Original Article

Construction and content validation of checklist for patient safety in emergency care

Construção e validação de conteúdo de checklist para a segurança do paciente em emergência

Construcción y validación del contenido de la lista de verificación para la seguridad del paciente en emergencia

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ABSTRACT

Objective: To construct and validate a checklist for patient safety in emergency care.
Method: This is methodological research conducted in Curitiba, in 2015, with construction and validation stages. The checklist was based on the guidelines of the Brazilian patient safety programme and validated online using the Delphi method, with a questionnaire, and with the participation of 23 Brazilian specialists in the first round and 20 in the second round. The data were analysed using the Content Validity Index (CVI), Cronbach's *α*, and Fisher's Exact Test.
Results: We produced a checklist with 18 valid and reliable items (94% of CVI, Cronbach's $\alpha = 0.91$).
Conclusions: The checklist comprises patient safety actions and items to predict risk situations, corrective actions, and promote safety in emergency services and other health-related contexts.
Keywords: Patient safety. Emergency medical services. Checklist. Validation studies.

RESUMO

Objetivo: Construir e validar *checklist* de ações de segurança do paciente em atendimento de emergência.
Método: Pesquisa metodológica realizada em Curitiba, em 2015, com etapas de construção e validação. O *checklist* foi norteado pelas diretrizes do programa brasileiro para a segurança do paciente e validado pela Técnica Delphi online; com utilização de questionário próprio, e participação de 23 especialistas brasileiros na primeira rodada e 20 na segunda. Para a análise, utilizou-se o Índice de Validade de Conteúdo (IVC), o *α* de Cronbach e o Teste Exato de Fisher.
Resultados: Obteve-se *checklist* com 18 itens válidos e confiáveis (94% de IVC, *α* de Cronbach=0,91).
Conclusões: O *checklist* contempla ações para segurança do paciente, permite verificar situações preditivas de risco, direcionar ações de correção e promover a segurança em serviços de emergência e outros contextos de saúde.
Palavras-Chave: Segurança do paciente. Serviços médicos de emergência. Lista de checagem. Estudos de validação.

RESUMEN

Objetivo: construir y validar la lista de verificación de acciones de seguridad del paciente en la atención de emergencia.
Método: investigación metodológica realizada en Curitiba, en 2015, con etapas de construcción y validación. La lista de verificación se guió por las directrices del programa brasileño para la seguridad del paciente y fue validado por la Técnica Delphi on-line; con el uso de una encuesta propia y la participación de 23 especialistas brasileños en la primera etapa y 20 en la segunda. Para el análisis, se utilizó el Índice de Validación de Contenido (IVC), el *α* de Cronbach y el Test Exacto de Fisher.
Resultados: se obtuvo una lista de verificación con 18 ítems válidos y confiables (94% de IVC, *α* de Cronbach = 0,91).
Conclusiones: la lista de verificación abarca acciones para la seguridad del paciente, permite comprobar situaciones predictivas de riesgo, guiar acciones de corrección y promover la seguridad en servicios de emergencia y en otros contextos de la salud.
Palabras clave: Seguridad del paciente. Servicios médicos de urgencia. Lista de verificación. Estudios de validación.

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INTRODUCTION

The promotion of safe healthcare and incident prevention gained visibility with the World Alliance for Patient Safety, established by the World Health Organization (WHO) in 2004. This programme proposes global and local actions and encourages the use of checklists to guide safe care operations and prevent errors[1], regarded as adverse events when they affect patients[2].

It is estimated that 9.2% of admitted patients suffer a care-related adverse event, and 43.5% of these events are preventable[3]. In Latin American countries, these events affect 10.5% of users[4]. Sensitive to the problem, the Brazilian Ministry of Health launched, in 2013, the national patient safety programme with six basic protocols[5] related to the international patient safety goals.

In the Brazilian healthcare system, urgent and emergency services meet much of the demands of users, to the detriment of primary care units, and are considered the front line of care. The search for these services has steadily increased, generating long waiting lists of users awaiting diagnosis, tests, and hospitalisation. Other factors, such as the growing urban violence, are worsening this scenario[6] and increasing exposure of users in an environment prone to adverse events. Moreover, the shortage of human resources, the excessive workload, and continuous interruptions in these environments cause stress in the healthcare teams, and may compromise the safety of care[7-8].

