CROSS-CULTURAL ADAPTATION AND VALIDATION OF THE NHS ENGLAND CLASSIFICATION OF LEVELS OF HARM ASSOCIATED WITH PATIENT SAFETY EVENTS FOR THE BRAZILIAN UNIFIED HEALTH SYSTEM (SUS): A STUDY PROTOCOL

ADAPTAÇÃO TRANSCULTURAL E VALIDAÇÃO DA CLASSIFICAÇÃO DOS NÍVEIS DE DANO ASSOCIADOS A EVENTOS DE SEGURANÇA DO PACIENTE DO NHS ENGLAND PARA O SISTEMA ÚNICO DE SAÚDE (SUS): UM PROTOCOLO DE ESTUDO

ADAPTACIÓN TRANSCULTURAL Y VALIDACIÓN DE LA CLASIFICACIÓN DE LOS NIVELES DE DAÑO ASOCIADOS A EVENTOS DE SEGURIDAD DEL PACIENTE DEL NHS ENGLAND PARA EL SISTEMA ÚNICO DE SALUD BRASILEÑO (SUS): UN PROTOCOLO DE ESTUDIO

10.56238/sevened2026.019-098

Márcia Amaral Dal Sasso[1], **Ádala Nayana de Sousa Mata**[2], **Grasiela Piuvezam**[3], **Helaine Carneiro Capucho**[4]

ABSTRACT

Patient safety is a strategic priority for health systems, and the classification of the level of harm is essential information for gauging the consequences of incidents, guiding institutional prioritisation, and supporting data comparability. In Brazil, the "degree of harm" field of the Health Surveillance Notification System (Notivisa), aligned with the International Classification for Patient Safety (ICPS), uses broad descriptors and does not structurally differentiate physical from psychological harm, which may increase interpretive variability among professionals and limit the comparability of the information. The levels-of-harm classification of NHS England, the body responsible for coordinating the National Health Service (NHS) in England, is part of the Learn from Patient Safety Events Service (LFPSE), distinguishes the categories of physical and psychological harm, and adopts descriptors and decision criteria potentially useful for the Brazilian context. This manuscript presents the protocol of a prospective methodological study aimed at developing, in Brazilian Portuguese and within the Brazilian Unified Health System (SUS), an adapted and validated version of the classification of levels of harm associated with patient safety events published by NHS England. The study will be conducted in sequential stages: initial translations, synthesis of the translations, back-translations, committee review of the translated document, normative and organisational contextualisation to the SUS, content validation using the Delphi method, and face validation with professionals who may use the classification in their institutional practice. There will be no direct patient involvement. The study is expected to produce a version conceptually equivalent to the source material and compatible with the normative and organisational context of the SUS, preserving the structure of harm categories, levels of harm, level descriptors, and decision criteria, and contributing to greater precision, standardisation,

[1] Doctoral candidate in Health Sciences. Universidade de Brasília (UnB). E-mail: marcia_sasso@hotmail.com
Orcid: https://orcid.org/0000-0001-5592-8269 Lattes: http://lattes.cnpq.br/5535572490136805
[2] PhD in Collective Health. Universidade Federal do Rio Grande do Norte (UFRN). E-mail: adala.mata@ufrn.br
Orcid: https://orcid.org/0000-0003-3929-2082 Lattes: http://lattes.cnpq.br/8921465279478859
[3] PhD in Health Sciences. Universidade Federal do Rio Grande do Norte (UFRN).
E-mail: grasiela.piuvezam@ufrn.br Orcid: https://orcid.org/0000-0002-2343-7251
Lattes: http://lattes.cnpq.br/0391780760729166
[4] PhD in Sciences. Universidade de Brasília (UnB). E-mail: capuchohelaine@gmail.com
ORCID: https://orcid.org/0000-0002-5438-7963 Lattes: http://lattes.cnpq.br/0079781302123191

and comparability of harm-related information and to more proportionate, transparent, and learning-oriented institutional responses to patient safety events.

Keywords: Patient Safety. Patient Harm. Risk Management. Unified Health System. Cross-Cultural Comparison.

RESUMO

A segurança do paciente constitui prioridade estratégica dos sistemas de saúde, e a classificação do nível de dano é informação essencial para dimensionar as consequências dos incidentes, orientar a priorização institucional e favorecer a comparabilidade dos dados. No Brasil, o campo “grau do dano” do Sistema de Notificações para a Vigilância Sanitária (Notivisa), alinhado à Classificação Internacional para a Segurança do Paciente (CISP), utiliza descritores amplos e não diferencia, de forma estruturada, dano físico e dano psicológico, o que pode ampliar a variabilidade interpretativa entre profissionais e limitar a comparabilidade das informações. A classificação dos níveis de dano do NHS England, órgão responsável pela coordenação do Serviço Nacional de Saúde (National Health Service, NHS) na Inglaterra, integra o Learn from Patient Safety Events Service (LFPSE), distingue as categorias de dano físico e psicológico e adota descritores e critérios de decisão potencialmente úteis ao contexto brasileiro. Este manuscrito apresenta o protocolo de um estudo metodológico prospectivo para o desenvolvimento, em português brasileiro e no contexto do Sistema Único de Saúde (SUS), de uma versão adaptada e validada da classificação dos níveis de dano associados a eventos de segurança do paciente publicada pelo NHS England. O estudo será conduzido em etapas sequenciais: traduções iniciais, síntese das traduções, retrotraduções, revisão, por comitê, do documento traduzido, contextualização normativa e organizacional ao SUS, validação de conteúdo por método Delphi e validação de face com profissionais que poderão utilizar a classificação em sua prática institucional. Não haverá participação direta de pacientes. Espera-se produzir uma versão conceitualmente equivalente ao material de origem e compatível com o contexto normativo e organizacional do SUS, preservando a estrutura de categorias de dano, níveis de dano, descritores dos níveis e critérios de decisão, e contribuindo para maior precisão, padronização e comparabilidade das informações sobre dano e para respostas institucionais a incidentes de segurança do paciente mais proporcionais, transparentes e orientadas à aprendizagem.

Palavras-chave: Segurança do Paciente. Dano ao Paciente. Gestão de Riscos. Sistema Único de Saúde. Comparação Transcultural.

RESUMEN

La seguridad del paciente constituye una prioridad estratégica de los sistemas de salud, y la clasificación del nivel de daño es información esencial para dimensionar las consecuencias de los incidentes, orientar la priorización institucional y favorecer la comparabilidad de los datos. En Brasil, el campo "grado del daño" del Sistema de Notificaciones para la Vigilancia Sanitaria (Notivisa), alineado con la Clasificación Internacional para la Seguridad del Paciente (CISP), utiliza descriptores amplios y no diferencia, de forma estructurada, el daño físico del psicológico, lo que puede ampliar la variabilidad interpretativa entre profesionales y limitar la comparabilidad de la información. La clasificación de los niveles de daño del NHS England, organismo responsable de la coordinación del Servicio Nacional de Salud (National Health Service, NHS) en Inglaterra, integra el Learn from Patient Safety Events Service (LFPSE), distingue las categorías de daño físico y psicológico y adopta descriptores y criterios de decisión potencialmente útiles para el contexto brasileño. Este manuscrito presenta el protocolo de un estudio metodológico prospectivo dirigido a desarrollar, en portugués brasileño y en el contexto del Sistema Único de Salud brasileño (SUS), una versión adaptada y validada de la clasificación de los niveles de daño asociados a eventos

de seguridad del paciente publicada por el NHS England. El estudio se llevará a cabo en etapas secuenciales: traducciones iniciales, síntesis de las traducciones, retrotraducciones, revisión por comité del documento traducido, contextualización normativa y organizacional al SUS, validación de contenido mediante el método Delphi y validación de apariencia con profesionales que podrán utilizar la clasificación en su práctica institucional. No habrá participación directa de pacientes. Se espera producir una versión conceptualmente equivalente al material de origen y compatible con el contexto normativo y organizacional del SUS, preservando la estructura de categorías de daño, niveles de daño, descriptores de los niveles y criterios de decisión, y contribuyendo a una mayor precisión, estandarización y comparabilidad de la información sobre el daño y a respuestas institucionales a incidentes de seguridad del paciente más proporcionadas, transparentes y orientadas al aprendizaje.

Palabras clave: Seguridad del Paciente. Daño del Paciente. Gestión de Riesgos. Sistema Único de Salud. Comparación Transcultural.

1 INTRODUCTION

Patient safety constitutes a strategic priority for health systems, given the magnitude of preventable harm associated with care and its impact on the population's trust in health institutions (Panagioti *et al.*, 2019). This agenda was reinforced by the Global Action Plan for Patient Safety 2021-2030 of the World Health Organization (WHO), which directs governments and health organisations towards the elimination of preventable harm and the incorporation of safety as a dimension inseparable from the quality of care (World Health Organization, 2021).

The recording of the incident, however, is only the first step of the institutional response. Notification systems for learning depend on structured information, on the identification of patterns, and on the analysis of the elements that make up work processes and of the people who operate within them, so as to sustain improvement actions proportionate to the risk and impact of the incidents (Goekcimen *et al.*, 2022; McDonald *et al.*, 2010). Within this process, the classification of the level of harm to the patient is critical information: it gauges the effect of the incident, supports institutional prioritisation, guides communication, and sustains the comparability of data over time (Cooper *et al.*, 2018).

