 1      | 2 |
| C24  | Was there a sample for pathological anatomy from the cesarean section?<br><input type="checkbox"/> No <input type="checkbox"/> Yes and it has been stored and labeled according to service standards. | 1      | 2 |
| C25  | Does the nursing team identify if there is a problem with equipment to be solved?<br>No <input type="checkbox"/> Yes. If so, which?   | 1      | 2 |
| C26  | The surgical team reviews key concerns for the postpartum recovery and management of the patient.   | 1      | 2 |

\* A: before the anesthetic induction; B: before the surgical incision; C: before the patient leaves the operating room; † 1: the item is in compliance; 2: the item is not in compliance. NA: not applicable.

Comparing tables 1, 2 and 3, it is observed that items A1 and A2 were subdivided into four items (A1, A2, A3 and A4) in the subsequent version. The respondents pointed out a consensus of 87%, 77%, 77% and 86.6% of the sum of the rankings to be indispensable and extremely important.

It was questioned the permanence of the item A3 referring to the surgical site by some judges, since there would be no change of the place to be operated, since the cesarean section approaches the abdominal region. However, this item was maintained due to the possibility of unforeseen interferences in which the surgical site could be enlarged and/or modified, such as due to an accidental perforation of an intestinal loop, for example,

or a difficult fetal extraction in which the incision can become longitudinal.

The items of the first version A3 and A4 were grouped to become item A5, which made reference to the essential equipment used in a cesarean section delivery. It was obtained agreement of 87% of respondents of the scale Likert, who judged the item as indispensable and extremely important. Item A5 in the first version became the A8, with more detailed description.

In the first version of the instrument, items A6, A7, A8, B11 and B15 and their corresponding in the second version, items A9, A10, A11, B14 e B17, had their descriptions reformulated and they obtained, in the semantic analysis, a consensus among par-



ticipants of 90%, 100%, 97%, 90% and 93%, respectively, regarding the sum of the classifications for indispensable and extremely important.

The items B13, B10, B17 and B18 and their corresponding B12, B13, B19 and B20 obtained, respectively, 77%, 83.3%, 97% and 73.3% of the ratings are indispensable and extremely important, whereas items B13 and B14 of the first version were grouped and corresponded to item B16, at the suggestion of the participants with a consensus of 90% of the classifications to be extremely important and indispensable.

The remaining items belonging to the range from B10 to B16 and their corresponding items B13 to B18 have been modified to become more understandable and operational. The item B19 was eliminated in the preliminary version with the justification of already having specific protocols for several diseases. There was no request for the resumption of this item in the analysis of the instrument neither by the brainstorming participants nor by the respondents of the Likert scale.

The items C20, C23 and C24 and their corresponding items C22, C24 and C26 were simplified in the secondary version; and the items C21 and C22 in the first version were grouped and corresponded to item C23. All of them had consensus above 80%.

All the aforementioned considerations were accepted, including the addition of one more item to the instrument, C21, which deals with checking the identification bracelet of the mother and newborn, obtaining 100% agreement of the classifications as indispensable. The item C25 appeared in the secondary version of the instrument, and it deals with the possibility of equipment problems at the end of the cesarean section, and this item should be checked before and after the surgery.

In the total result of the semantic analysis, the items judged corresponded to more than 80% of the overall sum of the classifications indicated as indispensable and extremely important, with the exception of items A3, A4 and B12 and B20 of the secondary version, with the same value of 77% for the first three, and 73.3% for the latter.

By applying some validity and reliability tests to the instrument, the results presented a general index of content validity of 0.96 and Inter-rater Agreement (IRA) of 1. The total Cronbach's alpha coefficient was 0.86.

The mean scores of the A, B and C dimensions were calculated through the average of the sums of consensus that respondents gave to items of the same size. This value was transformed into a score, which varied from 0 to 100, representing the evaluation of the interviewees as shown in table 4.

**Table 4 - Mean of the dimension scores. Brasília, FD, Brazil, 2015**

| Dimension | Average | Standard Deviation | Minimum | Maximum |
|-----------|---------|--------------------|---------|---------|
| A*        | 93.8    | 5.6                | 80.0    | 100.0   |
| B*        | 89.7    | 9.6                | 53.3    | 100.0   |
| C*        | 93.6    | 8.5                | 66.6    | 100.0   |

\*A: before the anesthetic induction; B: before the surgical incision; C: before the patient leaves the operating room.

