Original Article

# Brazilian instrument for investigating adverse events in health: validation study

## Instrumento brasileiro para investigação de eventos adversos na saúde: estudo de validação

## Instrumento brasileño para investigación de eventos adversos en salud: estudio de validación

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## Abstract

**Objective:** To build the Brazilian instrument for investigating adverse health events and evaluate the evidence of content validity and the response process.

**Methods:** This psychometric study was conducted according to the Standards for Education and Psychological Testing in the following stages: search for evidence of content validity and response process. In the content evidence, 46 experts from all regions of Brazil participated. In the response process, 76 professionals from 31 health institutions participated. The Statistical Package for the Social Sciences program was used for the distribution of quantitative variables and synthesis, via the calculation of descriptive statistics. In the content evidence stage, the acceptable Content Validity Ratio (CVR) greater than the expected critical CVR for *N* judges was used; the critical CVR of 0.35 was used in this study. The focus group has been performed for the response process.

**Results:** In total, 46 experts participated in the content validation stage, predominantly training nurses (84.8%), and nurses who graduated 11 years ago (60.7%) or more. The results obtained for each level in content validation were as follows: levels I, II, and III respectively presented the following CVR values: 0.88, 0.76, and 0.97. In the response process stage, adjustments to the nomenclature and sequence of steps were performed.

**Conclusion:** Building and validating the first Brazilian Instrument for Investigating Adverse Events in Health was possible with the necessary sources to ensure the content and response process. The best evidence articulated with national and international references was considered, making it possible to improve investigation systems in private and public health institutions.

## Resumo

**Objetivo:** Construir o instrumento brasileiro para investigação de eventos adversos em saúde e avaliar as evidências da validade de conteúdo e o processo de resposta.

**Métodos:** Este estudo psicométrico foi realizado conforme o *Standards for Education and Psychological Testing* e conduzido nas seguintes etapas: busca por evidências da validade de conteúdo e do processo de resposta. Na evidência de conteúdo participaram 46 especialistas de todas as regiões do Brasil. No processo de resposta, participaram 76 profissionais de 31 instituições de saúde. Foi usado o programa *Statistical Package for the Social Sciences* para distribuição de variáveis quantitativas e síntese, via cálculo de estatísticas descritivas. Na etapa de evidência de conteúdo, foi usado o *Content Validity Ratio* (CVR) aceitável maior que o CVR crítico esperado para *N* juízes; neste estudo, foi usado o CVR crítico de 0,35. Já o grupo focal foi realizado para o processo de resposta.

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**Resultados:** No total, 46 especialistas participaram na etapa de validação de conteúdo, predominantemente enfermeiros de formação (84,8%) formados há 11 anos (60,7%) ou mais. Os resultados obtidos na validação de conteúdo para cada nível foram: nivel I apresentou um CVR: 0,88, nível II 0,76 e nível III 0,97. Já na etapa de processo de resposta, foram realizados ajustes na nomenclatura e encadeamento das etapas.

**Conclusão:** Foi possível construir e validar o primeiro Instrumento Brasileiro para Investigação de Eventos Adversos na Saúde com as fontes necessárias para assegurar o conteúdo e processo de resposta, considerando as melhores evidências articuladas com as referências nacionais e internacionais, permitindo o aprimoramento dos sistemas de investigação para instituições de saúde privadas e públicas.

## Resumen

**Objetivo:** Elaborar un instrumento brasileño para la investigación de eventos adversos en salud y evaluar las evidencias de la validez de contenido y el proceso de respuesta.

**Métodos:** Este estudio psicométrico fue realizado de acuerdo con el *Standards for Education and Psychological Testing* y cumplió las siguientes etapas: búsqueda de evidencias de la validez de contenido y del proceso de respuesta. En la evidencia de contenido participaron 46 especialistas de todas las regiones de Brasil. En el proceso de respuesta, fueron 76 profesionales de 31 instituciones de salud. Se utilizó el programa *Statistical Package for the Social Sciences* para la distribución de variables cuantitativas y síntesis, a través del cálculo de estadísticas descriptivas. En la etapa de evidencia de contenido, se utilizó el *Content Validity Ratio* (CVR) aceptable más alto que el CVR crítico esperado para *N* jueces. En este estudio, el CVR crítico usado fue 0,35. Para el proceso de respuesta, se realizó un grupo focal.