This function is inscribed within the classical logic of risk management. The international standard ISO 31000:2018 structures this process into stages of identification, analysis, evaluation, treatment, monitoring, and communication, an approach equally applicable to health organisations to ground decisions guided by consequences, priorities, and control measures (International Organization for Standardization, 2018).

In Brazil, the "degree of harm" field of the Health Surveillance Notification System (Notivisa), the national base for recording adverse events of the Brazilian Health Regulatory Agency (Anvisa), classifies the harm resulting from the patient safety incident into five levels (none, mild, moderate, severe, and death), in accordance with the International Classification for Patient Safety (ICPS) (Agência Nacional de Vigilância Sanitária, 2025). Developed by the WHO, the ICPS sought to address the absence of a common language in the field, harmonising concepts, terms, and definitions that favour the description, measurement, monitoring, and comparison of information on incidents between different services and health systems (World Health Organization, 2010).

Despite its relevance as a national reference, this field presents broad and succinct descriptors for the levels of harm, without making explicit decision criteria that are sufficiently operational to guide classification in the routine of services. Some descriptors resort to semantically broad expressions that are difficult to delimit, such as "short duration" and "long term", which may favour variable interpretations among professionals and compromise the

standardisation of the record. Added to this is the absence of structured differentiation between the categories of physical and psychological harm, which reduces analytical precision, increases interpretive variability, and compromises the comparability of data (Goekcimen *et al.*, 2022; Cooper *et al.*, 2018; Agência Nacional de Vigilância Sanitária, 2025).

The Global Patient Safety Report 2024, the first WHO report to present a comprehensive overview of the implementation of patient safety worldwide, aligned with the Global Action Plan for Patient Safety 2021-2030, adopts a multidimensional understanding of harm: in addition to physical harm, which may reach death or permanent disability, it considers the population scale of the problem and its economic, social, and psychological effects, and argues that policies, measurement, and institutional responses should contemplate this entire spectrum, and not only the immediate physical injury (World Health Organization, 2024).

The literature on the repercussions of adverse events on patients and family members confirms the understanding of harm proposed by the WHO, which contemplates different dimensions, by identifying physical, psychological, social, and financial impacts. Psychological harm is one of the most frequent and persistent dimensions, although it is still poorly recognised in institutional responses. It may manifest as anger, fear, guilt, grief, post-traumatic stress disorder (PTSD), and, in extreme cases, suicidal ideation, with effects that may last a decade or more. The way the institution responds to the event directly influences the intensity of this suffering, reinforcing the importance of empathetic communication, transparency, and continued psychological support following patient safety incidents (Ottosen *et al.*, 2021). In Brazil, the notification and classification instruments still concentrate predominantly on physical harm, which reinforces the need for a classification capable of recognising and measuring psychological harm as well.

In NHS England, the body responsible for coordinating the National Health Service (NHS) in England, a public service with universal coverage—a characteristic that converges with the structuring principles of the Brazilian Unified Health System (SUS)—the classification of levels of harm is part of the Learn from Patient Safety Events Service (LFPSE), a national platform for recording and learning from patient safety events (Weaver; Stewart; Kay, 2021; NHS England, 2023). The LFPSE replaced the National Reporting and Learning System (NRLS), the national repository of incident notifications in force since 2003, in the context of a broader reorganisation of patient safety in the country, driven by criticisms of the quality of investigations, the limited capacity to promote organisational learning, and the fragmentation of institutional responses within the NHS (Weaver; Stewart; Kay, 2021; Oikonomou *et al.*, 2019; Mesinioti *et al.*, 2025).

In comparison with the NRLS, the LFPSE strengthens an approach oriented towards learning and continuous improvement by incorporating more objective descriptors and decision criteria for the classification of levels of harm and by encouraging not only the recording of patient safety events but also of successful responses and improvements implemented from these events. Among its advances, the distinction between the categories of physical harm and psychological harm stands out, which confers greater precision to the characterisation of the consequences of patient safety incidents (NHS England, 2023).

This reorganisation of the NHS had as a structuring change the implementation of the Patient Safety Incident Response Framework (PSIRF), a national framework for responding to patient safety incidents that replaced the Serious Incident Framework (SIF), the previous model centred on the mandatory investigation of serious incidents. The PSIRF redefined the way the NHS guides the institutional response to incidents, coming to favour responses proportionate to the impact of the incident, the potential for learning, and the possibility of reducing future risks, rather than taking the severity of harm as the sole criterion for defining the conduct of the response. In this new arrangement, responses to incidents should involve the people affected, adopt a socio-technical analysis of the work system and the interactions between its components, promote qualified oversight of improvement actions, and translate the findings into timely redesign of processes (NHS England, 2022; Louch *et al.*, 2025; Iacobucci, 2019; Hallam, 2023).

The change was also accompanied by legislative and institutional initiatives. The Healthcare Safety Investigation Branch (HSIB), created in 2017 for the independent and systemic investigation of patient safety incidents (Dyer, 2017; Macrae, 2019; Crompton *et al.*, 2025), was subsequently converted into the Health Services Safety Investigations Body (HSSIB), a statutory body established by the Health and Care Act 2022 (Mayberry; Farrukh, 2026).

In Brazil, this debate gains momentum in light of recent milestones that reposition the patient and their safety at the centre of SUS decisions. Lei nº 15.378, de 6 de abril de 2026, which established the Estatuto dos Direitos do Paciente, recognises safety as a right and strengthens the participation of the patient in decisions and practices related to safe care (Brasil, 2026a). In a convergent manner, Portaria GM/MS nº 11.527, de 9 de junho de 2026, established the National Policy for Quality and Patient Safety (PNQSP) within the scope of the SUS, with the purpose of promoting safe, equitable, and person-centred care, as dimensions of the quality of health care, organised in an integral and territorialised manner and oriented towards the Health Care Networks (RAS) (Brasil, 2026b). In continuity with the National Patient Safety Programme (PNSP), established in 2013 (Brasil, 2013), these

milestones reinforce the need to qualify the information produced in notification, monitoring, and learning systems, including clearer and more consistent instruments to define the harm resulting from patient safety incidents.

The SUS is used directly by approximately 76% of the Brazilian population, accounts for around 2.8 billion appointments annually, and mobilises approximately 3.5 million professionals across multiple levels of care and care contexts (Castro *et al.*, 2019). On this scale, patient safety assumes a strategic character, and preventable harm acquires an expressive collective dimension, both due to the volume of people served and the role of the SUS as the only means of access to health for a significant portion of the population. Its repercussions fall on the continuity of care, operational efficiency, sustainability in the use of public resources, and social trust in the system (Kumah, 2025). National evidence gauges this effect: in a retrospective study conducted in Brazilian public hospitals, 65.7% of adverse events resulted in prolonged hospitalisation, a situation that exposes patients to additional risks, restricts the availability of beds, and compromises the access of other RAS users (Mendes *et al.*, 2018; Lima Júnior *et al.*, 2023).

It is in this scenario that the qualification of the classification of levels of harm assumes strategic value. The adoption of well-delimited harm categories, consistent levels of harm, clearer descriptors, and more objective decision criteria may standardise the information produced, support the identification of priorities and the definition of proportionate responses, in addition to promoting a more homogeneous understanding of the consequences of incidents among professionals from different services and regions. In a system of such breadth and care diversity, as is the SUS, the quality of these data sustains more equitable and transparent decisions and strengthens health management and surveillance (Goldman *et al.*, 2026).

Adopting a classification already consolidated in another system is a frequent strategy for this improvement; its transposition, however, cannot dispense with methodological rigour. Mere translation, even if reviewed by specialists, does not replace a formal process of cross-cultural adaptation and validation, which seeks to preserve the equivalence between the original and adapted versions in their semantic, idiomatic, experiential, and conceptual dimensions, in addition to contributing to content and face validity in the new context of application (Guillemin; Bombardier; Beaton, 1993; Beaton *et al.*, 2000; Alavi; Le Lagadec; Cleary, 2026).

In view of this scenario, this manuscript presents the protocol of a methodological study, of a prospective nature, aimed at conducting the translation, cross-cultural adaptation, and validation, into Brazilian Portuguese, of the classification of levels of harm associated

with patient safety events published by NHS England, with the objective of making available a version conceptually equivalent to the original and compatible with the normative and organisational context of the SUS. By structurally stratifying both physical and psychological harm, it is expected that this version will qualify the information produced in notification systems, favouring monitoring and learning and sustaining more proportionate and transparent responses to patient safety incidents in the SUS.

2 METHOD

2.1 STUDY DESIGN AND REPORTING REFERENCES

This is a protocol of a methodological study of a prospective nature, intended for the translation, cross-cultural adaptation, and validation, into Brazilian Portuguese, of the classification of levels of harm associated with patient safety events published by NHS England. The objective is to produce a version conceptually equivalent to the source material (Herdman; Fox-Rushby; Badia, 1998) and, simultaneously, compatible with the normative, organisational, and operational context of the SUS, so as to support institutional processes of notification, analysis, and monitoring of the response to patient safety incidents. The development will follow sequential and interdependent stages: initial translations, synthesis of the translations, back-translations, committee review of the translated document, normative and organisational contextualisation to the SUS, content validation using the Delphi method, and face validation with professionals who may use the classification in their institutional practice. There will be no inclusion of patients, collection of individualised clinical data, or implementation of care interventions.