In this respect, the early identification of risk situations can contribute to the provision of quality care and a culture of safety. Since the nursing staff is present throughout the healthcare process, it is subject to errors[9]. Consequently, nurses must have the instruments they need to detect the risks of harm to patients.

Intervention measures, such as checklists, arguably improve communication, reduce the occurrence of faults of omission[1], and serve as a powerful tool in the promotion of safe, quality care. Since there is no defined model for this context of care, the aim of this research was to build and validate a checklist for patient safety in emergency care.

METHOD

This article was excerpted from a master's thesis defended in 2015[10] in Curitiba, Paraná, Brazil. This is a methodological research with a quantitative approach, conducted from April to July 2015, consisting of two stages: construction of the instrument in checklist format and content validation.

The construction of this instrument for emergency hospital care was based on the six protocols of the national patient safety programme[5], namely identification, hand hygiene, pressure ulcer prevention, fall prevention, prescription safety, use and administration of medicines, and safe surgery. The content of these protocols and scientific publications were used to identify safety actions considered critical in the practice and appropriate check items for the proposed instrument.

The initial version of the checklist started with the content validation stage using the Delphi model, which seeks consensus of a group of experts on the subject matter, called committee of experts in this study. Google Docs® was used as an online tool between the researchers and experts to send the invitation letter and informed consent statements, to submit the checklist and judgment questionnaire, describe the participants, and to receive and store the answers until the end of the research.

The committee was intentionally composed of two sub-groups considering the importance of assessing an instrument by specialists on patient safety and the emergency care practice.

The first sub-group was created according to the following inclusion criteria: Brazilian nurse, physician or pharmacist; with a doctor's degree and a background in patient safety; and listed in the Lattes platform of the Conselho Nacional de Desenvolvimento Científico e Tecnológico do Brasil.

The second sub-group was formed by the committee of experts using the snowball technique, in which the initial and intentionally selected members of the sample identify other potential respondents[11], according to the following inclusion criteria: nurse and at least one year experience in hospital emergency care in Brazil. These criteria sought to ensure that the professional who works or worked in the studied context could detect specific issues observed during the routine work at the service. Moreover, the instrument is a tool nurses can use in their workplace.

With respect to the criterion for exclusion, one of the participants stopped working during the second assessment round, which was notified to the researchers.

Data collection refers to the checklist content validation process consisting of two simultaneous rounds of evaluation using the Delphi model with all the participants. The first round took place in April 2015 and lasted for 25 days, while the second round occurred in June of the same year and ended on the 30th day of the round.

For the rounds of validation, we used a questionnaire created for research based on the versions of the evaluated checklist, divided into five parts, as follows: I – Invitation to take part in the survey with an informed consent

statement; II – Sociodemographic data to characterise the participants; III – Judgment of the contents of the checklist; IV – Overall judgment of the set of questions and categories listed in the checklist.

The evaluative steps (III, IV, and V) contained 32 questions, and the judgment of each participant was registered using a Likert-type scale, as follows: 1 (strongly disagree), 2 (disagree), 3 (agree) and 4 (strongly agree).

To analyse each answer of the judgment, we used the Content Validity Index (CVI) calculation, where the total number of experts who attributed score 3 and 4 is divided by the total number of experts who participated in the round[12]. Each item was considered valid when it reached a score equal to or higher than 70% of concordance among the experts[13]. The reliability of the checklist was assessed using Cronbach's α, considering the following values: > 0.90 – excellent; > 0.80 – good; > 0.70 -acceptable; > 0.60 – questionable; > 0.50 – poor, and < 0.50 – unacceptable[14].

The data were analysed using the Statistical Package for Social Science programme (version 19.0; IBM® SPSS®). Fischer's exact test was used to examine whether there was divergence in the responses between the two sub-groups of experts, and the results lower than 0.05 indicate a significant difference of judgment.