**Resultados:** En total, participaron 46 especialistas en la etapa de validación de contenido, predominantemente enfermeros de formación (84,8 %) graduados hace 11 años (60,7 %) o más. Los resultados obtenidos en la validación de contenido de cada nivel fueron: CVR 0,88 en el nivel I, 0,76 en el nivel II y 0,97 en el nivel III. En la etapa de proceso de respuesta, se realizaron ajustes en la nomenclatura y en la concatenación de las etapas.

**Conclusión:** Fue posible elaborar y validar el primer Instrumento Brasileño para la Investigación de Eventos Adversos en Salud, con las fuentes necesarias para garantizar el contenido y el proceso de respuesta, y las mejores evidencias conectadas con las referencias nacionales e internacionales, lo que permite la mejora de los sistemas de investigación para instituciones de salud públicas y privadas.

## Introduction

In the United States of America (USA), the Institute of Medicine (IOM) published the report "To Err is Human" estimating the occurrence of 44-98 thousand deaths resulting from adverse events (AE) each year. Since then, a mobilization of health professionals and the general population was triggered by issues related to patient safety.[1,2] Thus, the IOM incorporated *patient safety* as one of the six quality attributes along with effectiveness of care, patient-centeredness, timeliness of care, efficiency, and equity.[1,2] In this context, an exponential evolution on the topic of incident and adverse event management has been observed in health institutions in recent years.[2,3]

In 2021, the World Health Organization (WHO) published the Global Action Plan for Patient Safety 2021-2030. Eliminating preventable harm in healthcare was its objective as it was estimated that one in 10 patients is subject to an adverse event during the hospital stay. More recent studies suggest that 134 million events resulting from poor care and/or unsafe care occur every year in hospitals in low-middle-income countries, potentially resulting in 2.6 million deaths annually.[3-5]

In the USA, one in four patients admitted to hospitals suffered an adverse event in 2018. Additionally, each year 8-12% of hospitalized patients in Europe experience some type of incident-related harm or injury during the care they receive.[6] In Brazil, 333,275 incidents were reported from July 2022 to June 2023. The main ones were related to failures during healthcare involving intravenous catheters, pressure injuries, and patient falls. Regarding "never events" (those that should never occur), 3,525 were recorded. They must be prioritized by health services for a systematic investigation to better understand the failure mode.[4]

According to the WHO, incidents are classified as risk circumstances, incidents without damage, "near miss", and incidents with damage. These, also known as adverse events, can be classified according to damage degree as mild, moderate, severe, or death.[7]

In health services, management and operationalization of the proactive and reactive approach to risk management (such as identification, analysis, evaluation, monitoring, treatment, and communication of risks) are the responsibility of the Patient Safety Nucleus Center (PSN/C) through a National

Brazilian Patient Safety Plan.[7-9] The proactive approach consists of managing risks, whereas actions and activities that act as barriers are identified, planned, and implemented to prevent risks from resulting in an incident. The reactive approach consists of managing incidents because risks have already been identified as incidents.[7-9]

The reactive approach (investigation of adverse events in health services) is considered a requirement of the PSN/C. It is essential to identify and map failures in assistance, explore the possible causes that led to the incident, and draw action plans to reduce the damage degree and prevent a possible recurrence.[7-9]

However, a gap regarding these investigation processes still exists since the implementation of the reactive risk management methodology in healthcare organizations: most incident investigation tools come from other segments such as industry, logistics, total quality management, aviation, etc.[8-13]

Currently, the quality and patient safety offices have several responsibilities: risk management, incidents, indicators, and documents, clinical protocols, and auditing. Furthermore, the incident detection stage and the decision to investigate generate operational overhead, creating a *superficial* investigation process and a lack of monitoring of improvement actions. The London Protocol, which is recommended by the Ministry of Health, is the most used tool in Brazil to investigate clinical incidents in healthcare.[9-13]

The present study aimed to develop the first Brazilian instrument to investigate clinical incidents, allowing an approach according to the damage degree. The London Protocol does not allow for scaling the investigation process and operationalizing the monitoring mode of improvement actions, beyond the steps aimed at the second victim, the accountability matrix, and incident management involving senior leadership. It is important to highlight that national and international recommendations are the basis of the instrument.[3,9-20]

Therefore, the objective of the present study was to build the Brazilian Instrument for Investigating Adverse Events in Health and evaluate the evidence of content validity and the response process.