The translation and adaptation process will adopt as a central reference the stages proposed by Beaton *et al.* (2000), complemented by the good practice principles of the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) for translation and cross-cultural adaptation (Wild *et al.*, 2005) and by the guidelines of Sousa and Rojjanasrirat (2011). The generation and interpretation of validity evidence are guided by the framework of sources of validity evidence of the Standards for Educational and Psychological Testing (American Educational Research Association; American Psychological Association; National Council on Measurement in Education, 2014) and by the recommendations of the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) initiative, used in the pertinent aspects as support for the organisation of content validity evidence, considering that the object does not constitute a psychometric instrument nor produces a score (Terwee *et al.*, 2018). The reporting of the Delphi rounds will follow the Guidance on Conducting and Reporting Delphi Studies

(CREDES) (Jünger *et al.*, 2017). The protocol will be registered on the Open Science Framework (OSF), a platform maintained by the Center for Open Science (Center for Open Science, [s.d.]), prior to the start of data collection, providing transparency, dating, and reproducibility.

2.2 METHODOLOGICAL FOUNDATION

The translation and cross-cultural adaptation will seek to preserve the semantic, idiomatic, experiential, and conceptual equivalences between the source classification and the adapted version (Herdman; Fox-Rushby; Badia, 1998; Beaton *et al.*, 2000). Semantic equivalence will assess whether terms and statements preserve the meaning attributed in the source material; idiomatic equivalence will examine whether expressions characteristic of the English language have been rendered in a natural and comprehensible manner in Brazilian Portuguese; experiential equivalence will analyse whether the situations, practices, and criteria described are recognisable and applicable to Brazilian health services; and conceptual equivalence will verify whether the central concepts of the classification, especially those related to the categories of physical and psychological harm and the respective levels of harm, maintain their meaning in the normative, organisational, and care context of the SUS.

Considering that the object does not consist of a psychometric scale or self-report instrument, but rather an operational classification composed of harm categories, levels of harm, level descriptors, and decision criteria that do not produce numerical scores, the adaptation reference will be applied with adjustments to the nature of the object (Ye *et al.*, 2026; NHS England, 2023). The emphasis will fall on validity evidence based on content and on response processes, as well as on conceptual and normative consistency, with no analyses being carried out based on internal structure or relations with other variables, nor estimates of reliability through internal consistency, characteristic of psychometric instruments with a score. As a result of this nature, two stages of the reference of Beaton *et al.* (2000) will be adapted. The pre-test stage, originally conducted with patients, will be operationalised as face validation with professionals who may use the classification in their institutional practice, producing evidence related to comprehension, interpretability, and applicability of the criteria. The expert committee review stage provided for by Beaton *et al.* (2000) will be maintained according to the methodological reference, with the purpose of consolidating the translated material into a consensus version (section 2.7.4). Subsequently, the normative and organisational contextualisation to the SUS will be carried out, from which the pre-final version to be submitted for validation will result (section 2.7.5). In the absence

of a developer of the original instrument to whom to submit the final reports, the auditability of the process will be ensured by the systematic recording of decisions at all stages (Beaton *et al.*, 2000; Polit; Beck, 2006; Polit; Beck; Owen, 2007).

The conceptual and experiential equivalences, in this object, have a nature distinct from that observed in instruments whose items describe individual experiences. As the decision criteria refer to types of care, temporal parameters, levels of care intervention, and recording conditions regulated in a specific manner in each country, verifying whether these concepts maintain meaning and applicability in the SUS requires examining, in a systematic manner, the correspondence between the criteria of the source classification and the Brazilian normative, sanitary, and organisational framework, including the terminology adopted within the scope of the PNSP and the organisation of the incident response processes recommended by Anvisa. This examination constitutes the stage of normative and organisational contextualisation to the SUS and is, therefore, the procedure by which the conceptual and experiential equivalences are established in this study, and not an additional stage to the cross-cultural adaptation. By making explicit, systematic, and auditable a verification that, in strictly linguistic adaptations, would remain implicit, the contextualisation also constitutes the main methodological differential of this protocol. Its operationalisation, by means of a matrix of normative and conceptual correspondence, is detailed in section 2.7.5.

Content validation will be conducted using the Delphi method, with structured, anonymised, and iterative judgement by specialists, in accordance with Hasson, Keeney, and McKenna (2000), and estimated by the Item-level Content Validity Index (I-CVI), by the Scale-level Content Validity Index based on the average of the items (S-CVI/Ave), and by the modified kappa, according to Polit, Beck, and Owen (2007). Face validity will be examined based on evidence related to the response process of the professionals who may use the classification in their institutional practice: clarity, comprehensibility, organisation, interpretability, and usability, with calculation of the Item-level Face Validity Index (I-FVI) and the Scale-level Face Validity Index based on the average of the items (S-FVI/Ave), according to Yusoff (2019). Content and face validity will be interpreted in an integrated manner, articulating quantitative results, qualitative justifications, and evidence of normative and conceptual coherence, so as to maximise the robustness of the evidence and the reproducibility of the process (Sousa; Rojjanasrirat, 2011; Terwee *et al.*, 2018).

2.3 ORIGINAL DOCUMENT AND MATERIAL TO BE ADAPTED

The original material will be extracted from the section Definitions: harm grading of the electronic document Policy guidance on recording patient safety events and levels of harm,

published by NHS England under the reference PRN00444, on 15 August 2023, in the version updated on 16 March 2026, adopted as a reference in this study, with recording of the date of access and the electronic address for traceability purposes. The document constitutes technical-institutional guidance for the recording of patient safety events in the LFPSE and is made available under the Open Government Licence v3.0, which permits reuse, translation, and adaptation upon attribution of the original source (NHS England, 2023). In this study, the object of the adaptation is restricted to the classification of levels of physical and psychological harm presented in this section. Subsequent updates will only be incorporated upon specific and documented methodological deliberation.

For the purposes of this study, the classification will be understood from four structural components present in the source document. The first is the harm category, which indicates the type of harm to be recorded, physical or psychological. The second is the level of harm, which expresses the gradation of severity within each category. The third is the level descriptor, corresponding to the statement that characterises the general meaning of that level. The fourth is the decision criterion, understood as the operational condition that guides the framing of the harm at a given level.

The LFPSE replaces the single gradation previously used in the NRLS with a classification organised into two categories, physical and psychological, as synthesised in Table 1. The psychological harm category does not contemplate a level corresponding to the fatal outcome. The terms in Portuguese presented in this section and in Table 1 derive from one of the initial translations of the source document and are of a provisional nature, and may be modified in subsequent stages (Guillemin; Bombardier; Beaton, 1993; Beaton *et al.*, 2000; Alavi; Le Lagadec; Cleary, 2026).

Table 1

Comparison between the previous NRLS gradation and the levels of physical and psychological harm of the LFPSE

PREVIOUS GRADATION (NRLS / SINGLE MEASURE)	LEVELS OF PHYSICAL HARM (LFPSE)	LEVELS OF PSYCHOLOGICAL HARM (LFPSE)
No harm	No physical harm	No psychological harm
Low harm	Low physical harm	Low psychological harm
Moderate harm	Moderate physical harm	Moderate psychological harm
Severe harm	Severe physical harm	Severe psychological harm
Death	Fatal	Not applicable

Source: adapted from the section Definitions: harm grading of the electronic document Policy guidance on recording patient safety events and levels of harm, NHS England, published in 2023 and updated in March 2026.

The source document directs that the classification of the level of harm represent the effectively observed impact of the incident on the patient, based on the best information available at the time of recording. Thus, the classification should not be based on speculation about more serious potential harm, although it may be revised when new information becomes available. The attribution of the level of harm involves professional judgement and, whenever possible, should consider the perspective of the affected patient (NHS England, 2023).

In the physical harm category, the LFPSE organises the levels into no physical harm, low physical harm, moderate physical harm, severe physical harm, and fatal. The level descriptors are accompanied by decision criteria that consider, among other elements, the need for observation or minor treatment, the need for and duration of additional care, prolongation of hospitalisation, the need for immediate clinical intervention for preservation of life, impact on functional independence, repercussion on pre-existing conditions, permanence of the harm, probable reduction of life expectancy, and possible contribution of the incident to death. The low physical harm level has a cumulative logic, requiring the fulfilment of all the criteria defined for this level; the moderate and severe levels are attributed by the presence of at least one of the criteria specific to each level, which exceed, respectively, the limits defined for the immediately lower level; and the fatal level is applicable when, at the time of recording, the patient has died and the incident may have contributed to death, including pregnancy loss or stillbirth (NHS England, 2023).

In the psychological harm category, the LFPSE organises the levels into no psychological harm, low psychological harm, moderate psychological harm, and severe psychological harm, without a level corresponding to the fatal outcome. The source document makes explicit that the recording of psychological harm does not require a formal diagnosis nor assessment by a professional specialised in mental health, since the initial selection of the level of harm should reflect the information available at the time of recording and the judgement of the professional responsible for the record, and may be revised when new information becomes available. The level descriptors are accompanied by decision criteria that consider psychological distress, the need for and probable duration of treatment, repercussion on usual activities, impairment of independent living, new mental health diagnosis or significant worsening of a pre-existing condition, and expectation of recovery. Unlike low physical harm, the levels of low, moderate, and severe psychological harm are defined by the presence of at least one criterion specific to each level. The gradation between the levels occurs mainly through the intensity and expected duration of the repercussions: psychological harm of shorter duration and without persistent functional repercussion tends

to be framed within the low level; harm with the need for treatment or functional impact of less than six months guides classification as moderate; and harm with treatment, functional repercussion, or absence of expected recovery beyond six months guides classification as severe (NHS England, 2023).