The research was approved by the Research Ethics Committee of the Universidade Federal do Paraná with opinion CEP/SD number 777.624, on 03 September 2014. It also observed all the ethical precepts for research according to the standards of Resolution 466/2012 of the National Health Council. The informed consent statement was signed digitally using Google Docs®, and the participants were identified with codes to ensure confidentiality and protect their identities.

RESULTS

Construction of the checklist

The checklist was divided into six safety categories, with 18 check items that refer to safety items that must be checked during user assistance (first column); with the answer options Yes, No, and Not applicable – NA (second column). The third column of the instrument contains corrective actions, called interventions in the final version, which refer to optional actions performed for each identified risk situation.

Validation process

The committee of experts was the same in both rounds, consisting of 23 experts in the first round of evaluation and 20 in the second round since three participants did not return the instrument in a timely manner. Most of the participants were nurses with doctor's degrees and between 3 and 38 years of training. The committee also had a physician and a pharmacist; however, the absolute number of resumes found in the Lattes platform of these professionals was lower than that of the nurses.

In the first validation round, the CVI reached 87% concordance among the experts, indicating that the instrument was already validated. In Cronbach's α, it reached 0.91, showing the excellent reliability of the checklist. Despite the satisfactory results, we chose to consider the suggestions of the experts and conduct a new round to enhance the instrument. By the end of the process, the CVI increased to 94% and Cronbach's α remained the same.

The results, according to the categories of the checklist, are shown below, descriptively and comparatively between the rounds, and the final version is shown in figures 1 and 2.

Category 1 – Patient identification consists of four questions. The first item, "Patient identified?" obtained 100% concordance in the first round, and after suggestions it was changed to, "Is patient identified?" with 95% concordance. Therefore, the first wording was maintained in the final version. The second question "Identification readable?" obtained 87% in the first round and 100% in the second, with the wording "Is identification readable?". The article "the" was added in the final version, resulting in "Is the identification readable", after spelling review considerations. The third question, "Identification with ≥ 2 items of information?" went from 91.3% to 100% concordance after it was altered to, "Does identification contain two or more items of information?". The last question of this category, "Identification of risk classification?" was modified to "Risk classification identified?" and respectively obtained 73.9% to 70% concordance. Despite the lower CVI in the second round, the wording was maintained in the final version since it expressed the aim of verifying and registering the user risk classification more clearly.

In Category II – Administration of medicines, the first question, "Is patient allergic?" obtained a CVI of 87% and 80% in the first and second round, respectively, and without changes to the wording. The second question, "If allergic, identified as such?" reached 82.6% concordance in the first round, after which it was modified to, "If allergic, is allergy identified?" and obtained a CVI of 100%. The question "Infusions identified?" reached a concordance of 91.3% in the first round and 100% in the second round after it was modified to, "Are infusions identified?".

