

# Validation of graphic protocols to evaluate the safety of polytrauma patients

Validação de protocolos gráficos para avaliação da segurança do paciente politraumatizado

Validación de protocolos gráficos para la evaluación de la seguridad del paciente politraumatizado

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## Keywords

Patient safety; Multiple trauma; Protocols; Health evaluation

## Descritores

Segurança do paciente; Traumatismo múltiplo; Protocolos; Avaliação em saúde

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## Abstract

**Objective:** The content and face validation of graphic protocols to evaluate the structure, process and outcome of nursing care to polytrauma patients in emergency situations.

**Methods:** Methodological and quantitative study. The Delphi technique was applied in two rounds (Delphi I and Delphi II) for data collection. The Delphi I sample included 15 judges and Delphi II had 13 judges. All items of protocols with Content Validation Index (CVI) greater than 0.78 and a consensus of more than 70.0% in the Delphi technique were considered valid. Data were analyzed using descriptive and inferential statistics (Wilcoxon and Binomial Test). The  $p$ -value  $\leq 0.05$  was adopted for statistical significance. In addition, the Cronbach's alpha ( $\alpha$ ) was applied to evaluate the internal consistency of protocols. The item with  $\alpha \geq 0.7$  was considered reliable.

**Results:** All protocol evaluation requirements reached agreement higher than 80.0% among judges, and all items reached statistically significant evaluation levels. At the end of Delphi II, the three protocols were expressively valid (structure [CVI = 0.92], process [CVI = 0.96], and outcome [CVI = 0.96]) and reliable (structure [ $\alpha$  = 0.95], process [ $\alpha$  = 0.95], and outcome [ $\alpha$  = 0.89]).

**Conclusion:** The content and face complete validation of the protocols was achieved, as well as the internal validation.

## Resumo

**Objetivo:** Validar o conteúdo e a aparência dos protocolos gráficos para avaliação da estrutura, processo e resultado do cuidado seguro de enfermagem ao paciente politraumatizado em situação de emergência.

**Métodos:** Estudo metodológico e quantitativo. Para a coleta de dados, aplicou-se a técnica de Delphi em duas rodadas (Delphi I e Delphi II). A amostra do Delphi I consistiu em 15 juizes e o Delphi II arrolou 13 juizes. Considerou-se válidos aqueles itens dos protocolos com Índice de Validação de Conteúdo (IVC) maior que 0.78 e consenso de mais de 70,0% na técnica de Delphi. Os dados foram analisados por meio de estatística descritiva e inferencial (Teste de Wilcoxon e Binomial). Adotou-se o  $p$ -valor  $\leq 0,05$  para a significância estatística. Além disso, aplicou-se o Alfa de Cronbach ( $\alpha$ ) para avaliar a consistência interna dos protocolos. Considerou-se confiável aquele item que apresentasse o  $\alpha \geq 0,7$ .

**Resultados:** Todos os requisitos de avaliação dos protocolos alcançaram concordância entre os juizes superior a 80,0%, bem como todos os itens alcançaram níveis de avaliação estatisticamente significativos. Ao final do Delphi II, os três protocolos se apresentaram expressivamente válidos (estrutura [IVC = 0,92]; processo [IVC = 0,96]; e, resultado [IVC = 0,96]) e confiáveis (estrutura [ $\alpha$  = 0,95]; processo [ $\alpha$  = 0,95]; e, resultado [ $\alpha$  = 0,89]).

**Conclusão:** Atingiu-se a validação de conteúdo e de aparência dos protocolos integralmente, assim como, a validação interna com exímio.

## Resumen

**Objetivo:** Validar el contenido y la apariencia de los protocolos gráficos para evaluar la estructura, proceso y resultado del cuidado seguro de enfermería al paciente politraumatizado en situación de emergencia.

**Métodos:** Estudio metodológico y cuantitativo. Para la recolección de datos, se aplicó la técnica de Delphi en dos rondas (Delphi I y Delphi II). La muestra del Delphi I estuvo conformada por 15 jueces y el Delphi II contó con 13 jueces. Se consideraron válidos aquellos ítems de los protocolos con Índice de Validación de Contenido (IVC) mayor a 0.78 y consenso de más del 70,0% en la técnica de Delphi. Los datos fueron analizados por medio de estadística descriptiva e inferencial (Prueba de Wilcoxon y Binomial). Se adoptó  $p$ -valor  $\leq 0,05$  para la significancia estadística. Además, se aplicó el Alfa de Cronbach ( $\alpha$ ) para evaluar la consistencia interna de los protocolos. Se consideró confiable aquel ítem que presentara un  $\alpha \geq 0,7$ .

**Resultados:** Todos los requisitos de evaluación de los protocolos alcanzaron concordancia superior al 80,0% entre los jueces, así como todos los ítems alcanzaron niveles de evaluación estadísticamente significativos. Al final del Delphi II, los tres protocolos se presentaron expresamente válidos (estructura [IVC = 0,92], proceso [IVC = 0,96], y, resultado [IVC = 0,96]) y confiables (estructura [ $\alpha$  = 0,95], proceso [ $\alpha$  = 0,95], y, resultado [ $\alpha$  = 0,89]).

**Conclusión:** Se alcanzó la validación integral de contenido y de apariencia de los protocolos, así como la validación interna con experto.

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## Introduction

Traumatic injuries are a serious public health problem, and their main causes are traffic accidents and violence. Such injuries account for the mortality of approximately 5.8 million people annually worldwide, and represent around 10% of death causes. This reality is more quantitatively representative than the combined number of fatalities due to malaria, tuberculosis and HIV/AIDS.<sup>(1)</sup>

This high death rate from trauma-related injuries demands an increasing urgency to provide adequate and organized care in order to minimize the chances of post-treatment sequelae and death.<sup>(2)</sup>

In addition, delays in treatment of traumatic injuries and acute illnesses are known to cause increased morbidity and mortality in emergency care.<sup>(3)</sup> Therefore, health services must have adequate and qualified personnel for ensuring safe and quality care.