The separation between physical and psychological harm is a structuring component of the material to be adapted. By recognising psychological outcomes as a category proper to the consequence of incidents, the classification expands the capacity for characterising harm and aligns with the literature that advocates its incorporation into systems of notification, classification, and learning from patient safety incidents (Pfeiffer *et al.*, 2025).

2.4 SETTING AND TARGET SYSTEM

The target health system will be the SUS, a public system that is decentralised, regionalised, and guided by the principles of universality, integrality, and equity (Paim *et al.*, 2011; Massuda *et al.*, 2023). The adaptation will seek to render compatible the classification originally developed in NHS England with the normative, terminological, and organisational context of the SUS, considering the heterogeneity of the RAS, the PNQSP, the PNSP, and the Notivisa. The study will be conducted remotely, with the participants of the adaptation and validation stages acting from different Brazilian regions, without ties to a specific health service.

2.5 CONSIDERATION OF THE PERSPECTIVE OF PATIENTS AND FAMILY MEMBERS

Although patients and family members do not participate in the stages of this study, the patient safety system in force in NHS England, including the PSIRF and the LFPSE, recommends their participation in the response to patient safety incidents. In coherence with this principle, and in addition to the publication directed at the scientific community, a synthesis of the results will be prepared in accessible language, intended for SUS users, including patients and family members, and for other interested parties, with the objective of favouring understanding about the study and its findings and of providing transparency to the process of adapting the classification to the SUS context.

2.6 PARTICIPANTS AND SELECTION CRITERIA

The participants will be defined by methodological stage and will include translators, back-translators, members of the committee for the review of the translated document, specialists for the content validation, and professionals for the face validation. The research team will be responsible for the methodological and operational conduct, comprising the

organisation of the source material, the preparation of the instruments, the coordination of the stages, the consolidation of the versions, the analysis of the contributions, the preparation of the feedback to the specialists between the Delphi rounds, and the systematic recording of decisions. It will also fall to the team to construct the matrix of normative and conceptual correspondence, select the pertinent Brazilian documents, systematise the comparative analyses, propose preliminary adaptive decisions, and carry out the version control that sustains the adapted version.

In the initial translation, two independent translators will be included, bilingual, with Brazilian Portuguese as their mother tongue and command of English: one with training and practice in the health field and prior knowledge of the ICPS, and another professional from the language field, without prior involvement with the object nor knowledge of the objectives of the classification. This composition, one translator with knowledge of the topic and another without prior familiarity with it, follows Beaton *et al.* (2000) and the ISPOR (Wild *et al.*, 2005), balancing conceptual precision, terminological adequacy, and linguistic naturalness. In the back-translation, two independent translators will be included, bilingual, with English as their mother tongue and command of Brazilian Portuguese, distinct from the initial translators and without access to the source document, so as to reduce biases. The review committee will be composed of the translators, the back-translators, a specialist in research methodology with experience in cross-cultural adaptation, and the research team.

Content validation will be carried out with the participation of seven specialists, intentionally selected by complementary competence profiles in public health, patient safety, quality management in health services, and mental health, all with prior experience in the SUS; the sizing of seven evaluators observes the recommendations of Lynn (1986) and of Polit, Beck, and Owen (2007), who recommend a group of six or more specialists for the adoption of the threshold of I-CVI ≥ 0.78 with adequate control of chance agreement. The inclusion of specific competence in mental health aims to strengthen the evaluation of the criteria relating to the psychological harm category, since it constitutes a harm category still poorly consolidated in the national incident notification systems.

Face validation will be conducted with eight professionals working in Patient Safety Centres (NSP), with experience in the analysis of adverse events and in the coordination of improvement actions arising from these events, and representation of different Brazilian regions. Eligibility will require prior experience in the SUS. Participation in the validation stages will occur only after formal agreement and signature of the Free and Informed Consent Form (TCLE).

2.7 STAGES OF THE STUDY

2.7.1 Initial translation

The source classification will be translated independently from English into Brazilian Portuguese by two bilingual translators, resulting in two initial versions (T1 and T2). The translator from the health field will prioritise the conceptual precision of the harm categories, the levels of harm, the level descriptors, and the decision criteria; the language professional will prioritise clarity, fluency, and naturalness. Each translator will record, in their own form, difficulties, uncertainties, and justifications for relevant terminological choices.

2.7.2 Synthesis of the translations

Versions T1 and T2 will be compared with each other and confronted with the source classification, identifying terminological divergences, differences in formulation, ambiguities, losses of meaning, and alternatives more suited to Brazilian Portuguese. From this analysis, the synthesis version (T12) will be prepared, by consensus between the research team and the translators, considering conceptual precision and linguistic adequacy. All decisions will be documented, with recording of the alternatives discussed, the selected option, and the respective justification.

2.7.3 Back-translation

Version T12 will be submitted to two independent back-translations into English (BT1 and BT2), with the purpose of verifying, in an indirect manner, whether the central meanings of the harm categories, the levels of harm, the level descriptors, and the decision criteria have been preserved. The back-translators will systematically record difficulties, uncertainties, and observations relevant to the evaluation of equivalence with the source material.

2.7.4 Committee review of the translated version

The committee review will analyse comparatively the source classification, versions T1, T2, and T12, the back-translations BT1 and BT2, and the previous methodological records. Each component of the classification, including harm categories, levels of harm, level descriptors, and decision criteria, will be appraised in terms of the semantic, idiomatic, experiential, and conceptual equivalences, by means of a structured form, in which each member will classify the degree of equivalence and indicate the need for adjustment; the agreement among the members and the comments will support the collegiate decision. Special attention will be given to the preservation of the original meaning and of the logical

structure of the decision criteria, including the requirement of fulfilment of all criteria in the low physical harm level and of at least one criterion in the other levels of harm.

Once discrepancies, ambiguities, omissions, shifts of meaning, or insufficient formulations are identified, the committee may propose wording adjustments, resume previously discussed alternatives, or recommend new formulation, provided that conceptual equivalence with the source classification is preserved. The decisions will be recorded in a specific instrument, with indication of the analysed unit, the problem, the alternatives considered, the decision adopted, and the justification. At the end, the committee's consensus version will be produced, in Brazilian Portuguese.

2.7.5 Normative and organisational contextualisation to the SUS

While the semantic and idiomatic equivalences are verified above all in the previous linguistic stages (initial translation, synthesis, back-translation, and committee review), the committee's consensus version will be submitted to the normative and organisational contextualisation to the SUS, a stage that operationalises the verification of the conceptual and experiential equivalences, given the normative dependence of the criteria of the classification (section 2.2).

The research team will analyse each harm category, each level of harm, and the respective level descriptors and decision criteria, identifying correspondences with Brazilian legislation, regulations, sanitary guidelines, and technical documents. A matrix of normative and conceptual correspondence will be constructed, organised by harm category, level of harm, level descriptor, and decision criterion. For each level descriptor and respective decision criterion, the fields of the matrix presented in Table 2 will be filled in.

Table 2

Structure of the matrix of normative and conceptual correspondence: fields and respective content recorded for each level descriptor and decision criterion

MATRIX COMPONENT	CONTENT RECORDED FOR EACH DESCRIPTOR AND DECISION CRITERION
Normative correspondence	Existence or absence of legislation, regulation, sanitary guideline, or Brazilian technical document related to the descriptor or decision criterion
Sources identified	Identification of the corresponding Brazilian documents
Implications	Implications of the normative correspondence, or of its absence, for the adaptation of the passage
Proposed decision	Maintenance, modification, inclusion, suppression, or insertion of an explanatory note

Adapted wording	Adapted wording of the descriptor or of the decision criterion, when applicable
Technical justification	Technical grounding of the adaptive decision adopted

Source: prepared by the authors (2026).

The adaptive decisions will preserve conceptual equivalence with the source classification and, simultaneously, favour coherence with the normative, sanitary, and organisational framework of Brazilian public health. At the end, the pre-final version will be produced, accompanied by the matrix, to be forwarded to the specialists in the content validation.

2.7.6 Content validation using the Delphi method

Content validation will be conducted using the Delphi method, with the participation of seven specialists, with the purpose of obtaining structured, anonymous, and iterative judgement on the technical and conceptual adequacy of the adapted version. The specialists will receive, by electronic mail, the access link to a structured form on the Microsoft Forms platform, accompanied by the pre-final version of the classification and the matrix of normative and conceptual correspondence, containing the correspondences identified, the documents considered, the preliminary adaptive decisions, and their respective justifications.

The evaluation will be organised by harm category and by level of harm. For each level, the level descriptor and the respective decision criteria will be submitted for the appraisal of the specialists, so that the validation reaches not only the concrete conditions of classification, but also the statement that characterises each level. By way of illustration, in the severe psychological harm level, both the level descriptor and the respective decision criteria will be evaluated, such as distress with the need for treatment for more than six months, limitation of activities or of independent living for more than six months, and new diagnosis or worsening of a mental health condition without expected recovery within six months.

Each level descriptor and each decision criterion will be evaluated in terms of clarity, relevance, and conceptual adequacy. Additionally, in each level of harm, sufficiency will be evaluated, that is, whether the descriptor and the set of criteria characterise in a complete manner the corresponding level. The appraisal will use a four-point ordinal scale, with 1 = not adequate, 2 = needs major revision, 3 = adequate with minor revision, and 4 = adequate. Scores 3 and 4 will be considered concordant. Scores 1, 2, and 3 will require justification in an open field. Considering that the score 3 expresses the need for minor revision, the elements whose consensus is predominantly based on this category may be improved before

consolidation, even if they reach the established quantitative threshold, so that numerical agreement does not dispense with qualitative improvement.