## Methods

This psychometric study followed the Standards for Education and Psychological Testing (1999, 2014). The instrument was built in two stages.

Initially, a scoping review was conducted according to the recommendations of the Joanna Briggs Institute (JBI) to map and deepen knowledge about the tools used to investigate adverse health events.[3,21,22] In addition to the scoping review, a survey was performed in 24 hospitals that have Patient Safety Centers to identify the steps and practical recommendations that should be included in the adverse health event investigation processes. The hospitals were distributed in the Southeast, Central-West, Northeast, and South regions of Brazil and received a structured questionnaire with closed questions about the adverse event investigation process.

The questions were based on scoping review recommendations, national and international literature, and tools recommended by national and international accreditation methodologies. Therefore, the instrument was created not only from a review but also from an articulation with clinical practice.[10-12]

Initially, the instrument was constructed with 33 items and 3 levels of incidents with (1) light damage, (2) moderate damage, and (3) serious injury and death. It was entitled Brazilian Instrument for Investigating Adverse Events in Health (IBIEAS/BIIAEH); its investigation model was built in stages that were followed by the investigation team. This initial version has been submitted to content evaluation by experts in adverse health events from all regions of Brazil and two bachelors in Literature. The experts' eligibility criteria were as follows: to be a health professional; to have a minimum specialist title in any clinical area (or quality management and patient safety); to work at least two years in the area of adverse event investigation; and to have applied at least five London Protocols (or other adverse event investigation method).

The recruitment of potential participants was performed via the Lattes Platform (March 2021), inviting members of scientific societies, associations, and institutes such as the Brazilian Institute

of Patient Safety (IBSP/BIPS); Brazilian Society for Quality of Care and Patient Safety (SOBRASP/BSQCPS); Association of Intensive Medicine (AMIB/AIM), and evaluators certified by the National Brazilian Accreditation Organization (ONA/NBAO). Experts received an email invitation with a link to watch a video (constructed using the Google Hangouts software, v. 110.0.5481.180) containing a brief explanation of the research and the impact of their participation in the study.

A total of 84 experts were invited and 46 of them agreed to participate in the study. After their acceptance, an email was sent containing the free and informed consent form (TCLE) to collect signatures, and the link to access the instrument (prepared using the Survey Monkey online software) used in data collection. Guests had 10 days to return the questionnaire.

The first version of the IBIEAS/BIIAEH (pdf format) was sent by email along with the questionnaire link to evaluate the relevance, clarity, and organization of the items using a Likert-type scale. At this stage, Lawshe's[23] quantitative criterion of acceptable Content Validity Ratio (CVR) greater than the critical CVR expected for *N* judges was analyzed; in this study, the critical CVR of 0.35 was used. The qualitative criterion was also used to evaluate the free text fields present in the questionnaire as some judges made recommendations about the proposed content.

After evaluating the evidence of content validity, the stage of verifying the validity of the response process by health professionals was performed. A total of 101 professionals from 31 public and private healthcare institutions throughout Brazilian territory were invited and 76 of them agreed to participate. The eligibility criteria were as follows: to be a higher-level professional, to be a member of the Patient Safety Center, to act in the analysis and investigation of incidents through a manual or electronic notification system, and not be away from their duties during the data collection period (November 2021 to February 2022).

The institutions were invited and selected through the existing database (Epimed Monitor System Adult ICU) and Patient Safety (Epimed Solutions). After acceptance and consent from the direction and approval from the Research Ethics Committee (CEP/REC), those responsible for the institutional patient safety centers received an email invitation with guidance on research.