Safe care refers to avoiding, preventing or ameliorating adverse outcomes or injuries arising from the healthcare process. Patient safety is an important dimension of health quality, which is defined as reducing the healthcare-associated unnecessary harm risk to an acceptable minimum<sup>(4,5)</sup> in individuals with multiple trauma in the emergency unit, since they are already at imminent risk of death.

This quality is a product of two factors, namely: 1) Science (scientific knowledge) and available health technology; and 2) Its application in patient care. This conception of quality care is characterized by the following seven pillars: efficiency, effectiveness, readiness, optimization, acceptability, legitimacy and equity.<sup>(6-8)</sup>

However, the quality of health services, technology and checking processes that support patient safety in practice can be variable, unsafe and ineffective. Some factors may contribute substantially to unsafe care, ineffectiveness and lack of efficiency of care provided, such as high professional workload, overcrowding and deficient distribution of financial resources.<sup>(9,10)</sup>

Faced with this reality, health evaluation is a potential contributor to the safest and most effective care possible, and for application of aspects for optimal quality of care.

From this perspective, Avedis Donabedian designed a health quality evaluation model based on three elements, namely structure, process and outcome. Structure refers to the physical, human, material and financial resources required for health care. Process covers the relationships between health professionals and patients, since the search for adequate diagnosis, treatment and care. The outcome comprises the final product of care, which is represented by the effectiveness and efficiency of actions and the level of satisfaction of patients, professionals and managers.<sup>(11)</sup>

The evaluation of health services can contribute significantly to the provision of quality and harm-free care, in order to subsidize the development and implementation of new interventions with the objective of improving the quality and safety of care and collaborate for the good prognosis of polytrauma patients.

In view of this, protocols can support the evaluation of patient quality and safety in health services, which involves a set of actions and decisions focused on results. Graphic representations or graphic protocols can be used for the clear and concise representation of these processes, and they should present good formal quality, comprehensible reading, validity, reliability, evidence-based content, and proven effectiveness.<sup>(12)</sup>

Protocols are legal instruments that must be developed within the principles of evidence-based practice. Therefore, their use as a graphic visual guide for health services evaluation has the following advantages: a global vision of the evaluation process; use of simple symbology with standardized communication; clear definition of actions to be evaluated; graphic representations must be intelligible, of quick comprehension and all steps must be connected with well delineated and defined beginning and end; instructions cannot be redundant or subjective and lead to different interpretations; and it contributes to the development of structure, process and outcome indicators.<sup>(12)</sup>

This study was guided by the following research question: what is the content and face validity of three graphic protocols for the evaluation of safe care for polytrauma patients in an emergency situa-

tion? In order to answer this question, we aimed at the content and face validation of graphic protocols for evaluation of the structure, process and outcome of safe nursing care to polytrauma patients in an emergency situation.

## Methods

This is a methodological study of quantitative approach to treatment and analysis of data. It was conducted between May and June 2016. This type of study is suitable to check the methods of obtaining, organizing and analyzing data with a view to the development, validation and evaluation of instruments and techniques for the research scope. In addition, the aim was to build a reliable, accurate and usable instrument that can be applied by other researchers.<sup>(13)</sup>

The Delphi technique was applied for data collection. The search for judges was performed through advanced search by subject on the Lattes platform of the Conselho Nacional de Desenvolvimento Científico e Tecnológico – CNPq (<http://lattes.cnpq.br/>) in order to identify qualified Brazilian health professionals for acting as judges of the instrument.

They were selected by using descriptors related to the study theme ('Emergency' and 'Trauma'). In addition, the 'area of practice' filter was applied to the results. The curricula were analyzed from affiliation, professional experience, participation in research projects and publication of scientific papers in journals related to the present study theme.

The validation process of the graphic protocols happened in two Delphi rounds (Delphi I and Delphi II). The population of Delphi I was composed of 156 judges registered in the Lattes Platform and the initial sample included the first 40 researchers who met the pre-established criteria. Judges who did not respond or did not agree to participate in the study were automatically excluded. Thus, the final Delphi I sample consisted of 15 judges. In Delphi II, were contacted the 15 judges who participated until the end of Delphi I, 13 of whom sent the completed form in the

pre-determined period, and they formed the sample of Delphi II. Recommendations on the acceptable number of judges for the validation process state there must be between seven and 30 subjects, and they were followed.<sup>(14)</sup> For the sample selection, were established some criteria that should add at least 4 points for including the professional in the study, namely: PhD in nursing (2 points); master's degree in nursing (1 point); minimum experience of three years in the emergency area (2 points); participation in research projects involving the scope of emergency (1 point); authorship in at least two papers in the three previous years published in journals focused on themes involving emergency (1 point); and thesis or dissertation in the emergency area (1 point).<sup>(15)</sup>

Nursing professionals who were far from emergency care situations for more than five years and/or without studies on the theme for more than two years, less than two papers published in journals on the area and judges who did not follow all steps for the content and face validation of protocols within the pre-established deadline were excluded.

The contact with judges occurred in four distinct steps: 1) Contact via e-mail for explaining the purpose and importance of the judges' participation in the study and questioning the possibility of their collaboration for the validation of graphic protocols by means of an invitation letter. The time established for the judges' response to the investigator was ten days; 2) The Informed Consent (IC) form and approval of the Research Ethics Committee were sent electronically for judges who expressed their interest, and the specialist was given seven days to sign the IC and forward it to the researcher; 3) Upon receipt of the signed IC, started the process of content and face validation of the graphic protocols, which were made available in full for evaluation via Google Forms. This phase was the Delphi I and a 20-day period was set for the return of judges' evaluation; and 4) After analyzing Delphi I data and redesigning the protocols as recommended by the judges, they were contacted and was sent a new electronic form with the adjusted instruments for a new evaluation - Delphi II. Another 20-day period was the deadline established for sending the evaluation to the researcher.

