



## ORIGINAL ARTICLE

# Design and development of a risk map for improving patient safety in pediatric emergency departments<sup>☆</sup>



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## KEYWORDS

Patient safety;  
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## Abstract

**Introduction:** Emergency departments are critical settings for patient safety. Risk mapping is a proactive tool for risk management.

**Objective:** To develop a risk map for pediatric emergency care within the Spanish Society of Pediatric Emergency Medicine (SEUP).

**Methods:** Study conducted between November 2021 and May 2023 in four phases: (1) Design: Four pediatricians with expertise in care quality and patient safety created an initial map, defining processes and identifying failure modes, effects, and contributory factors. (2) Consensus: Forty-one consultants from 22 hospitals refined the map using the Delphi method, resulting in the final version. (3) Validation: assessment of the frequency, severity, and detectability of each failure mode (scored from 1 to 5). (4) Final design: three versions of the risk map were defined following calculation of risk profile numbers (RPNs): complete risk map, recommended map (risks with RPN > 50th percentile), and core map (risks with RPN > 90th percentile).

**Results:** The group identified 8 processes and 104 failure modes. The median RPN in the complete risk map was 18, with a 90th percentile of 33.4. The recommended map included 45 failure modes and the core map 13. The most frequent contributory factors were related to the work environment and the characteristics of the staff and the task.

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*Conclusions:* The risk map is a valuable tool that can facilitate the implementation of proactive risk management models. Identifying contributory factors helps prioritize strategies to enhance patient safety.

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## PALABRAS CLAVE

Seguridad del paciente;  
Mapa de riesgos;  
Urgencias pediátricas

## Diseño y desarrollo de un mapa de riesgos para mejorar la seguridad del paciente en los servicios de urgencias pediátricas

### Resumen

*Introducción:* Urgencias es un área crítica para la seguridad del paciente. El mapa de riesgos es una herramienta proactiva para gestionar el riesgo.

*Objetivo:* Diseñar un mapa de riesgos para las urgencias pediátricas dentro de la Sociedad Española de Urgencias de Pediatría.

*Metodología:* Estudio realizado entre noviembre de 2021 y mayo de 2023 en 4 fases: (1) Diseño: cuatro pediatras expertos en calidad y seguridad elaboraron un mapa inicial (definición de procesos, identificación de modos de fallos, efectos y factores contribuyentes). (2) Consenso: 41 consultores de 22 hospitales revisaron el mapa mediante metodología Delphi, obteniendo la versión final. (3) Validación del mapa final: se evaluaron frecuencia, gravedad y detectabilidad de cada modo de fallo (puntuación del 1-5). (4) Diseño final: se calculó el índice de prioridad de riesgo (IPR) y se definieron tres versiones: mapa de riesgos completo, mapa de riesgos recomendado (IPR > p50) y mapa de riesgos imprescindible (IPR > p90).

*Resultados:* Se identificaron ocho procesos y 104 modos de fallo. La mediana del IPR en el mapa de riesgos completo fue 18 y el percentil 90, 33,4. El mapa de riesgos recomendado incluyó 45 modos de fallo y el imprescindible, 13. Los factores contribuyentes más frecuentes estuvieron relacionados con las condiciones de trabajo, seguidos de los individuales, profesionales y de la tarea.

*Conclusiones:* El mapa de riesgos es una herramienta útil para facilitar la implementación de modelos proactivos de gestión de riesgos. Identificar factores contribuyentes permite priorizar estrategias para la mejora de la seguridad del paciente.

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## Introduction

In recent years, the interest in patient safety has significantly increased, leading healthcare organizations to adopt strategies to improve the safety culture, introduce health care risk management measures, train professionals, involve patients, and implement safe practices to prevent incidents and adverse events.<sup>1,2</sup>

In the planning of risk management, special importance is given to patient safety in hospital emergency departments, as these are care settings with a high risk of adverse events.<sup>3</sup> Emergency departments face common challenges, such as the unscheduled influx of patients of varying complexity and the need to make quick decisions based on limited clinical information. These challenges, combined with factors at the level of individual staff, working environment, teamwork and the organization, increase the risk of safety issues.<sup>4-6</sup>

Pediatric emergency departments (PEDs) are particularly critical settings for patient safety, as, in addition to the challenges of the emergency departments, they have to manage the unique challenges presented by pediatric patients. These include the particular anatomical and physi-

ological characteristics of children, difficulties in explaining symptoms, limited clinical expressivity in some age groups, overlapping manifestations in very different diseases, and the complexity of pediatric drug dosing (individualized doses calculated based on weight), which make pediatric patients particularly vulnerable.<sup>7,8</sup>

In this context, risk maps are dynamic instruments that can be used to detect the risks to which a patient may be exposed throughout the care episode, laying the foundation for a proactive risk management strategy. The risk map makes it possible to anticipate vulnerabilities and can guide the implementation of preventive measures. This proactive approach complements reactive tools, such as incident reporting systems and adverse event analyses, which focus on learning from past events.