For this stage, the focus group strategy stratified by regions of the country was used. Five meetings were held on the Google Meet platform. Each focus group began by presenting IBIEAS/BIIAEH using the PowerPoint program. After the presentation by the mediator, participants presented their considerations and suggestions to clarify each IBIEAS/BIIAEH item in all dimensions. Thus, important contributions were presented about the response process and how the instrument can be applied in clinical practice. When statements and contributions become repetitive and predictable, the evidence of the response process was considered as achieved. After the meetings ended, the audios were transcribed onto the Google Docs platform. Each meeting lasted 86 min on average.

Statistical analyses were performed using the IBM SPSS (Statistical Package for the Social Sciences, v. 22.0) program. The distribution of quantitative variables over experts was summarized by calculating descriptive statistics. The research complied with all legal ethical aspects according to the National/Brazilian Health Council (CNS/NBHC; Resolution 466/2012) which regulates research involving human beings; it was submitted to the CEP of the proposing institution and approved (Opinion: (3.567.788/2020; Certificate of Presentation of Ethical Appreciation, CAAE: 17558819.9.0000.5243).

## Results

The experts who participated in the content evaluation were predominantly from the Southeast region (56.5%), female (78.3%), aged 38-45 years (65.2%), nursing students (84.8%), nurses who graduated 11-16 years ago (60.7%), with a Master in Business Administration (54.3%), and two specializations (60.9%) as the highest degree. The most frequent first specialization was

in Intensive Care (52.2%), followed by Quality Management in Health Services (45.0%), and Health Management (6.5%). The main positions held by these specialists were Quality Consultant (4.5%), Quality Coordinator (21.7%), and Quality Analyst (17.4%). They had been in the position for 4-7 years (63.1%) and worked in assistance for 5-10 years (67.3%), quality management for 4-7 years (67.4%), and Patient Safety Center 4-6 years ago (80.4%). Finally, all experts stated that they had already applied the London protocol and had done so 25-74 times (82.5%). The professionals had experience with the main health certifications consolidated in the country such as the National Accreditation Organization (ONA/NAO), Joint Commission International (JCI), and Qmentum. The CVR was analyzed for each IBIEAS/ level. Table 1 shows the results of the content assessment in the level 1 dimension.

**Table 1.** Content assessment in the dimension of incidents with minor damage (level 1)

| Investigation steps (Instrument items) | Rating criteria | CVR | Global Item CVR |
|---|---|---|---|
| 1: Grouping of adverse events | Relevance | 1.00 | 0.99 |
| | Clarity | 0.96 | |
| | Organization | 1.00 | |
| 2: Definition from the investigation team | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 3: Brainstorming | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 4: Data collection | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 5: Expert opinion | Relevance | 0.04 | 0.18 |
| | Clarity | 1.00 | |
| | Organization | -0.50 | |
| 6: Bow tié | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 7: Monitoring of corrective actions | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| Global | Relevance | 0.86 | 0.88 |
| | Clarity | 0.99 | |
| | Organization | 0.79 | |

CVR: Content Validity Ratio

In the above dimension, item 5 (expert opinion) did not reach adequate validity evidence concerning the relevance criterion. The main justifications were as follows: non-relevance of this item to the investigation of a minor incident generating overload for NSPs/ concerning the organization criteria (as it is an investigation that will be forwarded for analysis by a specialist and/or area manager). Therefore, this item has been excluded. Table 2 shows the results of the content assessment in the level 2 dimension.