The content and face validation of the graphic protocols followed the psychometric model recommendations as proposed by Pasquali, in which twelve evaluation criteria are addressed in order to consider a given construct as valid. However, three of these are not applicable to the type of instrument built and validated in the study, namely: variety, mode and equilibrium. In this context, Pasquali's criteria applied to the validation process and used as a parameter for judges' evaluation were: 1) Utility/Relevance (protocols are relevant and meet the proposed purpose); 2) Consistency/Amplitude (content is sufficiently deep for understanding the protocols); 3) Clarity (protocols are explicitly stated, simple and unambiguous); 4) Objectivity (protocols allow punctual response); 5) Simplicity (items express a single idea); 6) Feasibility (protocols are applicable); 7) Update (items follow the most current evidence-based practices); 8) Accuracy (each evaluation item is distinct from the others, and items do not get confused); and 9) Behavior (protocols do not have abstract items).<sup>(16)</sup>

For validation of protocols, the judges' evaluations were inserted into the Microsoft Excel 2010<sup>®</sup> database, tabulated and analyzed in SPSS version 22.0, where the scores attributed to each item were checked. The relevance of items was obtained by application of the Content Validation Index (CVI), which was calculated as follows:<sup>(13)</sup>

$$CVI = \frac{\text{total number of items considered relevant by judges}}{\text{total number of items}}$$

Items with CVI greater than 0.78 and consensus of more than 70.0% in the Delphi technique were considered valid.<sup>(13)</sup>

In addition, descriptive analysis (absolute and relative frequencies, minimum, maximum, median, median and standard deviation) and inferential analysis (Wilcoxon non-parametric test and binomial test) were performed in order to compare the medians, the consensus among judges and the CVI scores achieved in the Delphi rounds. For that end, the  $p$ -value  $\leq 0.05$  was set as a parameter for statistical significance. The Cronbach's alpha ( $\alpha$ ) was

used to assess the internal consistency of protocols. As advocated by authors,<sup>(17)</sup> items with  $\alpha \geq 0.7$  were considered reliable.

For the construction of graphic protocols, were followed the national and international guidelines of research organizations that work in the perspective of patient safety, the Brazilian legal framework with ordinances and resolutions, and data from a Scoping Review based on scientific literature evidence (Appendix 1). The phase of designing the graphic protocols also involved conducting a focus group with nursing professionals working daily in the emergency service to polytrauma patients. The purpose was to identify the necessary elements to compose the graphic protocols for evaluation of safe care to polytrauma patients related to the structure, process, and outcome of emergency care.

The study followed the ethical aspects of research with human beings. All participants were informed about the manipulation and dissemination of data and were ensured about their anonymity. The study was approved by the Research Ethics Committee under number 1.053.690 from April 24<sup>th</sup> 2015 and CAAE number 42951415.6.0000.5537.

## Results

Fifteen judges participated in the evaluation process of Delphi I. Their minimum age was 30 years and the maximum age was 55 years (mean = 40.4 and standard deviation = 9.1), minimum time since graduation was 8 years and maximum was 32 years (mean = 17.3 and standard deviation = 9.5), and minimum time in the emergency department was 4 years and the maximum time was 24 years (mean = 13.0 and standard deviation = 5.9).

In Delphi II, 13 judges collaborated with the validation of graphic protocols, and they were aged between 31 and 55 years (mean = 41.9 and standard deviation = 9.2), time since graduation was between 9 and 33 years (mean = 18.6 and standard deviation = 9.7), and their time of experience in the emergency department was between 4 and 21 years (mean = 12.9 and standard deviation = 6.1).



In table 1 is described the characterization of judges participating in the two Delphi rounds.

**Table 1.** Characterization of judges participating in Delphi I and Delphi II

| Characterization of judges                | Delphi I (n=15)<br>n(%) | Delphi II (n=13)<br>n(%) |
|---|-------------------------|--------------------------|
| Sex                                       |                         |                          |
| Male                                      | 5(33.3)                 | 5(38.5)                  |
| Female                                    | 10(66.7)                | 8(61.5)                  |
| Professional qualification                |                         |                          |
| Master's                                  | 4(26.7)                 | 2(15.4)                  |
| PhD                                       | 11(73.3)                | 11(84.6)                 |
| Current working area                      |                         |                          |
| Teaching                                  | 4(26.7)                 | 4(30.8)                  |
| Urgency and emergency                     | 5(33.3)                 | 7(53.8)                  |
| Intensive care                            | 1(6.7)                  | 1(7.7)                   |
| Urgency and emergency and teaching        | 4(26.7)                 | 1(7.7)                   |
| Urgency and emergency and surgical center | 1(6.7)                  | 0(0.0)                   |
| Areas of practice                         |                         |                          |
| Teaching                                  | 3(20.0)                 | 3(23.1)                  |
| Care                                      | 1(6.7)                  | 2(15.4)                  |
| Care and Management                       | 1(6.7)                  | 1(7.7)                   |
| Teaching and Management                   | 2(13.3)                 | 2(15.4)                  |
| Teaching and Care                         | 5(33.3)                 | 3(23.1)                  |
| Teaching, Care and Management             | 3(20.0)                 | 2(15.4)                  |
| Time since graduation                     |                         |                          |
| Up to 10 years                            | 6(40.0)                 | 4(30.8)                  |
| More than 10 years                        | 9(60.0)                 | 9(69.2)                  |
| Time of experience in the emergency area  |                         |                          |
| Up to 10 years                            | 9(60.0)                 | 7(53.8)                  |
| More than 10 years                        | 6(40.0)                 | 6(46.2)                  |
| Region of practice                        |                         |                          |
| Northeast                                 | 4(26.7)                 | 2(15.4)                  |
| South                                     | 5(33.3)                 | 5(38.5)                  |
| Southeast                                 | 5(33.3)                 | 5(38.5)                  |
| Midwest                                   | 1(6.7)                  | 1(7.7)                   |

As shown in table 1, most judges participating in Delphi I were female (n=10; 66.7%), with a PhD degree (n=11; 73.3%), working in urgency and emergency departments associated with teaching (n=5; 33.3%). In addition, their time since graduation was of more than 10 years (n=9; 60.0%) and they were acting predominantly in the South (n=5; 33.3%) and Southeast (n=5; 33.3%) of Brazil.

