

Adaptation of an adverse events registration form for use in recording incidents in pediatric Emergency Departments

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OBJECTIVE. To adapt a registration form based on a regional study of care-derived adverse events (Spanish acronym: ERIDA) so that it could be used to register incidents compromising patient safety in pediatric Emergency Departments.

MATERIAL AND METHODS. The adaptation process had 2 phases: a review of the literature and steps to establish the consensus of experts. We searched the following databases in the first phase: the Cochrane Library, PubMed, EMBASE (Excerpt Medica Database), and CINHALL (Cumulated Index in Nursing and Allied Health Literature). In the consensus phase a group of 10 experts in pediatric patient safety from across Spain met to apply the Delphi method.

RESULTS. The literature review identified a large number of publications on adverse events and safety in nursing care, although few of the studies specifically addressed safety in pediatric Emergency Departments. Consensus was reached in a single round of the Delphi process, in which 9 publications with low quality scores (< 7) were eliminated and 2 new publications were added related to extravasation and behavioral changes under the heading of effects of adverse events. The process enabled the experts to adapt the form for use in pediatric Emergency Departments.

CONCLUSIONS. The experts developed a form (Spanish acronym, RISE-SUHP) appropriate for registering adverse events related to patient safety. The form should help Spanish pediatric emergency departments improve patient safety.

Keywords: Adverse events. Emergency Department, pediatric. Patient safety. Form adaptation. Registry forms.

Adaptación de un formulario de Registro de Incidentes de Seguridad en los Servicios de Urgencias Hospitalarios Pediátricos (RISE-SUHP)

OBJETIVO. Adaptar el formulario de incidentes derivados de la atención en urgencias (ERIDA) al ámbito de los Servicios de Urgencias Hospitalarios Pediátricos (SUHP), con la finalidad de disponer de un formulario específico para el registro de incidentes de seguridad en este entorno.

MATERIAL Y MÉTODOS. La adaptación se realizó en dos fases: una de revisión bibliográfica y otra por consenso de expertos. Las bases de datos consultadas fueron: Cochrane Library, PubMed, EMBASE y CINHALL. En la fase de consenso se usó la metodología Delphi, con un grupo de 10 expertos nacionales en seguridad del paciente pediátrico.

RESULTADOS. La revisión bibliográfica identificó un número significativo de publicaciones sobre "eventos adversos y seguridad en los cuidados de enfermería", aunque escasos estudios específicos sobre SUHP. En la fase Delphi se alcanzó consenso tras una única ronda, eliminándose 9 ítems por puntuación insuficiente (< 7) y añadiéndose dos nuevos (extravasación y alteración del comportamiento) al apartado de efectos de los incidentes. Esto permitió elaborar un formulario adaptado a las características y necesidades de los SUHP.

CONCLUSIONES. Se ha desarrollado un formulario específico para el registro de incidentes de seguridad en los SUHP españoles (RISE-SUHP), que creemos que puede servir de herramienta para mejorar la seguridad del paciente pediátrico en estos servicios.

Palabras clave: Incidentes de seguridad. Servicios de urgencias pediátricos hospitalarios. Seguridad del paciente. Adaptación. Formulario.

Introduction

The World Health Organization (WHO) defines patient safety (PS) as "the absence of preventable harm to a patient during the process of health care" and recognizes it

as a serious public health problem. A lack of attention to PS leads to increased morbidity and mortality, death, injury, disability, long lengths of stay, or increased consumption of health care resources, all related to health care.¹ It

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directly impacts patients' quality of life.² It is a concept that includes actions aimed at eliminating, reducing, and mitigating the adverse effects (AEs) of clinical practice.