**Table 2.** Content assessment in the dimension of incidents with moderate harm (level 2)

| Investigation steps (Instrument items) | Rating criteria | CVR | Global CVR of items |
|---|---|---|---|
| 1: Definition of the investigation team | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 2: Brainstorming | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 3: Data collection | Relevance | 1.00 | 1.00 |
| | Clarity | -0.04 | |
| | Organization | 1.00 | |
| 4: Tracer | Relevance | 1.00 | 0.33 |
| | Clarity | 1.00 | |
| | Organization | 0.04 | |
| 5: Expert opinion | Relevance | 1.00 | 0.80 |
| | Clarity | 1.00 | |
| | Organization | 0.40 | |
| 6: Definition of AE Scenario | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 7: Chronology | Relevance | 0.22 | 0.34 |
| | Clarity | 0.40 | |
| | Organization | 0.40 | |
| 8: Analysis of Root Cause with the contributing factors | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 9: 5 Whys | Relevance | 0.66 | 0.77 |
| | Clarity | 1.00 | |
| | Organization | 0.66 | |
| 10: Plan of Action (5W2H) | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 11: Legal Validation | Relevance | -0.26 | 0.16 |
| | Clarity | 1.00 | |
| | Organization | -0.26 | |
| Global | Relevance | 0.69 | 0.76 |
| | Clarity | 0.95 | |
| | Organization | 0.66 | |

CVR: Content Validity ratio; AE: Adverse Events

For level 2 (above), the recommendation regarding the absence of validity evidence was observed in steps 4, 7, and 11. The main reasons were as follows: lack of human resources to carry out the tracer and generate an overload for the patient safety centers to establish a chronology for each moderate incident. This may re-

sult in delayed investigation and early establishment of corrective actions due to the need for legal validation at the first moment. Therefore, steps 4, 7, and 11 have been excluded. Finally, table 3 shows the results of the content assessment in the level 3 dimension.

**Table 3.** Content assessment in the dimension of incidents with serious harm and death (level 3)

| Investigation steps (Instrument items) | Rating criteria | CVR | Global CVR of items |
|---|---|---|---|
| 1: Alert Crisis Committee | Relevance | 1.00 | 0.63 |
| | Clarity | - 0.12 | |
| | Organization | 1.00 | |
| 2: Definition of the investigation team | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 3: Data collection | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 4: Interviews | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 5: Tracer | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 6: Expert opinion | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 7: Definition of the AE Scenario | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 8: Chronology | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 9: Analysis of Root Cause with contributing factors | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 10: Accountability Matrix | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 11: Replacement Test | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 12: Action Plan (5W2H) with the intervention degree | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 13: Support for the Second Victim | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 14: Legal Validation | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| 15: CEO Validation | Relevance | 1.00 | 1.00 |
| | Clarity | 1.00 | |
| | Organization | 1.00 | |
| Global | Relevance | 1.00 | 0.97 |
| | Clarity | 0.92 | |
| | Organization | 1.00 | |

CEO: Chief Executive Officer; CVR: Content Validity ratio; AE: Adverse Events

At all steps, validity evidence for level 3 was found, allowing a systematized, qualified, and robust investigation for incidents with critical damage. However, the only adjustment based on the evidence was made in the clarity domain (step 1). According to experts, the term *committee* could imply the obligation to establish an additional committee, whereas investigation must be carried out by an independent team, and early communication is indicated to senior leadership. Chart 1 summarizes the researchers' decision regarding each item of the instrument based on the experts' suggestions during the focus group meeting.

## Discussion

Our results made it possible to seek evidence of IBIEAS validity content and response process through professionals who work in the incident investigation in all regions of Brazil. In addition, they contributed to reflecting on the importance of a robust and qualified investigation, using resources according to the degree of the incident initially detected, and strengthening an instrument developed and applicable to the Brazilian context.

As a limitation of the study, we highlight the small number of public institutions and the predominance of one professional category among the research participants. Thus, comparing the responses of different formation and region types was not possible, as the sample size of subgroups of other formations was small in all regions.

Regarding predominance, 84.8% of the group of specialists were nurses, mostly from the Southeast region (56.5%). This reinforces a recent study that revealed the profile of human resources in patient safety centers in Brazil.

Despite the specialization of participants in the group of evidence of content validity, we identified the predominant specialization in intensive care (52.2%). This points to the need for greater experience in care practice and a systemic clinical vision that allows for a better understanding of aspects related to disease, drugs, critical clinical support, prognostic scores, and interface with technology.