Most judges in Delphi II were female (n=8; 61.5%), with a PhD degree (n=11; 84.6%), care nurses and/or researchers in urgency and emergency (n=7; 53.8%), working in care and teaching (n=3; 23.1%) and only in teaching (n=3; 23.1%). Regarding time since graduation and experience in

urgency and emergency, there was preponderance among those who graduated more than 10 years before the study period (n=9; 69.2%), and those in the practice of urgency and emergency of up to 10 years (n=7; 53.8%) in the South (n=5; 38.5%) and Southeast (n=5; 38.5%) of Brazil.

Table 2 describes the final consensus among judges on the items that obtained full agreement ('I totally agree') according to Pasquali's evaluation criteria.

Table 2 shows that only the requirements regarding consistency (66.7%) and simplicity (66.7%) of the items of the structure were below recommendations for considering protocols as valid in Delphi I. In Delphi II, none of the requirements had agreement below 80.0%, which reflects a high approval rate of the graphic protocols.

However, the 'behavior' requirement related to the outcome showed a decrease in Delphi II (84.6%) compared with Delphi I (93.3%). This may be related to the reduction in the number of judges (n=2; 13.3%) in Delphi II who fully agreed in Delphi I. Another factor is the partial agreement among some judges, even with the support of justification and reference, regarding the item associated with the maximum recommended time for patient stay in the emergency department. The literature has different number of hours for such situation.

As for the level of statistical significance in the agreement between judges in Delphi I, the requirements of consistency, simplicity and behavior had no significance in the evaluation of items of the structure protocol. The inherent aspects of utility/relevance and update regarding the evaluation of items of the outcome protocol obtained a non-significant  $\rho$ -value in Delphi I. However, in Delphi II, all items evaluated were statistically significant ( $\rho \leq 0.05$ ) in relation to agreement between judges. The process protocol obtained statistical significance in all Delphi rounds.

The analysis related to the quality evaluation of the graphic protocols, and the Content Validation Index (CVI) and internal consistency (Cronbach's alpha) are shown in table 3.

In relation to the average evaluations of the quality of protocols, there was a variation between

**Table 2.** Consensus among judges on items evaluated in Delphi I and Delphi II

| Evaluation requirements | Structure                     |                                | Process                       |                                | Result                        |                                |
|-------------------------|-------------------------------|--------------------------------|-------------------------------|--------------------------------|-------------------------------|--------------------------------|
|                         | Delphi I<br>( $\rho$ -value*) | Delphi II<br>( $\rho$ -value*) | Delphi I<br>( $\rho$ -value*) | Delphi II<br>( $\rho$ -value*) | Delphi I<br>( $\rho$ -value*) | Delphi II<br>( $\rho$ -value*) |
| Utility/Relevance       | 80.0% (0.04)**                | 92.3% (0.03)**                 | 93.3% (0.001)**               | 100.0% (0.00)**                | 73.3% (0.12)                  | 92.3% (0.003)**                |
| Consistency             | 66.7% (0.30)                  | 92.3% (0.003)**                | 80.0% (0.04)**                | 92.3% (0.003)**                | 80.0% (0.04)**                | 92.3% (0.003)**                |
| Clarity                 | 86.7% (0.007)**               | 100.0% (0.00)**                | 80.0% (0.04)**                | 84.6% (0.02)**                 | 86.7% (0.007)**               | 92.3% (0.003)**                |
| Objectivity             | 80.0% (0.04)**                | 84.6% (0.02)**                 | 86.7% (0.007)**               | 92.3% (0.003)**                | 86.7% (0.007)**               | 100.0% (0.00)**                |
| Simplicity              | 66.7% (0.30)                  | 92.3% (0.003)**                | 93.3% (0.001)**               | 100.0% (0.00)**                | 86.7% (0.007)**               | 100.0% (0.00)**                |
| Feasibility             | 80.0% (0.04)**                | 100.0% (0.00)**                | 93.3% (0.001)**               | 100.0% (0.00)**                | 86.7% (0.007)**               | 100.0% (0.00)**                |
| Update                  | 80.0% (0.04)**                | 100.0% (0.00)**                | 86.7% (0.007)**               | 100.0% (0.00)**                | 73.3% (0.12)                  | 100.0% (0.00)**                |
| Accuracy                | 80.0% (0.04)**                | 84.6% (0.02)**                 | 80.0% (0.04)**                | 92.3% (0.003)**                | 93.3% (0.001)**               | 100.0% (0.00)**                |
| Behavior                | 73.3% (0.12)                  | 84.6% (0.02)**                 | 86.7% (0.007)**               | 100.0% (0.00)**                | 93.3% (0.001)**               | 84.6% (0.02)**                 |

Source: Pimenta CA, Lopes CT, Amorim AF, Nishi FA, Shimoda GT, Jensen R. Guide for the construction of nursing care protocols. São Paulo: Regional Nursing Council; 2015.<sup>12</sup>

\*Binomial test; \*\*  $\rho \leq 0.05$

**Table 3.** Judges' judgment on the quality of graphic protocols in Delphi I and Delphi II

| Evaluation                    | Structure |       |            | Process |       |            | Outcome |       |            |
|-------------------------------|-----------|-------|------------|---------|-------|------------|---------|-------|------------|
|                               | DI*       | DII** | p-value*** | DI*     | DII** | p-value*** | DI*     | DII** | p-value*** |
| Median                        | 9.0       | 9.0   | 0.321      | 9.0     | 9.0   | 0.454      | 10.0    | 9.0   | 0.874      |
| Standard deviation            | 2.0       | 0.8   | -          | 1.1     | 0.8   | -          | 1.0     | 1.0   | -          |
| CVI                           | 0.77      | 0.92  | 0.007      | 0.87    | 0.96  | 0.007      | 0.84    | 0.96  | 0.020      |
| Cronbach's alpha ( $\alpha$ ) | 0.51      | 0.95  | -          | 0.75    | 0.92  | -          | 0.56    | 0.89  | -          |

\*Delphi I; \*\*Delphi II; \*\*\*WILCOXON test

3.0 and 10.0 for structure; 7.0 and 10.0 for process; and between 7.0 and 10.0 for the outcome, with general average values of 8.4, 9.0 and 9.3 in Delphi I, respectively. In Delphi II, average values ranged from 8.0 to 10.0 in structure, process and outcome, and these overall mean values were 9.1, 9.2 and 9.2, in due order. There was no statistically significant variation between median values, as shown in table 3.