## DISCUSSION

In the synthesis of the integrative review, two thematic axes have emerged: promotion of patient safety and the cesarean delivery through the surgical safety checklist and recommendations for improving the quality of the care provided in the cesarean delivery. Studies show that all the actions that involve patient safety in the cesarean section aim to establish norms, protocols and programs that make health professionals aware of the importance of building a safety culture. Such protocols

may come in the form of surgical safety checklists, adapted to the peculiarities of the obstetric area in different scenarios.<sup>13</sup>

In the content and apparent validation phase, the CVI general index of the instrument was obtained by the sum of the CVI of each item and divided by the quantity of items, obtaining the recommended agreement of at least 80%.<sup>17,21</sup>

The CVI demonstrated consistency in the content to be measured by the calculation used for each item of the instrument based on the sum of the

number of judges, who evaluated the item as “3” or “4”, dividing the value by the total number of these. It is recommended that items that scored as “1” or “2” are reviewed or deleted.<sup>25-27</sup>

The instrument presented relevance, clarity and adequacy of the items, thus, it has an apparent validity.<sup>17,20</sup> The semantic analysis allowed us to verify if the items were intelligible, both for the population of lesser skill level and for the one of greater ability, obtained by the group discussion and by the application of the Likert scale. Thus, using short, simple and clear sentences was fundamental, since the statement should represent actions to be performed.<sup>17</sup>

It was verified that the instrument has content validity, semantic and apparent. The reliability was verified by the total coefficient of Cronbach’s alpha for the instrument, estimating its reliability. Values above 0.9 indicate the existence of items that are expressing the same information; and below 0.7, the items may not represent the desired factor or dimension. However, indispensable subjective aspects, such as the relevance of the item to the instrument, must be taken into account.<sup>22,28</sup>

Regarding the means of the scores of the dimensions, it is observed that all received a high score from the average of the consensuses obtained, which, according to the literature is around 50% to 80%.<sup>19</sup> In this way, the relevance of all the items of the instrument is reinforced, which means that, on average, the interviewees believe in how important the procedures of those dimensions are.

It is important to highlight the importance that the checklists have for the promotion of surgical safety in the cesarean section. Thus, because it is an unpublished study carried out in Brazil and because this instrument was adapted and validated from the WHO surgical safety checklist for the cesarean section and Brazilian reality, it was not possible to conduct a discussion based on other national literature published.

Studies conducted in Canada, the Netherlands, Japan, Austria and Spain on the use of WHO checklists in obstetric care, showing a significant improvement in the safety and quality of the care practices in the services where they were used, are evidenced.<sup>29-33</sup>

Thus, the surgical safety checklist in the cesarean delivery adapted and validated may contribute to promote patient safety as an instrument to improve quality and safety in obstetric care in the service studied.

The limitations of this study were due to the fact that the investigation was carried out in only one public obstetrical center in the Federal District (Brazil), and it was not possible to carry out before and after research using the adapted and validated checklist.

## CONCLUSION

The methodological study used to adapt and validate an instrument in a checklist format to perform the safe cesarean delivery followed the appropriate methodological rigor and proved to be valid and reliable to be used. The objective of the research was achieved by clearly, accurately and simply contemplating the main needs foreseen in a cesarean delivery checklist.

This research is relevant because of the implications for the care provided by the surgical team and, especially, by the nursing team, since the instrument adapted and validated has applicability in the obstetric center where the study was conducted. Thus, it may constitute health technology indispensable for the promotion of surgical safety in the cesarean delivery, and its practical utility may extend to other similar health services in Brazil.

Further studies that reveal possible changes after the insertion of the checklist in the service by means of training of all the surgical team of the obstetric center are suggested. This would make it possible to obtain comparisons of results that demonstrate possible improvements in the safety of the patient in the post-intervention cesarean delivery with the use of the checklist.

Regarding the implications of this study for the care practice in obstetrics, the results obtained instigate reflections and discussions as a relevant contribution of scientific knowledge in the field of health and nursing for the management in patient safety. The main contribution lies in the possible introduction of the surgical safety checklist in the cesarean delivery as a technology tool in the management of the care process, which promotes the desired benefit for the multiprofessional team and the users of the Brazilian health system.

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