In 2014, the Risk Mapping Group of the Spanish Society of Emergency Medicine (SEMES) designed and validated a risk map to improve patient safety in hospital emergency departments.<sup>9</sup> At the pediatric level, several initiatives developed in pediatric emergency settings validate the use of risk maps as useful tools to identify and manage patient safety risks in PEDs. However, all of these initiatives were

implemented in single centers, and the use of risk maps not widespread in these care settings.<sup>10–13</sup>

## Objective

The aim of the study was to design and approve by consensus a risk map in the framework of the Sociedad Española de Urgencias Pediátricas (SEUP, Spanish Society of Pediatric Emergency Medicine), applicable to PEDs of different characteristics at the national level, that could serve as a reference for proactive risk management to improve patient safety.

## Material and methods

The study was designed within the framework of the SEUP Quality Improvement Working Group, based on the methodology used by the SEMES Risk Mapping Work Group<sup>9</sup> and using the Failure Mode and Effects Analysis (FMEA) tool.<sup>12,13</sup> The study was conducted from November 2021 to May 2023, in the following phases: design, consensus, validation and final design.

### Design phase (10 months)

A principal research team was formed, consisting of four emergency pediatricians who were members of the SEUP Quality Improvement Working Group, with experience in patient safety and the use of the FMEA tool. Two nurses provided support during this phase. The team represented four hospitals of varying complexity, each with prior experience in patient safety and risk management, located in three different autonomous communities in Spain.

The first step was the definition of the processes and subprocesses of the care episode, from arrival at the PED to discharge. This was followed by the identification of failure modes (potential risks) in each of these processes using a combined approach: literature review, review of the risk maps previously developed in each participating center, analysis of reported incidents, and brainstorming.<sup>10,12–14</sup> The possible causes and contributory factors for each identified failure mode were analyzed applying the classification of contributory factors proposed by the National Patient Safety Agency of the United Kingdom<sup>15</sup> adapted to Spanish. The team also analyzed the potential adverse events or reactions that could occur if the failure mode was not detected before reaching the patient. The data were entered in a Microsoft Excel FMEA template. All the processes were reviewed and discussed by the principal research team, making the appropriate modifications until unanimous consensus was reached. The results of this design phase were gathered in the 'Initial Risk Map' document.

### Consensus phase (2 months)

In this phase, the initial risk map document was submitted to a team of 41 consultants from 22 national PEDs of different levels of complexity (SEUP Risk Mapping Group). This Risk Mapping Group was composed of SEUP board and senior members, members of the SEUP Quality Improvement Work-

ing Group and health care professionals (pediatricians and pediatric nurses) with experience in patient safety and the FMEA tool. To carry out this phase, the members of the Risk Mapping Group were divided into 4 teams, each coordinated by one of the members of the principal research team. Each team was assigned two processes to review using the Delphi method in two rounds.<sup>16</sup> The first round was conducted through mailing lists. The consultants rated their degree of agreement or disagreement with each of the risks included in the initial risk map, applying the following scale: "I consider that the risk should be kept in the final map" (8–9 points); "I am not sure whether the risk should be kept in the final map" (6–7 points), "I consider that the risk should be excluded from the final map (1–4 points). They suggested additional risks, causes and/or effects that had not been identified or contemplated in the initial risk map. Risks were classified as follows based on the resulting scores: risks for which consensus was reached to keep them in the 'Final Risk Map' (mean score  $\geq 8$  with at least two-thirds of scores higher than 7); risks for which consensus was reached to eliminate them from the map (mean score  $< 6$ ); and risks that had to be submitted to a second Delphi round (the scores did not meet the criteria for either of the other categories). The second Delphi round was conducted in person at the SEUP Annual Senior Meeting, using the same rating scheme applied in the first round. This round also included a discussion among the members of each team followed by a meeting of the principal research team where the latter reached a consensus on the risks that should be included in the final risk map. Table 1 summarizes the process of validation of the risk map.