**Chart 1.** Mapping and regional distribution of validity evidence in the response process in the three dimensions of IBIEAS

| Steps | Midwest | North East | North | Southeast | South | Suggestions for Validity Evidence in the Response Process |
|---|---|---|---|---|---|---|
| **Level I** | | | | | | |
| 1 | ✎ | ✎ | ✎ | ✎ | ✎ | Clarify that the grouping of mild adverse events must be of the same category and description according to the WHO taxonomy. |
| 2 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 3 | ✎ | ✎ | ✎ | ✎ | ✎ | BRAINSTORMING must be carried out focusing on the scenario of incidents and ongoing improvement plans, generation of primary problem-solving ideas, and definition of the roles and responsibilities of each team member. |
| 4 | ✎ | ✎ | ✓ | ✎ | ✎ | Rename the item to DATA COLLECTION FROM MULTIPLE SOURCES. |
| 5 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 6 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| **Level II** | | | | | | |
| 1 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 2 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 3 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 4 | ✓ | ✎ | ✓ | ✎ | ✓ | The scenario definition must be identified from the caregiving problems and other processes mapped during previous steps. |
| 5 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 6 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 7 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 8 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| **Level III** | | | | | | |
| 1 | ✎ | ✎ | ✓ | ✎ | ✎ | Clarify that this dimension must be a CRISIS COMMUNICATION ALERT (communicate the initial report of the incident via the institutional email through a previously analyzed group for the following actors: medical director, nursing manager, legal/compliance sector, members of the PSC, and communication area). |
| 2 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 3 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 4 | ✓ | ✓ | ✓ | ✎ | ✓ | The INTERVIEW stage must make the operationalization process clear. |
| 5 | ✎ | ✎ | ✎ | ✎ | ✎ | Support for the second and third victims is MULTIDISCIPLINARY. |
| 6 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 7 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 8 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 9 | ✎ | ✓ | ✎ | ✎ | ✓ | Reinforce that this dimension is a CHRONOLOGICAL SYNTHESIS. |
| 10 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 11 | ✎ | ✎ | ✎ | ✎ | ✎ | Clarify the flow of the accountability matrix to facilitate its operation by professionals. |
| 12 | ✓ | ✎ | ✓ | ✎ | ✓ | Reinforce that the replacement test is for the PROFESSIONAL factor. |
| 13 | ✓ | ✓ | ✓ | ✓ | ✓ | Without changes |
| 14 | ✎ | ✎ | ✓ | ✎ | ✓ | Reinforce that legal validation must be formalized by email or any other method such as digital signature. |
| 15 | ✎ | ✎ | ✓ | ✎ | ✓ | Reinforce that CEO or Superintendent validation must be formalized by email or any other method such as digital signature. |

✎: Adjustments were necessary in the clinical practice response process; ✓: Without changes. CEO: Chief Executive Officer; IBIEAS: Brazilian Instrument for Investigation of Adverse Events in Health; PSC: Patient Safety Center; WHO: World Health Organization.

These factors allow for a more robust investigation with a critical analysis of the proposed therapeutic planning.[9-13]

However, it is important to highlight the second specialization (Quality Management in Health Services; 45.0%). Only with this knowledge clinical practice can be articulated with risk management tools and techniques, resulting in a specialized analysis with the necessary elements to identify the failure mode and establish improvement actions.

Therefore, the professional who investigates adverse events must have a systemic view, especially of the clinical care process. On the other hand, some authors state that currently some investigations are carried out routinely, but with a reference of accountability, not of reflection, identification of improvement opportunity, or learning.[14-18]

A study published in 2023, with 11 hospitals in Massachusetts (USA) and a random sample of 2,809 hospitalizations, identified at least one adverse event in 23.6% of the sample; 32.3% of them were classified as serious adverse events, highlighting that medication errors were the most common (39.0%), followed by surgical events (30.4%). Therefore, a comprehensive and independent investigation with all necessary techniques is important to identify the contributing factors and failure mode.[6]

We emphasize the importance of an instrument adapted to the Brazilian context that operationalizes and supports professionals in the search for this systemic vision, not only sequencing actions during the investigation but also allowing to standardize the identification of contributing factors. This would make it possible to carry out a benchmarking between institutions and the sharing of root causes in the future. Thus, global plans for improvement actions will emerge in care processes with an integrated view of the failure mode.[16-20]