The I-CVI will be calculated separately for each evaluated element and for each applicable attribute, that is, for each level descriptor and each decision criterion in terms of clarity, relevance, and conceptual adequacy, as well as for sufficiency in each level of harm. The use of the I-CVI for clarity, conceptual adequacy, and sufficiency follows extensions already employed in the content validation literature, maintaining relevance as the central attribute of this index. The elements with I-CVI = 1.00 in all attributes will be accepted directly. For the others, the minimum threshold of I-CVI ≥ 0.78 will be adopted. Considering the panel of seven specialists, this threshold will correspond, in practice, to the agreement of at least six evaluators. Should losses occur between the rounds and the minimum quorum of six specialists be maintained, the criterion will correspond to the agreement of at least five evaluators. The S-CVI/Ave will also be calculated, adopting as a reference a value ≥ 0.90, and the modified kappa, as a complementary measure of agreement adjusted for chance, interpreted as excellent (> 0.74), good (0.60 to 0.74), or satisfactory (0.40 to 0.59), according to Polit, Beck, and Owen (2007).

The process will be conducted in up to two rounds. After the first round, the elements that reach the acceptance parameters and do not present comments indicative of substantive revision will be maintained. The others will be revised by the research team in light of the qualitative justifications presented by the specialists. In the second round, the specialists will receive the pending elements already revised, accompanied by an anonymised synthesis of the results of the previous round, the main justifications, the alterations carried out, and the decisions adopted. The re-evaluated elements will again be submitted to the calculation of the I-CVI and the modified kappa.

The response rate and any losses between the rounds will be monitored and reported. There will be no substitution of specialists after the start of the process. The team will assess the maintenance of the minimum quorum of six specialists for the application of the previously defined thresholds. Consensus per evaluated element, level descriptor, or decision criterion will be considered reached when the element presents I-CVI ≥ 0.78, modified kappa in a range that is at least satisfactory, and absence of qualitative comments indicative of substantive revision. The S-CVI/Ave will be used as a global indicator of the content validity of the evaluated version, adopting a reference value ≥ 0.90.

Should the absence of consensus persist after the second round, the final decision will fall to the research team, in an exceptional manner, by means of technical justification grounded in conceptual equivalence with the source classification, in coherence with the

Brazilian normative and organisational framework, and in the qualitative contributions of the specialists. All decisions will be recorded in a traceability matrix, containing, for each evaluated element, the indices obtained, the relevant qualitative contributions, the decision adopted, the alteration carried out, when applicable, and the respective justification. The version resulting from the content validation rounds will constitute the revised version to be forwarded to the face validation.

2.7.7 Face validation by professionals who may use the classification in their institutional practice

Face validation will be conducted with eight professionals working in SUS NSP, from the version revised after the content validation. The stage will have as its purpose to examine evidence related to the response process and to the adequacy of the classification for institutional use. The participants will receive, by electronic mail, the access link to a structured form on the Microsoft Forms platform, accompanied by the revised version of the classification.

The form will contemplate items on language, comprehension of the descriptors and decision criteria, distinction between physical harm and psychological harm, organisation of information, interpretability, and ease of identification of the levels of harm. An open field will also be made available for recording difficulties, perceived ambiguities, unclear terms, and suggestions for improvement.

The appraisal will use a four-point ordinal scale: 1 = not clear or not comprehensible; 2 = needs major revision; 3 = clear and comprehensible, with minor revision; and 4 = clear and comprehensible. Scores 3 and 4 will be considered concordant. Scores 1, 2, and 3 will require justification in an open field, in order to support the qualitative interpretation of the responses and the identification of the necessary adjustments.

For each evaluated item, the I-FVI will be calculated, corresponding to the proportion of participants who attribute a score of 3 or 4. A minimum cut-off point of I-FVI ≥ 0.80 will be adopted. Considering eight participants, this criterion will correspond, in practice, to the agreement of at least seven evaluators. The S-FVI/Ave will also be calculated, as proposed by Yusoff (2019).

The modifications arising from this stage will be restricted, primarily, to adjustments of wording, presentation, and organisation of the classification, without alteration of the conceptual decisions consolidated in the content validation. Exceptionally, should convergent quantitative and qualitative evidence indicate a relevant risk of inadequate interpretation or

important difficulty of practical application, a more in-depth revision may be carried out, provided that it is technically justified and recorded.

All contributions of the participants and the decisions arising therefrom will be recorded in a traceability matrix, containing, for each evaluated item, the indices obtained, the relevant qualitative comments, the decision adopted, the corresponding justification, and the alteration carried out, when applicable. The version resulting from this stage will constitute the final version of the adapted classification.

2.8 DATA MANAGEMENT, PROTECTION, AND AVAILABILITY

The recording instruments will be prepared for each stage and developed within the Microsoft 365 ecosystem, being organised by type of product. The textual documents will be maintained in Microsoft Word and will comprise the successive versions of the classification (T1, T2, the synthesis version T12, the back-translations BT1 and BT2, the committee's consensus version, the pre-final version, the revised version, and the final version), in addition to the feedback document to the specialists, when there is a second Delphi round. The matrices and spreadsheets will be maintained in Microsoft Excel and will include the comparative spreadsheet of the synthesis, the committee review matrix, the matrix of normative and conceptual correspondence, the validation consolidation spreadsheets, intended for the calculation of the indices (I-CVI, S-CVI/Ave, and modified kappa; I-FVI and S-FVI/Ave), for the organisation of the qualitative contributions, and for the recording of the decisions, and the traceability matrix. The structured collection forms will be constructed on the Microsoft Forms platform and will encompass the appraisal of the review committee and the content and face validations, in addition to the forms for recording difficulties and justifications filled in by translators and back-translators; the responses of the validations will be exported to the consolidation spreadsheets in Excel.

The data will be managed in folders organised by stage, with standardised identification of the files, version control, and recording of origin, date, and person responsible for each alteration. Identifiable information of the participants will be kept separate from the analytical bases, replaced by alphanumeric codes and accessible only to the team. The files will be stored in Microsoft OneDrive, under the responsibility of the lead researcher, with access control by individual credentials and periodic backups, in compliance with the protocol approved by the Research Ethics Committee (CEP) and with the General Personal Data Protection Law (LGPD) (Brasil, 2018). The final version, the evaluation instruments, and the matrix of normative and conceptual correspondence will be made available in an open-

access repository at the end of the study; data that may allow the identification of the participants will not be shared.

2.9 DATA ANALYSIS

The data analysis will be conducted in a sequential, systematic, and integrated manner, combining comparative analysis of versions, documentary analysis of normative sources, quantitative analysis of the validity indices, qualitative analysis of the justifications and suggestions of the participants, and integrative synthesis of the methodological decisions. The central objective will be to demonstrate the equivalence of the adapted version in relation to the source classification, its coherence with the normative, terminological, organisational, and operational context of the Brazilian Unified Health System, and the evidence of content and face validity.

In the stages of initial translation, synthesis of the translations, back-translation, and committee review, the comparative analysis will encompass terminological divergences, ambiguities, losses of meaning, idiomatic inadequacies, conceptual inconsistencies, and any inadvertent alterations in the thresholds between the levels of harm. Each discrepancy will be recorded in a specific matrix, with description of the problem identified, alternatives considered, consensual decision, and corresponding technical justification.

The stage of normative and organisational contextualisation will be analysed by means of the matrix of normative and conceptual correspondence, with identification of convergences between the source classification and the national regulatory framework, gaps in regulation, terminological ambiguities, and needs for adjustment. The decisions arising from this analysis may involve maintenance, modification, inclusion, suppression, or insertion of explanatory notes, always with technical justification recorded.

In the content validation, the responses obtained on the ordinal scale will be described by absolute and relative frequencies, considering scores 3 and 4 as concordant. The I-CVI will be calculated separately for each evaluated element and for each applicable attribute, including clarity, relevance, conceptual adequacy, and sufficiency, when pertinent. With seven specialists, the cut-off point I-CVI ≥ 0.78 will correspond, in practice, to the agreement of at least six evaluators; should losses occur between the rounds and the minimum quorum of six specialists be maintained, the criterion will correspond to the agreement of at least five evaluators. The S-CVI/Ave will also be calculated, adopting as a reference a value ≥ 0.90, and the modified kappa, as a complementary measure of agreement adjusted for chance, interpreted according to the parameters defined in section 2.7.6.

In the face validation, the responses will also be described by absolute and relative frequencies, considering scores 3 and 4 as concordant. For each evaluated item, the I-FVI will be calculated, and the S-FVI/Ave will be obtained from the average of the respective I-FVI. With eight participants, the cut-off point I-FVI ≥ 0.80 will correspond, in practice, to the agreement of at least seven evaluators. In this stage, the quantitative results will primarily guide adjustments of clarity, organisation, presentation, and usability, without automatic reopening of the conceptual decisions consolidated in the content validation.