Regarding CVI, the final round of Delphi allowed the achievement of the best score in the content and face validation of the graphic protocols. The Wilcoxon test demonstrated statistical significance between the Delphi rounds of the three protocols, namely: structure ( $\rho = 0.007$ ), process ( $\rho = 0.007$ ) and outcome ( $\rho = 0.02$ ).

For Cronbach's alpha, only the process-related items presented acceptable reliability ( $\alpha = 0.75$ ) in Delphi I, and the others (structure and outcome) reached a valid internal consistency only in Delphi II. In the end, the three protocols demonstrated expressive reliability, as follows: structure ( $\alpha = 0.95$ ), process ( $\alpha = 0.95$ ) and outcome ( $\alpha = 0.89$ ).

Finally, judges did not object the recommendation for using graphic protocols in emergency

service practice. In Delphi I, 60.0% of judges indicated the use of the evaluation instrument provided that modifications were made. In Delphi II, almost 70.0% recommended its use without need for changes (Appendix 2).

## Discussion

Traumatic injury situations account for about 50.0% of the worldwide rates of mortality and motor and sensory impairment in populations of developed countries, especially among young people and adults aged between 15 and 44 years.<sup>(18,19)</sup>

This reality places traumatic events as a remarkable global health problem and contributes to a great burden of disability and suffering.<sup>(19,20)</sup> Given this situation, implementing measures for the safe and quality care to polytrauma patients is key.

Therefore, this study involved the participation of 15 judges in Delphi I (DI) and 13 judges in Delphi II (DII), with a view to making evaluation protocols of the safe care of polytrauma patients in emergency situations reliable and valid regarding content and face.

Validity and reliability are essential criteria for evaluating the quality of an instrument. Validity refers to how appropriate a particular instrument is for measuring what it is supposed to measure, i.e., its purpose. Reliability refers to its accuracy, that is, how accurately it reflects the actual measures of the investigated attribute.<sup>(13,21)</sup>

In this study, there was female hegemony (66.7% - DI and 61.5% - DII) among participating judges. Another study<sup>(22)</sup> has demonstrated this has been the reality in the profession since the beginning of the history of nursing, which is marked by the presence of women and their insertion in the labor market. This is ratified by data published by the Federal Nursing Council (Portuguese acronym: COFEn) that states the Brazilian scenario is formed by 87.2% of female nursing professionals.<sup>(23,24)</sup>

Regarding professional qualification, a great number of professionals with a PhD (73.3% - DI and 84.6% - DII) participated in this validation study. Researchers<sup>(25)</sup> report that professionals holding master's and PhD degrees are responsible for promoting the impact on practices and, consequently, advances in Nursing.

A study<sup>(26)</sup> states that Brazilian nurses with *stricto sensu* postgraduate studies (PhD and master's) fit in a reality guided by policies that strengthen and innovate their actions in order to achieve significant educational, socio-political and scientific-technological impacts for Nursing and Health, such as science, technology and the social profession.

Regarding the greater number of judges working in the care/teaching pair (33.3% - DI and 23.1% - DII), in nursing, as in any other health area, teaching and care represent a two-way street, since one does not exist without the other and the two interact constantly.<sup>(27)</sup>

Participation of experienced professionals involved in the field of research and care is strongly relevant for the validation of evaluation instruments to be applied in practice. As in the case of this study, which proposed the validation of evaluation protocols for the structure, process and outcome of emergency services.

The structure corresponds to the physical, human, material, and financial resources required for health care, and includes financing and availability of adequate and skilled workforce. The process involves activities related to health professionals and patients based on accepted standards. And the outcome involves the end product of the care provided, which considers the health and satisfaction of standards and expectations.<sup>(11)</sup>

In the validation process of the protocols (final product of the present study), judges reached a significant concordance index in all evaluated items. Therefore, the instrument is considered valid in relation to evaluation of utility/pertinence, consistency, clarity, objectivity, simplicity, feasibility, update, accuracy and behavior.<sup>(13)</sup> This certifies the instrument is suitable for a reliable practical application.

The content and face validation of the information in the instruments is essential for their safe and reliable application in the services and/or population to which they are aimed. Thus, recognizing the quality of instruments is fundamental for the legitimacy and credibility of the results of a study, which reinforces the importance of the validation process.<sup>(21,28,29)</sup>

Regarding CVI, was reached consensus among participants in the judgment of the protocols validity and on what it is aimed to measure. The evaluated instrument also has the necessary content to evaluate what is proposed. This becomes evident given the agreement among judges in the evaluation of components of the structure (CVI: DI - 0.77 and DII - 0.92), process (CVI: DI - 0.87 and DII - 0.96). and outcome (CVI: DI - 0.56 and DII - 0.89). Such variations were statistically significant ( $p \leq 0.05$ ), which indicates a better consensus associated with improvements of the instrument between the Delphi rounds.

In this study, the internal consistency measured by the Cronbach's alpha result was significantly better between the Delphi rounds. This coefficient reflects the reproducibility and stability in the protocols, so that multiple applications can generate similar and accurate results.<sup>(30,31)</sup> Thus, the Cronbach's alpha result indicates the internal consistency of the

instruments and consequently, of the items composing them.<sup>(32)</sup>

Nursing requires conceptualizations of the phenomena it treats and/or cares for. In this perspective, validation studies are fundamental for the scientifically-based practice that overcomes the establishment of inductive/deductive nursing diagnoses or care in order to increase the quality of care and the visibility of professional practice.<sup>(33)</sup>

A limitation of the present study was the specificity of protocols to evaluate patient safety linked to nursing care only. Therefore, is recommended further research for the construction and validation of instruments aimed at other emergency areas, such as pre-hospital. In addition, they should be broad enough to evaluate multi-professional care.