At level I (content evidence stage), the step described as expert opinion (0.18) was removed as this investigation had already been done by the responsible people in the units where the events occurred. Due to new trends and configurations in the job market, technological innovations and the increase in the offer of undergraduate nursing courses result in a highly competitive market, requiring qualified and specialized leaders in their knowledge areas.[24,25]

At level II, the tracer (0.33), chronology (0.34), and legal validation (0.16) steps were excluded as they could delay defining the outcome (*i.e.,* the damage initially detected) in addition to overloading professionals in patient safety centers in Brazil.[25,26] We emphasize that this level of investigation covers moderate adverse events and some health institutions analyze them in a consolidated manner. However, the Canadian protocol for investigating incidents outlines three types of investigation: concise, comprehensive, and multi-incident types, depending on the context.[20]

The authors of the Canadian protocol reinforce that the basic principles and steps of the analysis are the same regardless of the method used, but the complexity of the details and the scope of the review will be different for each type. Therefore, we reinforce the need to establish a process that does not increase the use of institutional resources.[20]

Furthermore, IBIEAS combines all pillars of the organizational accident model in a single instrument from the theoretical reference of James Reason (2005). He highlights the importance of understanding the failure mode, not by examining the defenses and barriers that have been *broken*, but by exhausting aspects of organizational culture, and latent and active failures of the process. Thus, this allows us to build a root cause analysis from an expanded, systematized, and categorized view of the contributing factors.[11,15,17,18]

At IBIEAS, we emphasize the step that involves the interview. According to an international study, the use of this technique is limited. However, it is used more than observation or tracer techniques in the daily operations of institutions. Therefore, this practice cannot be done in isolation as it may weaken the root cause analysis (RCA), and interviewees may present reasonings with some degree of bias.[27]

A recent study on adverse event investigation tools described that observing interviewees report what *should have happened* rather than what actually occurred at the time of the incident is common. However, when other techniques are used (*e.g.,* observation techniques and auditing of the therapeutic itinerary), they result in an investigation without bias, excluding the individual attitudes of professionals.[3,25-29]

At level III of the investigation, experts reinforced the need to clarify the communication of adverse events with death (0.33). However, all steps at this level reached a satisfactory value for evidence of content validity.

Serious adverse events (or those resulting in death) must be reported to regulatory agencies and hospital certification organs within a short time. Therefore, the investigation must be started early to quickly ratify the perception of serious damage or cause of death. In Brazil, the health service currently has 72 h to report the occurrence of death attributed to an adverse event (RDC 36/2013). In the USA, the RCA[2] document (Improving Root Cause Analyzes and Actions to Prevent Harm) from the National Patient Safety Foundation recommends completing the investigation process within 45 days.[9,16]

Thus, the results obtained in the response process expanded the systemic view of the instrument in the Brazilian context. Making the instrument applicable in any scenario was then possible from clinical practice professionals from different regions. Moreover, a pioneering study can be per-

formed in the future within the scope of validation studies (anchored in the Standards for Education and Psychological Testing; 1999, 2014) to research validity evidence (Test Consequence stage) and verify the clinical, care, organizational, and financial impacts of IBIEAS on health institutions.

## Conclusion

The Brazilian Instrument for Investigating Adverse Events in Health has now the necessary sources to ensure content considering the best evidence articulated with national and international references on tools and techniques for investigating adverse events. It is also aligned with the reality of different scenarios in health institutions in Brazil, enabling users to identify aspects and/or gaps related to institutional operationalization. Therefore, the instrument has the necessary validity evidence for application in health institutions from the perspectives of patients, professionals, and institutions. It allows for improving investigation systems in private and public health institutions, contributing to identifying the root cause, responsibility, failure mode, and direction for the construction of the action plan stratified by the degree of intervention force.

## Collaborations

Mello LRG, Christovam BP, Rebustini F, Moreira APA, Moraes EB, and Paes GO contributed to the design of the study, analysis and interpretation of data, writing of the manuscript, relevant critical review of the intellectual content, and approval of the final version to be published.

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