The interpretation of the results will not be limited to the quantitative indices. The values obtained will be analysed together with the justifications of the specialists, the comments of the participating professionals, and the matrix of normative and conceptual correspondence, so as to distinguish wording problems, conceptual inconsistencies, normative gaps, practical difficulties of application, and technically justifiable divergences. Elements with satisfactory quantitative indices may be adjusted when the comments indicate a risk of mistaken interpretation. In an exceptional manner, elements that do not reach quantitative consensus after the planned rounds may be maintained by means of technical justification grounded in conceptual equivalence with the source classification, in coherence with the Brazilian framework, and in the qualitative contributions of the participants, with explicit recording in the traceability matrix.

The open contributions obtained in the content and face validation stages will be submitted to descriptive-interpretative qualitative analysis. The comments will be organised by evaluated item and coded independently by two researchers of the team, considering analytical categories related, among other aspects, to clarity, terminology, conceptual equivalence, applicability to the SUS, normative coherence, ambiguity, and usability. Coding divergences will be resolved by consensus and, should disagreement persist, by a third researcher, ensuring traceability between comments, decisions, and alterations carried out.

At the end of the validation stages, the quantitative and qualitative findings will be integrated into a matrix of methodological decision and traceability, which will record, for each descriptor, decision criterion, or evaluated item, the indices obtained, the relevant qualitative contributions, the team's decision, the technical justification, and the alteration carried out, when applicable. The final version will be consolidated with a view to the preservation of conceptual equivalence with the source material, of the consistency of the structure of harm categories, levels of harm, level descriptors, and decision criteria, as well as of coherence with the normative, terminological, organisational, and operational context of the SUS.

2.10 ETHICAL ASPECTS

The study will be conducted in compliance with Resolução CNS nº 466/2012 (Brasil, 2012) and other Brazilian regulations applicable to research with human beings. The project was submitted to and approved by the Research Ethics Committee with Human Beings of the Faculdade de Ciências da Saúde of the Universidade de Brasília, under CAAE nº 60244722.5.0000.0030 and Opinion nº 7.562.342. Participation will occur upon signature of the TCLE, with a guarantee of voluntariness, confidentiality of information, anonymity among the participants in the validation process, and the right to withdraw at any time, without any prejudice.

2.11 CURRENT STATUS AND TIMELINE

At the date of submission of this manuscript, the study is in the initial translation phase. It is estimated that the stages of initial translation, synthesis of the translations, back-translation, committee review, and normative and organisational contextualisation to the SUS will be completed in approximately four weeks, resulting in the pre-final version of the classification and the respective matrix of normative and conceptual correspondence. Subsequently, approximately three months are foreseen for the final stages: two months allocated to the content validation using the Delphi method, with up to two rounds, and to the face validation; and one month allocated to the integrated analysis of the results, the recording of decisions in a traceability matrix, and the consolidation of the final version of the adapted classification. The detailed timeline and any amendments to the protocol will be recorded on an open-access platform, preserving the version history.

3 DISCUSSION

It is assumed that the incorporation, into another national context, of a patient safety classification conceived in a particular health system is not reduced to linguistic translation. It is admitted, based on the methodological literature, that instruments and classifications whose criteria depend on contextual interpretation demand formal cross-cultural adaptation, capable of preserving the semantic, idiomatic, experiential, and conceptual equivalences between the source version and the adapted one (Guillemin; Bombardier; Beaton, 1993; Beaton *et al.*, 2000).

In the case of the levels-of-harm classification of NHS England, it is presumed that cross-cultural adaptation is necessary, since its decision criteria involve organisational, care, and normative dimensions that would demand interpretation in light of the SUS context. In Brazil, this need would be associated with a possible gap: the "degree of harm" field of

Notivisa resorts to semantically broad descriptors and does not differentiate physical from psychological harm, which could compromise analytical precision and the comparability of data (Cooper *et al.*, 2018).

A central aspect is to treat the object as an operational classification, and not as a psychometric scale. Being composed of harm categories, levels, descriptors, and decision criteria, without generating scores, its adaptation is sustained on evidence of content and response process validity, not on analyses of internal structure or relation with external variables (American Educational Research Association; American Psychological Association; National Council on Measurement in Education, 2014; Terwee *et al.*, 2018). This delimitation adjusts the design to the nature of the object and makes explicit the scope of the validity inferences.

The normative and organisational contextualisation to the SUS is the main differential of this protocol in comparison with strictly linguistic adaptations. The criteria of the source classification incorporate references to types of care, temporal parameters, levels of care intervention, and recording conditions that may have correspondence, implications, or limits of application in the normative, organisational, and care context of Brazilian public health. Brazil already has, moreover, an institutional record of the degree of harm in Notivisa, which should be considered so that the adapted version dialogues with the practice in force and grounds, in a coherent manner, any recommendations for improvement. Transposing the criteria of the source document without prior examination of their normative, organisational, and terminological compatibility would preserve the form of the original classification, but would compromise its interpretive consistency and its practical applicability.

The Brazilian experience with the London Protocol illustrates the challenges of incorporating methods conceived in other health systems without formally described and publicly available cross-cultural adaptation. In Brazil, the method is employed above all in the analysis of incidents that resulted in death and of never events (Agência Nacional de Vigilância Sanitária, 2025; Agência Nacional de Vigilância Sanitária, 2026), but its application occurs in a normative context distinct from that in which it was developed. One example is the absence, in the Brazilian legal order, of a specific and operationally equivalent legal duty to the British Duty of Candour, which mandates open communication with patients and family members following serious adverse events (Care Quality Commission, 2025; Quick, 2022). This normative difference may generate uncertainties as to the operationalisation of components of the method that depend on formalised practices of transparency, communication, and involvement of the people affected, favouring interpretive doubts and

variations in the conduct of these practices in Brazil, including in the SUS. Such asymmetry reinforces the need for structured adaptation processes.

The distinction between physical harm and psychological harm, incorporated by the LFPSE of NHS England, represents a relevant advance in the gradation of harm associated with patient safety events and aligns with international efforts to render visible forms of harm that have historically been neglected (World Health Organization, 2024; Pfeiffer *et al.*, 2025). In a conceptual framework developed in oncology, Dreismann *et al.* (2025) define preventable psychological harm as that arising from actions or omissions in interactions with the health system, including communication failures, lack of respect, and inadequate organisational policies, which deviate from patient-centred care and may negatively affect the well-being and health behaviour of patients and family members. The proposal seeks to render measurable, analysable, and preventable harm that is frequently invisible in care practice.

In the SUS, this category of harm is not yet established in the instruments and processes for responding to patient safety incidents. Its adaptation, therefore, is not a mere stage of conceptual equivalence, but an opportunity to introduce, in a structured and methodologically grounded manner, an aspect still insufficiently contemplated in the national classification system, which justifies the inclusion of mental health specialists in the content validation.

The protocol starts from the premise that the structural and logical particularities of the source material that sustain the fidelity of the adaptation should be preserved, whenever possible. The research team intends, thus, to maintain the asymmetry between the five levels of physical harm and the four of psychological harm, without a fatal level in the latter, and the requirement of all criteria in the low physical harm level, in contrast to at least one criterion in the other levels. These decisions will be submitted to the appraisal of the specialists in the content validation using the Delphi method and may be adjusted should there be technical consensus as to the need for adaptation to the normative, terminological, and operational context of the SUS.

The choice of the Delphi method is justified by the need for structured, anonymous, and iterative judgement by specialists on criteria whose interpretation is sensitive to context (Hasson; Keeney; McKenna, 2000). Its strength, in this protocol, lies in the mixed reading: the quantification through indices with thresholds defined a priori confers objectivity, while the requirement of justification for the scores that signal revision ensures that the values are interpreted in light of the qualitative reasons of the evaluators (Polit; Beck; Owen, 2007).

This mixed reading articulates quantitative results, qualitative justifications, and a traceability trail of decisions, allowing wording problems to be distinguished from conceptual

inconsistencies, normative gaps, and technically justifiable divergences, and expanding the robustness and reproducibility of the process. Face validation with NSP professionals examines evidence of the response process: clarity, comprehensibility, organisation, interpretability, and usability, a decisive dimension for the routine application of the classification and coherent with the operational nature of the object (Yusoff, 2019).

Transparency and reproducibility are reinforced by the prior registration of the protocol in an open-access repository, with a persistent identifier, and by adherence to consolidated reporting references: the good practices of the ISPOR and the guidelines of Sousa and Rojjanasrirat for the adaptation, the CREDES for the conduct and reporting of the Delphi rounds, and the recommendations of COSMIN insofar as applicable to a non-psychometric object (Wild *et al.*, 2005; Sousa; Rojjanasrirat, 2011; Jünger *et al.*, 2017; Terwee *et al.*, 2018). Added to the auditable recording of decisions at all stages, this set permits external scrutiny of the path that sustains the adapted version.

The composition of the participants of the validation stages is likewise anchored in the methodological literature on content validation, the Delphi method, and face validation (Hasson; Keeney; McKenna, 2000; Polit; Beck; Owen, 2007; Yusoff, 2019). The selection of specialists and of professionals who may use the classification in their institutional practice, with prior experience in the SUS and originating from different Brazilian regions, favours the pertinence and applicability of the decisions to the target context.

The adapted version should be understood as an initial stage of a broader agenda for the qualification of patient safety in the RAS. Since the establishment of the PNSP, advances have been observed in the implementation of computerised notification systems and in the expansion of the use of Notivisa, indicative of greater maturity of the recording culture (Maia *et al.*, 2018; Faustino *et al.*, 2021; Villar; Martins; Rabello, 2021). This increase makes the qualification of the harm classification even more relevant, since more precise data more robustly sustain the prioritisation of analyses, the allocation of efforts, and the definition of improvement actions proportionate to the risk (Cooper *et al.*, 2018). The study is, moreover, opportune in light of recent milestones that reposition the person and safety at the centre of the system, such as the Estatuto dos Direitos do Paciente and the PNQSP, which reinforce the need for clearer and more consistent instruments to define the harm resulting from incidents (Brasil, 2026a; Brasil, 2026b).