Pediatric hospital Emergency Departments (PEDs) also present unique challenges in health care, as they are typically units with high clinical pressure, characterized by frequent interruptions, varying degrees of experience among physicians, and accumulated fatigue throughout shifts. Furthermore, the pediatric population is more sensitive to AEs due to presenting undifferentiated or highly acute conditions, their inability to adequately communicate their complaints, their need for weight-adjusted drug doses, and physical and developmental characteristics that affect diagnosis, treatment strategies, procedures, and drug regimens.⁷⁻⁹ However, although the challenges of providing clinical care in PEDs and the inherent vulnerability of children are known, making them a high-risk population from a PS perspective, few studies have been conducted in these services,^{10,11} and a high error rate has also been found.^{6,12}

The Canadian multicenter study "Canadian pediatric adverse events study"¹³ analyzed the incidence rate and types of adverse events in hospitalized children, demonstrating their high vulnerability due to their limited ability to manage their own care. The results highlighted that a significant percentage of patients experienced adverse events with serious consequences, such as disability, long lengths of stay, or readmission.

The incidence and prevalence of AEs in PEDs are not well-defined due to various methodological limitations. A study at a Boston hospital highlighted that only half of the AEs reported by patients were documented in their health records, and none appeared in the hospital incident reporting system.¹⁴ These limitations make it difficult to apply the results to clinical practice in PEDs.

Errors in health care remain a significant challenge in the pediatric population, both in hospital and outpatient settings, due to the complexity of their needs and the inherent vulnerability of this group. These facts prompted The American Academy of Pediatrics to publish a statement in 2019 to minimize pediatric medical errors and improve the quality of care.¹⁵ The statement focuses on three key issues: the importance of pediatric patient safety, the science behind safety culture, and strategies to ensure patient safety. This statement acknowledges that although the field of pediatric patient safety has improved significantly in recent years, with solid data on the epidemiology of errors in children, understanding their measurement is not optimal, and therefore further work on this safety culture is necessary.

Improving PS through the prevention of safety incidents is also a priority objective in quality policies and is present in the recommendations of various international organizations such as the above-mentioned WHO, the Pan American Health Organization (PAHO), and the Council of Europe, which in 2006 urged European countries to follow the recommendations published in relation to PS.¹⁶

During 2013-2014, the "Incidents derived from emergency care (ERIDA)" study¹⁷ was conducted. This observa-

tional cross-sectional study included patients older than 18 years selected by systematic random sampling. The methodology used was that of the previously described studies, ENEAS³ and EVADUR,⁶ although with modifications to the data collection notebook according to the current WHO taxonomy on PS¹⁸ and the AE notification system (SI-NASP).¹⁹

In summary, although in recent years, health care institutions have focused on PS, with increased research, there is still a lack of tools and/or studies in the field of PEDs. The objective of this work is to adapt the ERIDA questionnaire to the PED setting with the aim of obtaining a document for the registration of safety incidents in pediatric hospital Emergency Departments (RISE-PED).

Material and Methods

The adaptation of the incident evaluation form used in the ERIDA study¹⁷ to the pediatric population was conducted in 2 phases: one literature review phase and another phase by expert consensus. The study was approved by *Hospital Clínico Universitario Virgen de la Arrixaca* Assistance Ethics Committee of (Ref. 2018-6-HUCVA).

Literature Search

In phase #1, we conducted a literature search to determine the main causal factors and possible effects of incidents related to care in PEDs across the following databases: Cochrane Library, PubMed, EMBASE, and CINAHL. The search strategy (Supplementary data <https://reue.org/extra/262.pdf>) followed was the use of controlled vocabulary, and the MeSH descriptors used were pediatrics and emergencies, and as free text, adverse events and pediatrics. In a first attempt, both descriptors and free text were related with different Boolean operators ("and" and "or") without obtaining results. Subsequently, the items (descriptors and free text) were related to the study variables individually:

- Medication: medication errors, drug-related side effects and adverse reactions.
- Care: nursing care; extravasation (no descriptor); phlebitis.
- Diagnostic error: diagnostic error.
- Surgery/Trauma procedure: medical error.
- Nosocomial infection: cross infection.
- No registration: underregistration.
- Absence of protocols: clinical protocols.

Finally, the MeSH terms used were pediatrics, emergencies, medication errors, drug-related side effects, adverse reactions, nursing care, phlebitis, diagnostic error, medical error, cross infection, underregistration, and clinical protocols.