Nonetheless, this study will substantially contribute to draw attention of professionals regarding the importance of adaptations for providing safe care in the emergency service in order to contribute to a better prognosis of trauma victims and provision of harm free nursing care and reduction of deaths linked to adverse events.

## Conclusion

The validation process of graphic protocols involved 15 judges in Delphi I. They judged that only the items related to the structure were not adequate for consistency (66.7%) and simplicity (66.7%) and, consequently, obtained CVI below that recommended (CVI = 0.77). In addition, internal validation was not achieved in the evaluation of the structure ( $\alpha = 0.51$ ) and outcome ( $\alpha = 0.56$ ). Delphi II involved 13 judges, and the content and face validation of the protocols was achieved in full (Structure [CVI = 0.92], Process [CVI = 0.96] and Outcome [CVI = 0.96]), as well as internal validation (Structure [ $\alpha = 0.95$ ], Process [ $\alpha = 0.92$ ] and Outcome [ $\alpha = 0.89$ ]). In view of the results achieved, it is proven that the graphic protocols for evaluation of the safe care to polytrauma patients in an emergency situation are reliable and valid in

terms of content and face for use in clinical validation in health services.

## Acknowledgements

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## Collaborations

Gomes ATL, Ferreira Júnior MA and Santos VEP contributed in the conception and design, analysis and interpretation of data, writing of the article and critical review of intellectual content, and final approval of the version to be published. Alves KYA, Bezerril MS and Rodrigues CCFM collaborated in the relevant critical review of intellectual content and final approval of the version to be published.

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**Appendix 1. References used as basis for the construction of graphic protocols**

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## Appendix 2. Graphic protocols for the evaluation of safe care to polytrauma patients in emergency situations

### IDENTIFICAÇÃO DO AVALIADOR

|   |
|---|
| Nome do avaliador: _____  |
| Instituição de Saúde: _____   |
| Data de avaliação: ___/___/___      Início: ___h___      Término: ___h___ |

### INSTRUÇÕES PARA A APLICAÇÃO DOS PROTOCOLOS NOS SERVIÇOS DE SAÚDE

Caro avaliador, esse instrumento é composto por três partes, a saber: 1) avaliação da estrutura do serviço de emergência; 2) avaliação do processo do cuidado de enfermagem seguro aos pacientes politraumatizados em situação de emergência; e, 3) avaliação do resultado do cuidado de enfermagem seguro aos pacientes politraumatizados em situação de emergência.

Para tanto, a fim de mensurar a aplicação dos protocolos de avaliação da estrutura e do processo do cuidado seguro no serviço de emergência, atribuir-se-á uma pontuação de acordo com: adequado (2 pontos), parcialmente adequado (1 ponto) ou inadequado (0 pontos) para cada item avaliado.

Em relação á avaliação dos resultados, considerar-se-á o resultado seguro (2 pontos) ou inseguro (0 pontos), conforme a avaliação dos itens dispostos na representação gráfica.





Ressalta-se que o item será considerado adequado se todos os elementos estiverem presentes no momento da avaliação, parcialmente adequado se pelo menos um elemento estiver ausente e, por fim, a inadequação se dará no caso de faltarem todos os elementos.

Quanto a avaliação dos resultados, o item será considerado seguro se nenhum evento adverso ou erro relacionados aos indicadores de segurança do paciente e ferramentas de gatilho ocorrerem durante a avaliação do serviço e a insegurança se dará mediante a ocorrência de pelo menos um evento adverso ou erro associados aos indicadores e ferramentas de gatilho.

Após a aplicação dos protocolos, o somatório da pontuação final dos itens resultará na classificação da estrutura, do processo e do resultado em seguro, parcialmente seguro ou inseguro para o paciente, segundo os quadros disponíveis abaixo de cada representação gráfica.

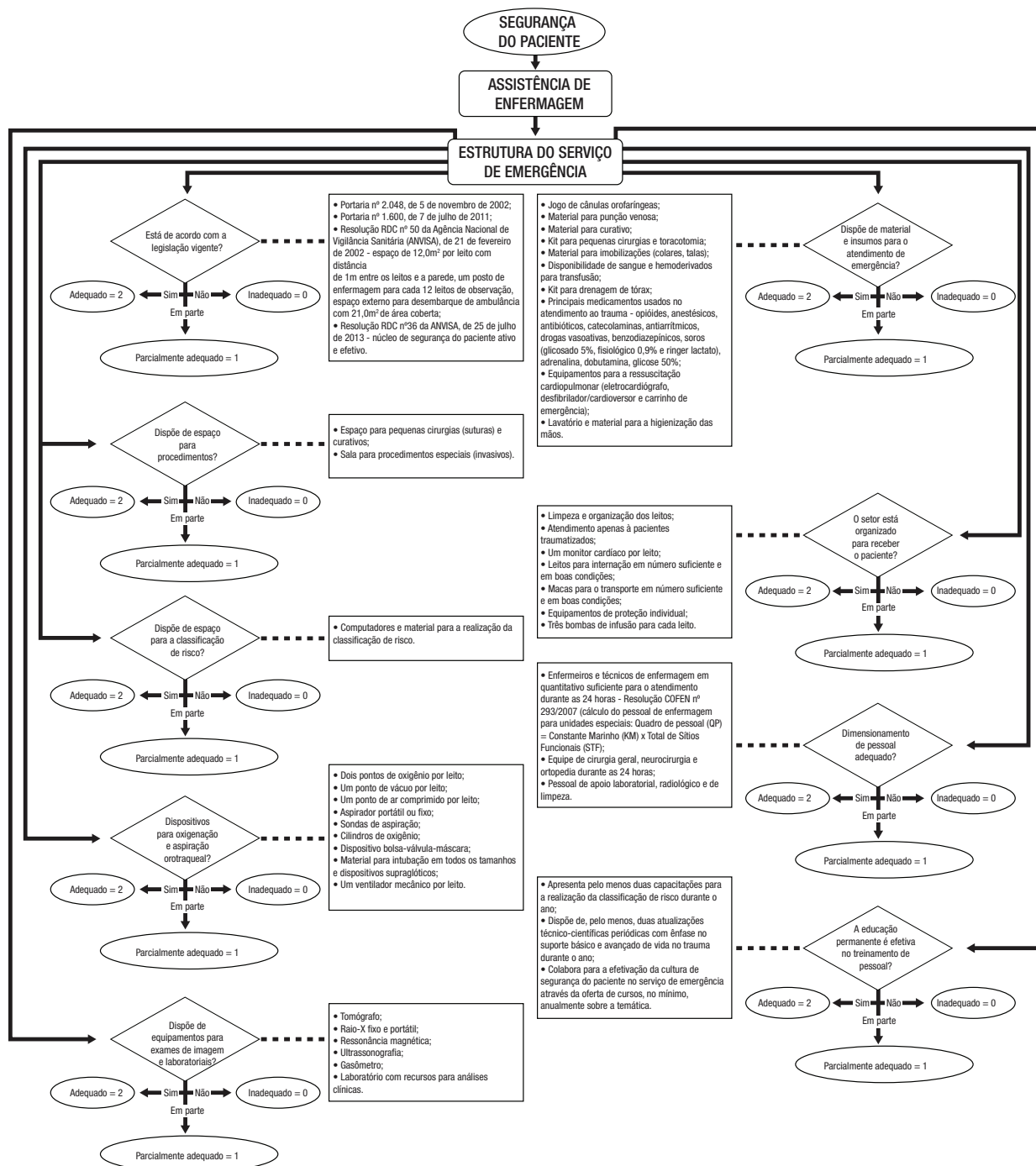
A segurança do serviço de emergência (estrutura e/ou processo e/ou resultado seguro (a)) está condicionada a não pontuar “zero” em nenhum dos itens avaliados.