### Validation phase (4 months)

The 'final risk map' document was sent by e-mail to all the members of the SEUP Risk Mapping Group, with the aim of having the risk map implemented in real-world practice in their respective work settings. Each failure mode was assigned a severity (S), likelihood of occurrence (O), and likelihood of detection (D) score following the scoring system described by the Institute for Healthcare Improvement<sup>14</sup> (Table 2). The severity (S) reflects the potential impact of the failure mode on patient safety, ranging from minor consequences to severe harm. The likelihood of occurrence (O) indicates how frequently the failure mode is likely to occur in routine practice. The likelihood of detection (D) refers to the likelihood that the failure mode will be identified before reaching the patient, with lower scores indicating higher detectability. The risk profile number can be calculated as a combination of these three scores ( $RPN = S \times O \times D$ ) for each failure mode, providing a quantitative measure for risk prioritization. This approach ensures a standardized and objective evaluation of potential threats to patient safety, facilitates comparison across processes, and supports the development of targeted interventions to mitigate the most critical risks.

### Final design phase (2 months)

The research team reviewed the final risk map considering the scores assigned by the consultants (medical and nurs-

**Table 1** Summary of the validation process of the risk map.

Characteristic	Description
Participants	41 consultants from 22 pediatric emergency departments
Composition of the group	Senior pediatricians and pediatric nurses with experience in patient safety
Organization	4 teams (coordinated by one principal investigator)
Processes assigned	2 processes reviewed by each team
Delphi method – 1st round	Consultants rated each risk on a 1–9 scale: <ul style="list-style-type: none"> <li>[●]8–9: keep in final risk map (score <math>\geq 8</math> with at least two thirds of scores <math>&gt; 7</math>)</li> <li>● 6–7: uncertain (second Delphi round)</li> <li>● 1–5: eliminate from final map Suggestions for new risks, causes, and/or effects were collected</li> </ul>
Delphi method – 2nd round	Consultants rated each risk on a 1–9 scale: <ul style="list-style-type: none"> <li>[●]8–9: keep in final risk map</li> </ul> <p>Round included intra-team discussions followed by a consensus meeting of the principal research team.</p>

ing staff) and calculating the median and 90th percentile of the RPNs. Both the median and 90th percentile were calculated globally, for all risks identified in the 'Complete risk map'. Based on these scores, three documents were produced: complete risk map, recommended risk map (which included risks with an RPN  $>$  median RPN) and core risk map (including risks with RPN  $>$  90th RPN percentile).

The study was approved by the ethics committee of one of the participating centers (research committee report reference 030/2022). This resolution was accepted as valid by all other collaborating hospitals, without requiring additional review. Health care professionals participated in the study, a quality improvement initiative, on a voluntary basis. They provided signed informed consent to their participation and to the publication of the study results. The study was sponsored by SEUP.

## Results

The risk map was designed for use by nurses or any other health care practitioner working in the pediatric emergency care setting. A total of 8 urgent care processes were initially identified (Fig. 1). Table 3 shows the total number of risks or failure modes, distributed by process, approved in each Delphi round and included in the final risk map. A total of 108 risks were initially identified and, after applying the Delphi method in two rounds, as described above, the final risk map included 104 risks. The processes for which the greatest numbers of risks were identified were diagnostic tests and treatment. The causal factors identified in each process are grouped and detailed in Table 4. The most frequent categories were task-related factors (65 risks), staff-related factors (64 risks), and working environment factors (87 risks). In contrast, organizational and strategic factors (16 risks) and team and social factors (21 risks) were identified less frequently. The overall median RPN, calculated based on all the risks identified in the complete risk map, was 18, with a 90th percentile of 33.4. The recommended risk map and the core risk map were defined based on this median and 90th percentile values. Table 5 shows

the number of total and process-specific risks for the three documents. The processes with the greatest reductions in the number of risks included in the map after prioritization were discharge (from 16 to 2 in recommended map and zero in core map) and diagnostic tests (from 22 to 12 in recommended map and 1 in core map). In contrast, the processes of treatment and patient care I–II retained the highest number of risks in both the recommended and core maps (Fig. 2).

Due to their comprehensive nature, the complete risk map and the recommended risk map are available in the supplemental material in the interest of clarity and accessibility (Appendix 1 and 2)

## Discussion

The development of a risk map, as described in this study, offers a proactive approach to patient safety by anticipating vulnerabilities and guiding the implementation of preventive measures. Unlike reactive tools, such as incident reporting systems and adverse event analyses, which focus on past experiences, risk maps provide a forward-looking perspective. The integration of both strategies is essential to strengthen safety culture, particularly in pediatric care, where early identification of risks is crucial.