Some limitations must be acknowledged. The selection of the specialists and of the professionals who may use the classification in their institutional practice is intentional and of limited size. This characteristic, added to the absence of direct participation of patients and family members in the judgement, may restrict the generalisation of the findings;

nevertheless, the form of involvement of these people is incorporated as an object of discussion in the validation stages. Although it contemplates regional diversity and multiprofessional competence, the design does not fully encompass the heterogeneity of care, normative, and organisational contexts of the SUS, so that the adaptive decisions may predominantly reflect the institutional experiences represented by the participants, which recommends caution in generalisation to very distinct scenarios. Such limitations are inherent to cross-cultural adaptation processes (Beaton *et al.*, 2000; Alavi; Le Lagadec; Cleary, 2026) and reinforce the pertinence of subsequent stages of evaluation of the classification in different contexts of the RAS.

Finally, the operational nature of the object delimits the scope of the validity inferences, which do not contemplate evidence of internal structure or of relation with external variables. The adapted version is tied, moreover, to a specific date and version of the source document, whose subsequent updates will only be incorporated upon new documented methodological deliberation.

By proposing a methodologically structured adaptation, instead of the direct incorporation of an international classification, this study intends to contribute in two dimensions. On the methodological plane, it seeks to reinforce rigour in the adaptation of operational harm classifications for systems with a normative and organisational framework distinct from that of origin, proposing a replicable path that integrates cross-cultural adaptation, normative contextualisation, and contemporary validity evidence. On the care and systemic plane, it adds to the efforts for the qualification of safe care in the SUS, by favouring more comparable data, responses proportionate to the different types and levels of harm, and the strengthening of learning from incidents. The main strengths and limitations of the protocol are synthesised in Table 3.

Table 3

Main strengths and limitations of the study

STRENGTHS
This study protocol combines a consolidated reference of cross-cultural adaptation (Beaton *et al.*; ISPOR; Sousa and Rojjanasrirat) with a contemporary framework of validity evidence, conferring rigour and reproducibility to the process.
The normative and organisational contextualisation to the SUS, operationalised by a correspondence matrix, is a differential in comparison with strictly linguistic adaptations.
The content validation, using the Delphi method, and the face validation are interpreted in a mixed manner, integrating quantitative indices with qualitative justifications and a documented path of decisions.
LIMITATIONS
As this is a classification of the level of harm, and not a psychometric instrument, no evidence of internal structure or of relation with external variables is produced, which delimits the scope of the validity inferences.

The choice of the specialists and of the professionals who may use the classification in their institutional practice is intentional and of limited size, without the direct participation of patients, which may restrict the generalisation of the findings.

Source: prepared by the authors (2026).

4 CONCLUSION

This protocol outlines the methodological path for the translation, cross-cultural adaptation, and validation, into Brazilian Portuguese, of the classification of levels of harm associated with patient safety events published by NHS England, oriented towards obtaining a version conceptually equivalent to the original and compatible with the normative and organisational context of the SUS. By stratifying the physical and psychological dimensions of harm and by offering more structured decision criteria for the attribution of the levels, it is expected that the validated version will qualify the information produced in notification systems, favour monitoring and organisational learning, and sustain more proportionate and transparent responses to patient safety events, contributing to the strengthening of the safety culture in the SUS.

REFERENCES

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Gestão de riscos e investigação de eventos adversos relacionados à assistência à saúde. Brasília, DF: Anvisa, 2025. Disponível em: https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/servicosdesaude/manuais/copy2_of_infecc_qualidade_cad_7_completo_web_20250915_final2.pdf. Acesso em: 4 maio 2026.

AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Plano integrado para a gestão sanitária da segurança do paciente em serviços de saúde 2026-2030. Brasília, DF: Anvisa, 2026. Disponível em: https://www.gov.br/anvisa/pt-br/assuntos/servicosdesaude/seguranca-do-paciente/Plano_Integrado_seguranca_do_paciente_2026_2030___FINAL_jan_2026.pdf. Acesso em: 7 jun. 2026.

ALAVI, M.; LE LAGADEC, D.; CLEARY, M. Challenges of cross-cultural validation of clinical assessment measures: a practical introduction. Journal of Advanced Nursing, v. 82, n. 2, p. 941-949, 2026. DOI: 10.1111/jan.16906.

AMERICAN EDUCATIONAL RESEARCH ASSOCIATION; AMERICAN PSYCHOLOGICAL ASSOCIATION; NATIONAL COUNCIL ON MEASUREMENT IN EDUCATION. Standards for educational and psychological testing. Washington, DC: American Educational Research Association, 2014.

BEATON, D. E. *et al.* Guidelines for the process of cross-cultural adaptation of self-report measures. Spine, v. 25, n. 24, p. 3186-3191, 2000. DOI: 10.1097/00007632-200012150-00014.

BRASIL. Conselho Nacional de Saúde. Resolução nº 466, de 12 de dezembro de 2012. Aprova diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos.

Brasília, DF: Conselho Nacional de Saúde, 2012. Disponível em: https://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf. Acesso em: 4 maio 2026.

BRASIL. Lei nº 13.709, de 14 de agosto de 2018. Lei Geral de Proteção de Dados Pessoais (LGPD). Brasília, DF: Presidência da República, 2018. Disponível em: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/lei/l13709.htm. Acesso em: 4 maio 2026.

BRASIL. Lei nº 15.378, de 6 de abril de 2026. Institui o Estatuto dos Direitos do Paciente. Diário Oficial da União: seção 1, Brasília, DF, 7 abr. 2026a. Disponível em: https://pesquisa.in.gov.br/imprensa/jsp/visualiza/index.jsp?data=07/04/2026&jornal=515&pagina=1&totalArquivos=213. Acesso em: 4 maio 2026.

BRASIL. Ministério da Saúde. Portaria GM/MS nº 11.527, de 9 de junho de 2026. Institui a Política Nacional de Qualidade e Segurança do Paciente. Diário Oficial da União: seção 1, Brasília, DF, 10 jun. 2026b. Disponível em: https://www.in.gov.br/web/dou/-/portaria-gm/ms-n-11.527-de-9-de-junho-de-2026-711400715. Acesso em: 10 jun. 2026.

BRASIL. Ministério da Saúde. Portaria nº 529, de 1º de abril de 2013. Institui o Programa Nacional de Segurança do Paciente (PNSP). Brasília, DF: Ministério da Saúde, 2013. Disponível em: https://bvsms.saude.gov.br/bvs/saudelegis/gm/2013/prt0529_01_04_2013.html. Acesso em: 4 maio 2026.

CARE QUALITY COMMISSION. Regulation 20: Duty of candour. London: Care Quality Commission, 2025. Disponível em: https://www.cqc.org.uk/guidance-regulation/providers/regulations-service-providers-and-managers/health-social-care-act/regulation-20. Acesso em: 7 jun. 2026.

CASTRO, M. C. *et al.* Brazil's unified health system: the first 30 years and prospects for the future. The Lancet, v. 394, n. 10195, p. 345-356, 2019. DOI: 10.1016/S0140-6736(19)31243-7.

CENTER FOR OPEN SCIENCE. Open Science Framework. Charlottesville: Center for Open Science, [s.d.]. Disponível em: https://osf.io/. Acesso em: 6 jun. 2026.

COOPER, J. *et al.* Classification of patient-safety incidents in primary care. Bulletin of the World Health Organization, v. 96, n. 7, p. 498-505, 2018. DOI: 10.2471/BLT.17.199802.

CROMPTON, A. *et al.* How can specialist investigation agencies inform system-wide learning for patient safety? A qualitative study of perspectives on the early years of the English Healthcare Safety Investigation Branch. Journal of Health Services Research & Policy, v. 30, n. 1, p. 31-39, 2025. DOI: 10.1177/13558196241291816.

DREISMANN, L. *et al.* Invisible harm in patient safety: a framework and definition for preventable psychological harm in cancer care. BMJ Open Quality, v. 14, e003466, 2025. DOI: 10.1136/bmjoq-2025-003466.

DYER, C. New NHS safety watchdog aims to promote openness and avoid "blame culture". BMJ, j4306, 2017. DOI: 10.1136/bmj.j4306.

FAUSTINO, T. N. *et al.* National Patient Safety Program in Brazil: incidents reported between 2014 and 2017. Journal of Patient Safety, v. 17, n. 8, p. e1202-e1208, 2021. DOI: 10.1097/PTS.0000000000000496.

GOEKCIMEN, K. *et al.* Addressing patient safety hazards using critical incident reporting in hospitals: a systematic review. Journal of Patient Safety, 2022. DOI: 10.1097/PTS.0000000000001072.

GOLDMAN, J. *et al.* Integrating equity into incident reporting and patient concerns systems: a critical interpretive synthesis. BMJ Quality & Safety, v. 35, n. 1, p. 64-74, 2026. DOI: 10.1136/bmjqs-2025-019118.

GUILLEMIN, F.; BOMBARDIER, C.; BEATON, D. Cross-cultural adaptation of health-related quality of life measures: literature review and proposed guidelines. Journal of Clinical Epidemiology, v. 46, n. 12, p. 1417-1432, 1993. DOI: 10.1016/0895-4356(93)90142-N.