Expert Consensus

In phase #2, a group of Spanish PS experts was created to reach consensus on the effects and causal factors of incidents in pediatric patients. For this phase, the Delphi methodology was used. Thirteen experts were invited to participate, and 10 responded. The final expert committee included 7 pediatricians belonging to the quality group of

Table 1. Hospitals and/or health centers participating in the Delphi Group

Hospital/Health Center	Profesional
Hospital Universitario Virgen de la Arrixaca (Murcia)	1 Pediatrician 1 Pharmacist
Centro de Salud de Yecla (Murcia)	1 Pediatrician
Hospital Universitario Cruces (Bilbao)	3 Pediatricians
Hospital San Joan de Déu (Barcelona)	2 Pediatricians
Hospital de Basurto (Bilbao)	1 Pediatrician
Hospital Vall d'Hebron (Barcelona)	1 Pediatrician

the Spanish Society of Pediatric Emergencies (SEUP). **Table 1** shows the participant hospitals/health centers to which the Delphi group members belonged. The 10 final participants were e-mailed 2 grids of items, one on the effects of incidents and the other on causal factors. In both grids, the items were categorized into groups. To prevent participants' responses from being influenced by those of the rest of the group, the anonymity of the collaborators was maintained until consensus results were sent.

Experts were asked to express their degree of agreement/disagreement (1 = total disagreement; 9 = total agreement) with the items included in the ERIDA study data collection form¹⁷ in the section on incident effects on the patient and possible causal factors. Items with a mean score < 7 points were eliminated. Furthermore, they were asked to add comments justifying their assessment to be used if there was no consensus. Additionally, they were invited to contribute new effects or causal factors of incidents associated with care in PHEDs.

Results

The results obtained from the different consulted bibliographic databases, along with the search terms and strategies used, are presented in the supplementary data 1 (<https://reue.org/extra/262.pdf>). Of these results, it is worth noting that no results were found in the Cochrane Library and only one result in the Teseo database of the Ministry of Health. In the other consulted databases (PubMed, Embase, and CINAHL), a larger number of works were found, among which the results for "Adverse events and safety in nursing care" numerically stand out.

In the expert consensus phase, using the DELPHI method, after the completion and analysis of the round #1 (in which consensus was obtained), we decided to eliminate 9 items on the effects of incidents, as they obtained a mean score < 7 points. Among the proposals submitted, after reviewing the literature and analyzing by the research team, we decided to add 2 items within the block of incident effects: extravasation and behavioral alteration.

Table 2 illustrates the eliminated items on the effects of incidents and the results obtained in the evaluation. During the adaptation phase, some researchers proposed adding more causal factors to the booklet, although they were not included due to a lack of consensus (**Table 3**). With the proposals provided by the expert group, the literature review, and the analysis by the research team, the final form called "Data Collection Notebook" (**Figure 1**) was prepared.

Table 2. Items removed from the "incidents derived from emergency care" (ERIDA) Data Collection Booklet

Effects of Incidents	Mean Score	Standard deviation	95% confidence interval
Falls and contusions/fractures	5.89	2.85	4.03-7.78
Edema, heart failure, shock	5.78	1.62	4.72-6.84
Drug-induced headache	5.22	2.54	3.56-6.88
Aspiration pneumonia	5.11	2.98	3.7-7.05
Constipation	5.11	2.62	3.4-6.82
Anxiety, stress, or depression	5	1.85	3.79-6.21
Hemorrhage due to anticoagulation	4.67	3.50	2.38-6.96
Cough, dyspnea, or dry mouth	4.56	2.74	2.77-6.35
MI, stroke, PE, DVT	3.33	2.78	1.51-5.15

MI: myocardial infarction; PE: pulmonary embolism; DVT: deep vein thrombosis.

Table 3. Causal factors of safety incidents in peds not included due to lack of Delphi Group Consensus

Incomplete discharge report
Human resources inadequate for clinical pressure
Inadequate organization for patient flow
Lack of systematic organization in critical patient care
Inadequate hospital transfer
Inadequate organization of procedures outside the emergency area
Inadequate maintenance of health care equipment
Erroneous diet

PED: Pediatric hospital Emergency Department.

Discussion

The main objective of this study was to adapt the ERIDA form¹⁷ to the pediatric setting, incorporating necessary adjustments to address the specific characteristics of PEDs.