***CHECKLIST* PARA A SEGURANÇA DO PACIENTE EM ATENDIMENTO DE EMERGÊNCIA**

Paciente: _____ Registro:_____

Box/leito: _____ Sexo: ◻ F ◻ M Idade:_____

IDENTIFICAÇÃO DO PACIENTE		INTERVENÇÃO
1. Paciente identificado?	◻ SIM ◻ NÃO	◻ Providenciada a identificação
2. A identificação está legível?	◻ SIM ◻ NÃO	◻ Identificação substituída
3. A identificação contém duas ou mais informações?	◻ SIM ◻ NÃO ◻ NSA*	◻ Inserida mais informação
4. Classificação de risco identificada?	◻ SIM ◻ NÃO ◻ NSA	◻ Registrada a classificação
ADMINISTRAÇÃO DE MEDICAMENTOS		**INTERVENÇÃO**
5. Paciente é alérgico?	◻ SIM _____ ◻ NÃO ◻ NÃO INFORMA	
6. Se alérgico, está identificado?	◻ SIM ◻ NÃO ◻ NSA	◻ Identificado
7. As infusões estão identificadas?	◻ SIM ◻ NÃO ◻ NSA	◻ Identificadas
RISCO DE QUEDAS		**INTERVENÇÃO**
8. Sinalizado o grau de risco para queda?	◻ SIM ◻ NÃO	◻ Avaliado e sinalizado o risco
9. Paciente/acompanhante orientado sobre o risco para queda?	◻ SIM ◻ NÃO	◻ Orientação realizada
10. As grades estão elevadas?	◻ SIM ◻ NÃO ◻ NSA	◻ As grades foram elevadas
RISCO DE INFECÇÃO		**INTERVENÇÃO**
11. Solução alcoólica próxima ao paciente?	◻ SIM ◻ NÃO	◻ Solução alcoólica disponibilizada
RISCO DE ÚLCERA POR PRESSÃO		**INTERVENÇÃO**
12. Apresenta risco para úlcera por pressão?	◻ SIM ◻ NÃO	◻ Avaliado**
13. Sinalizado o grau de risco?	◻ SIM ◻ NÃO	◻ Sinalizado o grau de risco
14. Apresenta úlcera por pressão?	◻ SIM ◻ NÃO	◻ Registrado em prontuário
RISCO CIRÚRGICO		**INTERVENÇÃO**
15. Paciente em pré-operatório?	◻ SIM ◻ NÃO	
16, Paciente em jejum?	◻ SIM Início_____ ◻ NÃO ◻ NSA	
17. Sítio cirúrgico demarcado?	◻ SIM ◻ NÃO ◻ NSA	◻ Solicitada a demarcação do sítio cirúrgico
18. Tipagem sanguínea realizada?	◻ SIM ◻ NÃO ◻ NSA	

*NSA— Não se aplica
**Escala de avaliação do risco no verso deste impresso.

Data: __/__/__ Horário:_____ Identificação/registro profissional:_____

Figure 1 – Checklist for patient safety in emergency care – final version, front of the checklist

In *Category III – Risk for falls*, the three question and their respective CVI were, "Risk for falls signalled?" – 91.3%, "Is there risk for falls?" – 78.3%, "High grades?" – 91.3%, respectively adjusted to "Is the degree of risk for falls signalled?" "Patient/Companion advised on risk for falls?", and "Are the bars raised?" all with CVI of 95%. The second question was altered according to the considerations of the experts, who stressed the risk for falls of these users due to a range of factors.

The only question related to Category IV – Risk of infection reached a CVI of 73.9% in the first round with the version, "Alcohol at service point?" and 90% in the final version, "Alcohol solution next to the patient?", which was also the definitive version.

Category V – Risk of pressure ulcer contained three questions: "Risk for skin integrity?" with a CVI of 78.3% in the first round, changed to, "Is risk for pressure ulcer present?" with 90% concordance. The second question, "Conduct adopted?" was a descriptive question that initially obtained 65.2% concordance. It was later replaced, as suggested, to, "Is the degree of risk signalled?" with a CVI of 100%. The last question of the category, "Is skin lesion installed?" was changed to "Is pressure ulcer present?" and the CVI jumped from 87% to 90%.

The categories *Risk for falls* and *Risk of pressure ulcer* were added to the scales that measure the risk of these events (Figure 2), as suggested by the experts, for use at the time of checklist application.

AVALIAÇÃO DO RISCO DE QUEDA

Morse Fall Scale	Respostas	Pontos
1. Histórico de quedas (até 3 meses da última queda)	NÃO - 0	
	SIM - 25	
2. Diagnóstico Secundário (mais de um diagnóstico)	NÃO - 0	
	SIM - 15	
3. Deambulação	Nenhum/Acamado - 0	
	Muletas/Bengala - 15	
	Apoia-se em mobiliário/Parede - 30	
4. Terapia Endovenosa/dispositivo endovenoso salinizado ou heparinizado	NÃO - 0	
	SIM - 20	
5. Marcha	Normal/Sem deambulação (cadeira de rodas) - 0	
	Fraca - 10	
	Comprometida/Cambaleante - 20	
6. Estado Mental	Orientado/capaz quanto a sua capacidade - 0	
	Superestima capacidade/Esquece limitações - 15	
PARÂMETROS	RISCO BAIXO: 0 - 24 RISCO MODERADO: 25 – 44 RISCO ALTO: ≥ 45	**TOTAL**

FONTE: Adaptado de Urbanetto *et al* (2013).