HALLAM, K. P-159 Better together: Patient Safety Incident Response Framework (PSIRF) through a collaborative approach. BMJ Supportive & Palliative Care, p. A69.2-A69, 2023. DOI: 10.1136/spcare-2023-HUNC.180.

HASSON, F.; KEENEY, S.; MCKENNA, H. Research guidelines for the Delphi survey technique. Journal of Advanced Nursing, v. 32, n. 4, p. 1008-1015, 2000. DOI: 10.1046/j.1365-2648.2000.t01-1-01567.x.

HERDMAN, M.; FOX-RUSHBY, J.; BADIA, X. A model of equivalence in the cultural adaptation of HRQoL instruments: the universalist approach. Quality of Life Research, v. 7, n. 4, p. 323-335, 1998. DOI: 10.1023/A:1008846618880.

IACOBUCCI, G. NHS will focus on investigating serious incidents with the best learning opportunities. BMJ, l4514, 2019. DOI: 10.1136/bmj.l4514.

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION. ISO 31000:2018: risk management: guidelines. Geneva: International Organization for Standardization, 2018.

JÜNGER, S. *et al.* Guidance on Conducting and REporting DElphi Studies (CREDES) in palliative care: recommendations based on a methodological systematic review. Palliative Medicine, v. 31, n. 8, p. 684-706, 2017. DOI: 10.1177/0269216317690685.

KUMAH, A. Poor quality care in healthcare settings: an overlooked epidemic. Frontiers in Public Health, v. 13, 1504172, 2025. DOI: 10.3389/fpubh.2025.1504172.

LIMA JÚNIOR, A. J. D. *et al.* Ocorrência e evitabilidade de eventos adversos em hospitais: estudo retrospectivo. Revista Brasileira de Enfermagem, v. 76, e20220025, 2023. DOI: 10.1590/0034-7167-2022-0025pt.

LOUCH, G. *et al.* How were patient safety incidents responded to, investigated, and learned from within the English National Health Service before the implementation of the Patient Safety Incident Response Framework? A rapid review. Journal of Patient Safety, v. 21, n. 1, p. e42-e55, 2025. DOI: 10.1097/PTS.0000000000001349.

LYNN, M. R. Determination and quantification of content validity. Nursing Research, v. 35, n. 6, p. 382-386, 1986.

MACRAE, C. Investigating for improvement? Five strategies to ensure national patient safety investigations improve patient safety. Journal of the Royal Society of Medicine, v. 112, n. 9, p. 365-369, 2019. DOI: 10.1177/0141076819848114.

MAIA, C. S. *et al.* Notificações de eventos adversos relacionados com a assistência à saúde que levaram a óbitos no Brasil, 2014-2016. Epidemiologia e Serviços de Saúde, v. 27, e2017320, 2018. DOI: 10.5123/S1679-49742018000200004.

MASSUDA, A. *et al.* Sustentabilidade e resiliência do Sistema Único de Saúde. [S. l.]: Partnership for Health System Sustainability and Resilience, 2023. Disponível em: https://www3.weforum.org/docs/WEF_Report_PHSSR_Brazil_Portuguese_2023.pdf. Acesso em: 13 jun. 2026.

MAYBERRY, J. F.; FARRUKH, A. The NHS's new police force. Medico-Legal Journal, v. 94, n. 1, p. 17-19, 2026. DOI: 10.1177/00258172251344745.

MCDONALD, T. B. *et al.* Responding to patient safety incidents: the "seven pillars". BMJ Quality & Safety, v. 19, e11, 2010. DOI: 10.1136/qshc.2008.031633.

MELLO, L. R. G. *et al.* Instrumento brasileiro para investigação de eventos adversos na saúde: estudo de validação. Acta Paulista de Enfermagem, v. 37, eAPE001125, 2024. DOI: 10.37689/acta-ape/2024AO00011255.

MENDES, W. *et al.* The application of Iberoamerican study of adverse events (IBEAS) methodology in Brazilian hospitals. International Journal for Quality in Health Care, v. 30, n. 6, p. 480-485, 2018. DOI: 10.1093/intqhc/mzy055.

MESINIOTI, P. *et al.* Closing investigations: the role of national policy in shaping structural, organisational and relational constraints on learning from patient safety incidents. Safety Science, v. 192, 106999, 2025. DOI: 10.1016/j.ssci.2025.106999.

NHS ENGLAND. Patient Safety Incident Response Framework. London: NHS England, 2022. Disponível em: https://www.england.nhs.uk/long-read/patient-safety-incident-response-framework/#links-to-other-processes. Acesso em: 11 jun. 2026.

NHS ENGLAND. Policy guidance on recording patient safety events and levels of harm. London: NHS England, 2023. Disponível em: https://www.england.nhs.uk/long-read/policy-guidance-on-recording-patient-safety-events-and-levels-of-harm/. Acesso em: 4 maio 2026.

OIKONOMOU, E. *et al.* Patient safety regulation in the NHS: mapping the regulatory landscape of healthcare. BMJ Open, v. 9, e028663, 2019. DOI: 10.1136/bmjopen-2018-028663.

OTTOSEN, M. J. *et al.* Long-term impacts faced by patients and families after harmful healthcare events. Journal of Patient Safety, v. 17, n. 8, p. e1145-e1151, 2021. DOI: 10.1097/PTS.0000000000000451.

PAIM, J. *et al.* The Brazilian health system: history, advances, and challenges. The Lancet, v. 377, n. 9779, p. 1778-1797, 2011. DOI: 10.1016/S0140-6736(11)60054-8.

PANAGIOTI, M. *et al.* Prevalence, severity, and nature of preventable patient harm across medical care settings: systematic review and meta-analysis. BMJ, v. 366, l4185, 2019. DOI: 10.1136/bmj.l4185.

PFEIFFER, Y. *et al.* Identifying hazards for psychological harm in cancer care using incident reports: searching for the invisible. International Journal for Quality in Health Care, v. 37, mzaf099, 2025. DOI: 10.1093/intqhc/mzaf099.

POLIT, D. F.; BECK, C. T. The content validity index: are you sure you know what's being reported? Critique and recommendations. Research in Nursing & Health, v. 29, n. 5, p. 489-497, 2006. DOI: 10.1002/nur.20147.

POLIT, D. F.; BECK, C. T.; OWEN, S. V. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. Research in Nursing & Health, v. 30, n. 4, p. 459-467, 2007. DOI: 10.1002/nur.20199.

QUICK, O. Duties of candour in healthcare: the truth, the whole truth, and nothing but the truth? Medical Law Review, v. 30, n. 2, p. 324-352, 2022. DOI: 10.1093/medlaw/fwac004.

SILVA, Z. P. da *et al.* Perfil sociodemográfico e padrão de utilização dos serviços de saúde do Sistema Único de Saúde (SUS), 2003-2008. Ciência & Saúde Coletiva, v. 16, n. 9, p. 3807-3816, 2011. DOI: 10.1590/S1413-81232011001000016.

SOUSA, V. D.; ROJJANASRIRAT, W. Translation, adaptation and validation of instruments or scales for use in cross-cultural health care research: a clear and user-friendly guideline. Journal of Evaluation in Clinical Practice, v. 17, n. 2, p. 268-274, 2011. DOI: 10.1111/j.1365-2753.2010.01434.x.

TERWEE, C. B. *et al.* COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. Quality of Life Research, v. 27, n. 5, p. 1159-1170, 2018. DOI: 10.1007/s11136-018-1829-0.

VILLAR, V. C. F. L.; MARTINS, M.; RABELLO, E. T. Incidentes e eventos adversos de segurança do paciente notificados pelos cidadãos no Brasil: estudo descritivo, 2014-2018. Epidemiologia e Serviços de Saúde, v. 30, n. 4, e2021005, 2021. DOI: 10.1590/s1679-49742021000400007.

WEAVER, S.; STEWART, K.; KAY, L. Systems-based investigation of patient safety incidents. Future Healthcare Journal, v. 8, n. 3, p. e593-e597, 2021. DOI: 10.7861/fhj.2021-0147.

WILD, D. *et al.* Principles of good practice for the translation and cultural adaptation process for Patient-Reported Outcomes (PRO) measures: report of the ISPOR Task Force for Translation and Cultural Adaptation. Value in Health, v. 8, n. 2, p. 94-104, 2005. DOI: 10.1111/j.1524-4733.2005.04054.x.

WORLD HEALTH ORGANIZATION. Conceptual framework for the International Classification for Patient Safety: version 1.1: final technical report January 2009. Geneva: World Health Organization, 2010.

WORLD HEALTH ORGANIZATION. Global patient safety action plan 2021-2030: towards eliminating avoidable harm in health care. Geneva: World Health Organization, 2021.

WORLD HEALTH ORGANIZATION. Global patient safety report 2024. Geneva: World Health Organization, 2024. Disponível em: https://www.who.int/publications/i/item/9789240095458. Acesso em: 7 jun. 2026.

YE, X. *et al.* Cross-cultural adaptation of an implementation science glossary into simplified Chinese: study protocol. Frontiers in Health Services, v. 6, 1799760, 2026. DOI: 10.3389/frhs.2026.1799760.

YUSOFF, M. S. B. ABC of content validation and content validity index calculation. Education in Medicine Journal, v. 11, n. 2, p. 49-54, 2019. DOI: 10.21315/eimj2019.11.2.6.