Maintaining anonymity during the consensus process was key to ensuring impartiality in participants' responses. This approach allowed collaborators to express their opinions freely, without fear of external influences, as highlighted by some researchers on the benefits of anonymity in the quality of ideas generated.²¹ This methodological aspect strengthens the validity of the results obtained and supports the usefulness of anonymity in studies employing Delphi-type methodologies.

Through a comprehensive literature review and an expert consensus process using the Delphi methodology, an adapted form for the registration of safety incidents in Pediatric Hospital Emergency Services (RISE-PHED) was developed. This instrument addresses the particularities of the pediatric population and the hospital emergency setting, providing a specific and, we believe, reliable tool to identify and manage safety incidents. Its implementation remains to be conducted, which we believe will represent an advancement in pediatric patient safety, facilitating an adequate diagnosis of safety problems and allowing the design of specific interventions to minimize risks and improve care quality in this area.

The RISE-PHED form, once it begins to be used by professionals in Spanish (and eventually Latin American) PEDs, will determine its potential for improving pediatric patient safety.

Figure 1. Data collection notebook for the safety incident registration form in pediatric hospital emergency services.

DATA COLLECTION NOTEBOOK

Case No.: Date: / /

Time of Arrival: **Age:** **Sex:** Male Female

Mode of Arrival at Emergency: Transfer from another hospital
 Self-initiated Referred after initial care in primary care or Mobile Emergency Unit (UME)

Is the consultation motivated by a **previous Safety Incident?** Yes No

Reason for Consultation: **Time:**

Category Respiratory Digestive Fever Musculoskeletal CNS Genitourinary
 Allergies/Skin lesions Intoxication ENT Ophthalmology Endocrine/Metabolic
 CV/Circulatory Pain Behavioral Alteration Psychiatric Abuse Other

Triage Level:

Attended by Emergency Staff Physician Staff Physician from other service
 Pediatric Resident Family Medicine Resident

Time of start of care

Previous Illnesses (Congenital Disease / Chronic Disease):
During their stay, were complementary tests ever performed?:
 No Lab tests Exudate RSV X-ray Ultrasound/CT Lumbar Puncture ECG Hemoculture Uroculture Stool Culture Other:.....

Was treatment prescribed in the emergency department? NO YES Specify:
 ORAL IM IV SC Inhaled Nebulized Intranasal RECTAL

Were procedures performed? NO YES Peripheral line Central line Urinary catheter
 NG tube Other:.....

Diagnosis at Discharge:..... **Time of Discharge:**

Destination at Discharge: Home Admission Transfer Exitus

Was there an incident in the initial care? No Yes, no harm Yes, with harm

The incident is recorded in: The medical record Discharge report Not recorded

FOLLOW-UP
 Follow-up should be done 7 days after the Emergency Department visit for ALL patients, whether they have suffered previous incidents or not. This will be done by reviewing the medical record for admitted patients or by telephone questionnaire for discharged patients. If an adverse event caused by emergency care on the day of the study is detected, the following sheet should be filled out. (one for each incident).

QUESTIONS FOR THE TELEPHONE INTERVIEW
 a.-¿ Have you experienced any problem related to the care or instructions given to you since your visit to the Emergency Department on [Date]? Yes No
 b.-What was the problem?: (To be filled in by the interviewer on the summary sheet)

Indicate the type of problem from the following (by the interviewer):
 Related to medication
 Related to other treatments applied
 Related to the care provided
 Related to the tests performed
 Related to the diagnosis

Total number of incidents detected:

SUMMARY of the Adverse Event or Incident (use one form per incident)

Time of occurrence: In the Emergency Department Within 7-day follow-up

1.- Describe the incident and the injury or complication it caused:

2.- Detail the contributing circumstances to the main issue that favored the occurrence of the incident or AE:

3.- Detail any other problem that significantly contributed to the occurrence of the AE:

4a.- What has been the impact on the patient?
 1 The incident did not affect the patient because it was detected in time.
 2 The incident reached the patient but did not cause harm.
 3 The incident did affect the patient and caused harm.