Various risk management initiatives, such as checklists and root-cause analysis, have been implemented in pediatric emergency care. However, risk maps provide a visual and systematic overview of potential hazards, helping care teams prioritize and address risks before harm occurs. Their strengths include promoting multidisciplinary collaboration and identifying latent threats that may otherwise be overlooked. However, their effectiveness depends on the quality of the collected data and the commitment of the organization to act on the findings. In addition, if risk maps are not updated regularly, they may lose relevance or fail to capture emerging risks.<sup>17</sup>

Despite these advantages, experiences in Spain remain limited.<sup>10,12,13</sup> Previous studies of risk maps have been con-

**Table 2** Severity, frequency, and detectability score. Institute for Healthcare Improvement.

	Criterion	Score
<b>SEVERITY: What is the likelihood that the failure mode will affect the patient and cause serious harm?</b>		
Minimal	It is not reasonable to expect that this minor failure will have any significant effect on the patient, even if it does reach the patient.	1
Minor	The incident may reach the patient without causing harm, but monitoring and/or intervention would be needed to ensure that no harm has occurred.	2
Moderate	The incident would contribute to or cause temporary harm and would require an extension of hospitalization or intervention.	3
Critical	The incident would contribute to or cause permanent harm or endanger the patient's life, requiring intervention to preserve life.	4
Catastrophic	If it reaches the patient, the incident could cause permanent disability or death.	5
<b>FREQUENCY/LIKELIHOOD OF OCCURRENCE: What is the likelihood that the failure mode will occur?</b>		
Very low	Isolated failures within the process or processes. They are reasonably expected over the lifetime of the process, although they are unlikely to occur within a few years	1
Low	Occasional failure appearing in the process or similar processes, about once a year.	2
Moderate	Probable failure. The failure has occurred with some frequency in the past in the process or similar processes, several times a year.	3
High	Highly probable failure. It is certain that the failure will occur frequently, on a monthly basis.	4
Very high	Almost inevitable failure. It occurs frequently, either daily or weekly.	5
<b>LIKELIHOOD OF DETECTION: What is our capacity (with the currently available barriers) to detect the failure before it reaches the patient?</b>		
Very high	The failure is obvious. It is highly unlikely that it will go undetected by existing controls (95–100%).	1
High	The failure, although obvious and detectable, could potentially be missed in an initial control, but would certainly be detected later (75–94%).	2
Intermediate	The failure is detectable and may not reach the patient. It is likely to be detected in the later stages of the process (40–74%).	3
Low	The failure is of a nature that makes it difficult to detect using current procedures (6–39%).	4
Improbable	The failure cannot be detected. It will almost certainly reach the patient (0–5%).	5

**Table 3** Risks approved or rejected in each phase of the project.

Process	Number of risks in initial risk map	Number of risks approved in 1st round	Number of risks subjected to 2nd round	Number of risks approved in 2nd round	New risks proposed	New risks accepted	Total number of risks in final Risk map
Registration/Admission	4	3	1	0	2	0	3
Triage	10	7	3	3	4	0	10
Patient care I–II	9	5	4	2	2	2	9
Patient care III–IV	7	5	2	2	4	3	10
Observation	11	8	3	2	2	2	12
Diagnostic tests	25	17	8	5	3	0	22
Treatment	23	19	4	2	4	1	22
Discharge	19	13	6	3	0	0	16
Total	108	77	30	19	21	8	104