A aparência dos protocolos gráficos foi elaborada de acordo com a proposta de material publicado pelo Conselho Regional de Enfermagem de São Paulo<sup>(1)</sup>, em que há o emprego de formas gráficas com determinados significados no constructo, conforme demonstrado na legenda abaixo.

| FORMA GRÁFICA   | SIGNIFICADO  |
|---|--|
|  | Indica início e final do processo.                       |
|  | Indica a ação a ser executada.                           |
|  | Indica momentos de tomada de decisão ou questionamentos. |
|  | Conecta uma caixa explicativa.                           |

<sup>1</sup> Pimenta CA, Lopes CT, Amorim AF, Nishi FA, Shimoda GT, Jensen R. Guia para a construção de protocolos assistenciais de enfermagem. São Paulo: Conselho Regional de Enfermagem; 2015.

### AVALIAÇÃO DA ESTRUTURA DO CUIDADO SEGURO DE ENFERMAGEM AO PACIENTE POLITRAUMATIZADO EM SITUAÇÃO DE EMERGÊNCIA

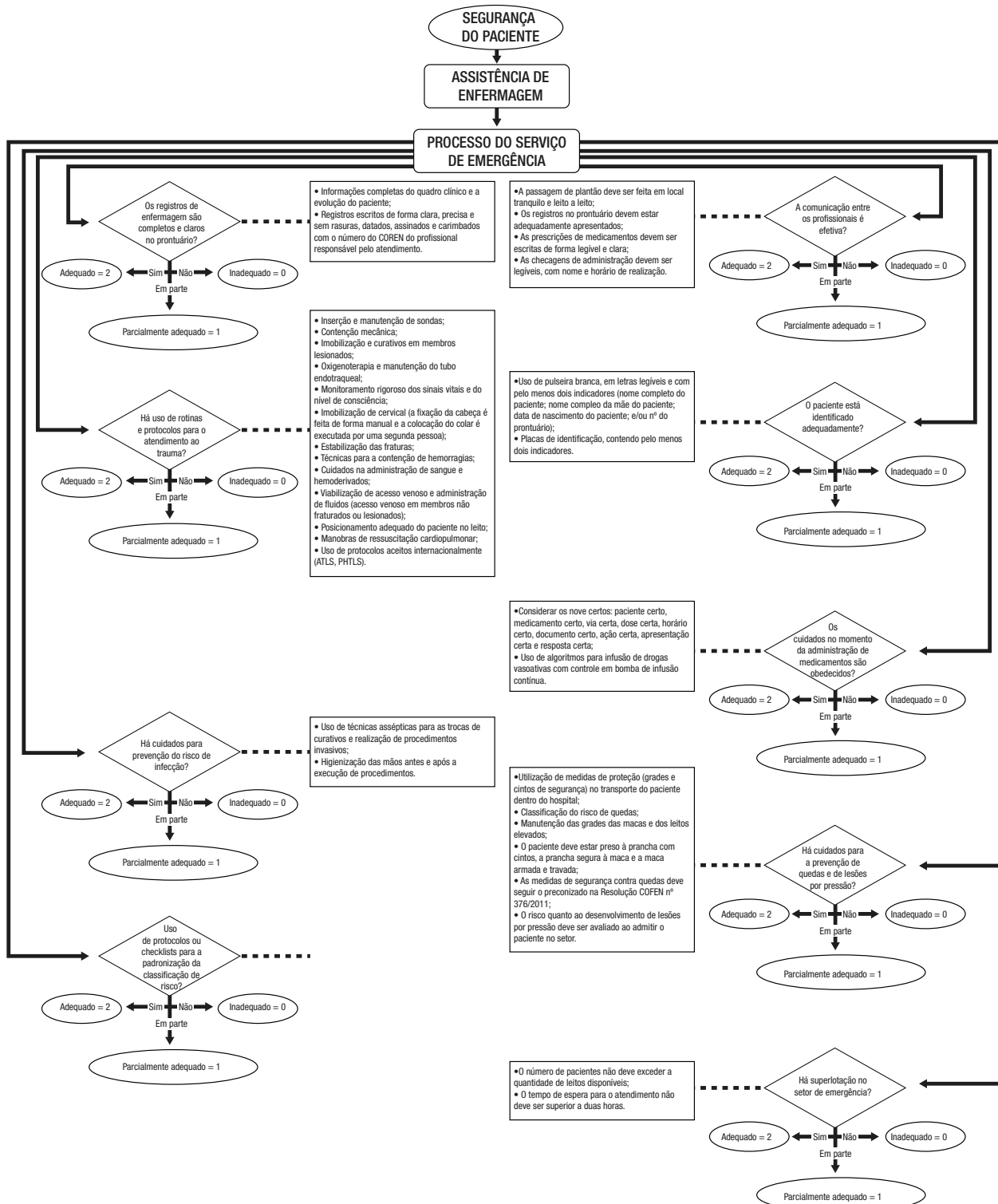


**AVALIAÇÃO DA ESTRUTURA**

0 a 6 pontos = Estrutura insegura  
7 a 12 pontos = Estrutura parcialmente segura  
13 a 18 pontos = Estrutura segura