4b.- If harm occurred, what was the impact?
 1 It caused psychological or emotional harm, without physical damage.
 2 It only required additional observation time or diagnostic tests to rule out consequences.
 3 There was physical harm without requiring additional treatment.
 4 There was physical harm that required additional treatment.
 5 The patient was in critical condition.
 6 The patient died as a result of the adverse event.

5.- Indicate the EFFECTS that have occurred in the patient:

A. Related to a procedure
 1.- Hemorrhage or hematoma due to a procedure or surgery.
 2.- Hematuria related to catheterization.
 3.- Problems with splints/bandages.
 4.- Suture dehiscence.
 5.- Other complications from procedures.

B. Related to nosocomial (hospital-acquired) infection
 1.- Surgical wound infection
 2.- Catheter-associated urinary tract infection (UTI).
 3.- Device-associated bacteremia.
 4.- Other nosocomial infection.

C. Related to patient care
 1.- Phlebitis.
 2.- Burns, erosions.
 3.- Extravasation.
 4.- Other care-related consequences.

D. General
 1. Worsening of the underlying disease.
 2. Need to repeat the procedure.
 3. Need for a repeat visit.

No effect

E. Drug-induced
 1. Nausea, vomiting, or drug-related diarrhea
 2. Drug-induced discomfort or pain (e.g., epigastric pain)
 3. Drug-or-dressing-induced itching, rash, or skin lesions
 4. Systemic allergic reactions
 5. Poor pain management
 6. Drug-induced neurological side effects
 7. Drug-induced hypotension
 8. Upper GI bleeding
 9. Electrolyte imbalance
 10. Drug-induced arrhythmia or heart rate changes
 11. Functional impairment (liver, kidney, thyroid)
 12. Poor glycemic control
 13. Local reactions or fever after vaccine or drug
 14. Other

F. Other consequence

6.- What care did the patient receive as a result of the incident?

1.- Healthcare services were not affected.
 2.- It required a higher level of observation/monitoring.
 3.- Requires additional testing (X-ray, analysis, etc.).
 4.- Additional medical or surgical treatment.
 5.- Required further consultation or referral, without admission.
 6.- It led to hospital admission.
 7.- Required life support treatment (intubation, CPR).

7.- Indicate all the CAUSAL FACTORS of the incident

A.- Related to medication
 1. Adverse drug reaction (ADR)
 2. Wrong medication
 3. Incorrect dose
 4. Omission of dose, medication, or vaccine
 5. Incorrect administration frequency
 6. Insufficient monitoring
 7. Dispensing error
 8. Wrong patient
 9. Incorrect treatment duration
 10. Lack of adherence to treatment
 11. Drug interaction
 12. Delay in medication administration

B.- Related to communication
 1. Physician-patient communication
 2. Nurse-patient communication
 3. Physician-nurse communication
 4. Physician-physician communication
 5. Language barrier
 6. Cultural barrier

C.- Related to management
 1. Patient identification error
 2. Duplicate medical record
 3. Loss of documents
 4. Mistaken patient information (e.g., test results from other patients)
 5. Prolonged wait time
 6. Issues with electronic medical records
 7. Wrong appointment scheduling

D.- Related to diagnosis
 1. Diagnostic error
 2. Delay in diagnosis
 3. Delay in referral or consultation
 4. Error in initial assessment/triage level

E.- Related to care
 1. Inadequate patient management
 2. Inadequate technical performance
 3. Improper maintenance of catheters
 4. Inadequate response to warning signs

F.- Other:

8.- To what extent was the care provided the cause of the injury?

1 The injury is entirely due to the patient's underlying condition (Not an AE)
 2 Minimal likelihood that care was the cause
 3 Slight likelihood that care was the cause
 4 Moderate likelihood that care was the cause
 5 Very likely that care was the cause
 6 Clear evidence that care was the cause of the adverse event.

9.- Was this clearly a failure in clinical performance? YES NO

10.- To what extent could this event have been prevented? (scale from 1 to 6)

Clear evidence it was preventable	1	2	3	4	5	Impossible to prevent	6
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11.- What could have been done to prevent this problem?

Figure 1. Data collection notebook for the safety incident registration form in pediatric hospital emergency services.

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