AVALIAÇÃO DO RISCO DE ULCERA POR PRESSÃO

Braden Scale	1 ponto	2 pontos	3 pontos	4 pontos	Pontos
PERCEPÇÃO SENSORIAL: capacidade de responder à pressão do desconforto	Completamente limitado	Muito limitado	Levemente limitado	Nenhuma limitação	
UMIDADE: exposição da pele	Constantemente	Muito	Ocasionalmente	Raramente	
ATIVIDADE	Acamado	Restritos à cadeira	Caminha ocasionalmente	Caminha frequentemente	
MOBILIDADE: habilidade de controlar posições	Completamente imobilizado	Muito limitado	Levemente limitado	Nenhuma limitação	
NUTRIÇÃO: ingestão alimentar	Muito pobre	Provavelmente inadequado	Adequado	Excelente	
FRICÇAO E CISALHAMENTO	Problema	Problema em potencial	Nenhum problema aparente		
PARÂMETROS	23-19 – sem risco		14-13 - risco moderado		**TOTAL**
	18-15 - risco leve		Menor ou igual a 12 - risco elevado		

FONTE: Adaptado de Paranhos e Santos (1999).

Figure 2 – Checklist for patient safety in emergency care – final version, back of the checklist

In the last category, *Surgical risk*, the CVI of the question, "Preoperative patient?" went from 78.3% to 100% between the first and second round after the descriptive item on the note was removed. The second question, "Patient in fasting?" got 91.3% in the first round and 95% in the second round after the descriptive field on the record referring to the start of fasting was excluded. The third question, "Surgical site marked?" had a CVI of 91.3%, which changed to 100% after the intervention, "Marking of surgical site requested" was added. The fourth and last question, "Blood typing performed?" had a concordance of 95.7% to 100% after inclusion of the response "not applicable", and removal of the descriptive field on the record of observations.

The evaluation questionnaire contained questions referent to the overall assessment of the checklist, and observed the judgment of experts in relation to clarity, objectivity, accuracy, relevance, validity, and feasibility. The CVI results were 95% and 100%, in the first and second rounds, respectively. The same indices were obtained on questions relating to the appropriateness of the title of each category; minimum safety actions; validity of the instrument for incident prevention and to identify user risk; and the possibility of replicating the instrument in other services.

Concerning the judgment of missing elements, most participants disagreed and considered the checklist complete and sufficient.

At the end of the content validation process, we defined the final version of the checklist (figures 1 and 2).

The Fischer test was applied to the intersections of the first and second round of evaluations, between doctors and non-doctors; expertise on patient safety and emergency care; and field of professional activity, teaching or healthcare. In the association participant expertise, in the first round, the requirement "clarity" of the instrument obtained a significant difference ($p = 0.0457$); however, in the second round and analysis, no significant difference was detected. Therefore, no significant difference was considered in the evaluations between the subgroups of the committee of experts.

DISCUSSION

The assessment tool comprising six categories and 18 check items obtained an overall CVI of 94% and Cronbach's α of 0.91. Consequently, the "Checklist for patient safety in emergency care" proved valid and appropriate to verify patient safety, improve quality, reduce adverse events, and promote a culture of safety[6].

No subjects, categories or approaches were added to the initial format, suggesting that the experts considered the items sufficient to verify patient safety in emergency care. The only changes were essentially in form, and mostly resulted in increased concordance.

The adopted methodology is important to enhance checklists based on expert evaluations. In this research, we consider that the simultaneous review by two sub-groups of experts and without significant divergence in the responses represents the consistency assigned to the checklist. The instrument was judged valid and reliable both by the experts on the subject of patient safety and by the nurses who work in emergency services.

This instrument serves as a guideline in emergency services and in different healthcare contexts. Although it was not initially applied in practice, the institutions can use the checklist as a model and adapt it according to their real needs. In fact, changes to the proposed models are recommended by the WHO[1] in light of the different demands of health services.

In relation to content, identifying patients in emergency care is critical since they are usually in a state of mental confusion, panic, or unconsciousness. In this category, the checklist includes questions that reached a high level of validity, thus reiterating the importance attributed to user identification for patient safety.