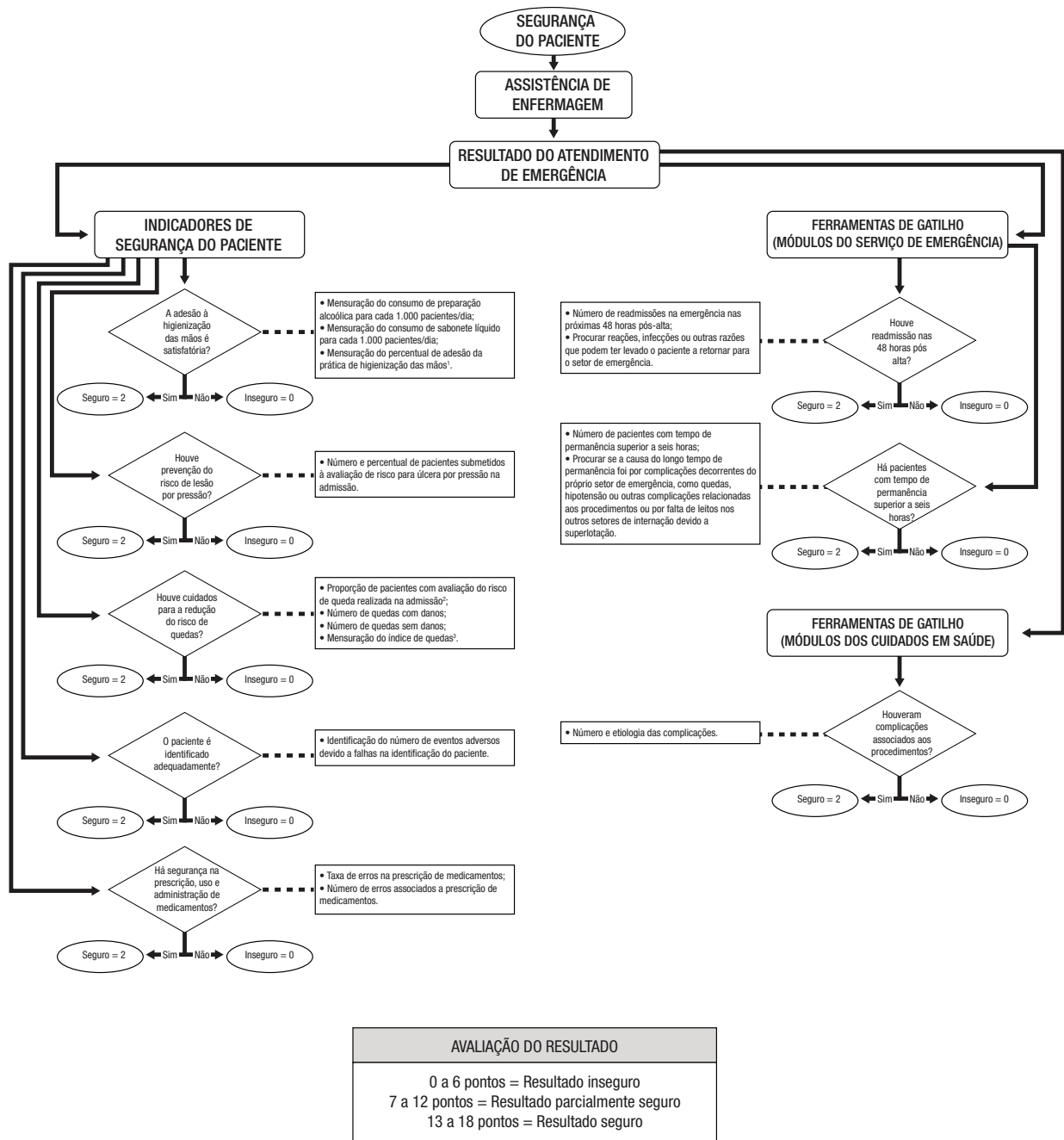
### AVALIAÇÃO DO PROCESSO DO CUIDADO SEGURO DE ENFERMAGEM AO PACIENTE POLITRAUMATIZADO EM SITUAÇÃO DE EMERGÊNCIA



**AVALIAÇÃO DO PROCESSO**

0 a 6 pontos = Processo inseguro  
 7 a 12 pontos = Processo parcialmente seguro  
 13 a 18 pontos = Processo seguro

### AVALIAÇÃO DO RESULTADO DO CUIDADO SEGURO DE ENFERMAGEM AO PACIENTE POLITRAUMATIZADO EM SITUAÇÃO DE EMERGÊNCIA<sup>2</sup>



<sup>1</sup> Percentual de adesão: Número de ações de higiene das mãos realizadas pelos profissionais de enfermagem (N1) / Número de oportunidades ocorridas para higiene das mãos (N2), multiplicado por 100, isto é, N1 / N2 x 100 = total de adesão de higienização das mãos entre os profissionais de enfermagem.  
<sup>2</sup> Número de pacientes avaliados / Número de pacientes não avaliados = Proporção de pacientes com avaliação do risco de queda.  
<sup>3</sup> [(Número total de eventos / Número de paciente-dia) x 1000] = Índice de quedas.

Source: Pimenta CA, Lopes CT, Amorim AF, Nishi FA, Shimoda GT, Jensen R. Guide for the construction of nursing care protocols. São Paulo: Regional Nursing Council; 2015.