The standard methods of identification, such as bracelet with at least two identifiers, and verification prior to procedures by the care teams are advocated by international organisations and the Brazilian safety programme[1,5], and represent a fundamental barrier to the occurrence of adverse events. The identification of risk classification is another relevant item performed by nurses since it sets the priority of care according to seriousness and prevents the worsening of the clinical status of users, thus promoting safe care[15].

Another item included in the checklist is the *Administration of medicines* since users in emergency rooms especially require rapid attention and the associated use of medication. Questions 5 and 6 in this category stress the need to identify and signal whether the user has a history of allergies. This investigation is important because it can prevent serious events related to allergies. A study[16] shows that errors could be prevented by detecting allergies at the time of drug administration, when the nurses ask the patients about their history of allergies before procedure.

Also in *Administration of medicines*, verifying solutions can prevent the switching of medication, side effects caused by incorrect infusion time, dosage error, inadequate administration of medicine due to user/medication mistakes, among others[1]. In addition, identification is important because recording infusion data can aid rapid intervention by another member of the team in case of allergic reactions.

The categories of *Risk for falls* and *Risk of pressure ulcer* include additional research questions about falls and pressure injury, and encourage the implementation of preventive measures to remedy the lack of actions in health services[17]. Preventive actions can also be guided by the indicators of risk scales.

Users in emergency care, frequently placed on stretchers, can suffer falls that worsen their clinical condition, and have a greater risk of developing skin lesions due to immobility and remaining in the same position for too long. Falls in this case can also be associated with sudden changes in their level of consciousness. The inclusion of Morse and Braden scales, at the suggestion of the experts, added educational value to the checklist and supports the calculation of risk for falls and injury from pressure, respectively, when the instrument is applied.

The checklist also includes basic actions for the prevention of infections, such as hand hygiene, which, although simple and effective, is insufficiently practiced and flawed in the process[18-19]. Emergency services require quick actions, so some professionals might not wash their hands if forced to look for a sink or a bottle with alcohol solution.

The WHO acknowledges alcoholic solutions as a gold standard for hand hygiene due to its effectiveness in re-

ducing microorganisms and easy application; therefore, it should be readily available in points of care as a critical strategy to prevent infection and stimulate usage[20].

Lastly, and equally relevant, several users in emergency care receive an indication for surgical, exploratory, or reconstructive interventions due to clinical conditions or trauma. Thus, care must ensure the best safety conditions prior to sending patients to the surgery room. For this purpose, the questions of the *Surgical risk* category were based on the guidelines of the programme *Cirurgias Seguras Salvam Vidas* (safe surgery saves lives)[1], with the aim of verifying and ensuring the critical elements, such as fasting, blood typing, and marking of the surgical site. This category received a better content validation index after the descriptive items in the first round were removed, resulting in greater objectivity.

FINAL CONSIDERATIONS

The goal of constructing and validating the proposed instrument was achieved. The product of this research entitled, "Checklist for patient safety in emergency care" contains 18 check items arranged in the safety categories Patient identification, Administration of medicines, Risk of infection, Risk for falls, Risk of pressure ulcers, and Surgical risk.

This research contributes to nursing education because it guides the evaluation and execution of patient safety actions, and contributes to continuing education since it contains the assessment scales of risk for falls and pressure ulcers. The product of this research is a tool for the healthcare practices, professional training, risk assessment, and reflections on the subject of patient safety.

This instrument can be used to research the use of basic patient safety elements in urgent and emergency services, and serves as a model for the construction of new care tools. In the nursing practice, it can also be used for the early identification of risk, to anticipate adverse events, and support corrective measures. Moreover, this tool can document the care provided to users and guide patient safety actions.

This instrument is a strategy to promote the safety of patients and healthcare workers, reduce near misses, and minimise adverse events and the ethical-legal implications of healthcare institutions and professionals.

The limitation of this research is the inclusion of protocols only applicable to direct patient care (point of care) in emergency care to verify the feasibility of instrument application, rather than including all the recommendations in the protocols of the national programme.

Finally, the instrument can potentially be used to identify weaknesses and strengths of healthcare services and help produce indicators for the planning of actions that promote quality care in urgent and emergency services.

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