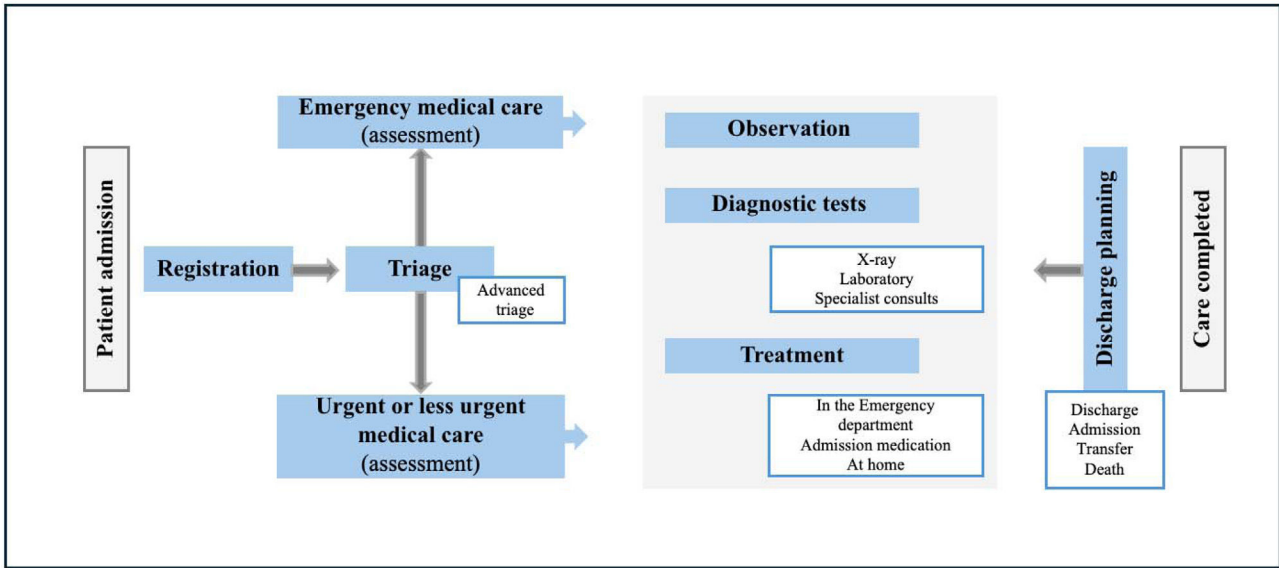


Figure 1 Patient flow in the emergency department.

PROCESSES AND SUBPROCESSES	Risks	Effects	Contributing factors
TRIAGE	Assigning the wrong triage level: undertriage	Delay in urgent patient care. Clinical deterioration of the patient during the waiting period.	ISF, TF, ETF, WE
PATIENT CARE I-II	Incorrect medical indications (diagnostic and/or therapeutic procedures)	Incorrect diagnosis. Inadequate treatment. Clinical deterioration of the patient, death.	ETF, TF, CF, TSF
	Problems in team coordination	Difficulties in stabilizing the patient. Increased likelihood of errors. Conflict between professionals. Poor patient/family experience.	PF, ISF, TSF, ETF,
PATIENT CARE III-V	Inadequate initial assessment	Inadequate approach to management. Worsening of condition, complications.	TF, TSF, ETF
	Incomplete or incorrect history-taking or physical examination	Incorrect diagnosis. Inadequate treatment. Worsening of condition, complications.	PF, ISF, CF, TF, TSF, ETF, ERF, WE
	Inadequate patient handoff during shift change	Incomplete or inadequate management. Incorrect diagnosis. Inadequate treatment.	ISF, CF, TF, WE
DIAGNOSTIC TESTS	Error in interpretation/ date error (mistaking an "old" result for a current one)	Error in diagnosis and treatment. Poor clinical outcome. Iatrogenic effect. Poor patient/family experience.	ISF, TF, ETF, ERF, WE
TREATMENT	Inappropriate prescription (prescribing a treatment not indicated by protocols or failing to prescribe a treatment when indicated)	Iatrogenic (administration of unnecessary treatment). Antibiotic resistance. Poor clinical outcome for the patient. Increased morbidity and mortality. Poor patient/family experience.	PF, ISF, TF, ETF, WE
	Administration of medication to the wrong patient (identification error)	Iatrogenic. Risk of adverse reaction (administration of treatment to the wrong patient). Delay in treatment for the correct patient.	PF, ISF, TF, ETF, WE
	Instructions for treatment are not adequately communicated to the family	Error in the preparation or administration of treatment. Therapeutic failure. Overdosage. Adverse reaction.	PF, ISF, CF, WE
	Changes in treatment recorded in the health record are not communicated to the nursing staff or are not recorded	Newly prescribed treatment is not administered or is delayed. Risk of administering discontinued treatment.	FIP, FC, FT, FFE, CT
	Error in medication preparation (calculation, dilution)	Dosing errors. Adverse reactions (overdosage). Therapeutic failure (underdosage).	ISF, TF, ETF, WE
OBSERVATION	Communication problems among professionals	Loss of information. Adverse events related to continuity of care. Poor patient/family experience.	ISF, TSF

Classification of contributory factors (National Patient Safety Agency): CF, communication factors; ERF, equipment and resource factors; ETF, education and training factors; ISF, individual staff factors; PF, patient factors; TF, task-related factors; TSF, team and social factors; WE, working environment.

Figure 2 Core risk map.

Classification of contributory factors (National Patient Safety Agency): CF, communication factors; ERF, equipment and resource factors; ETF, education and training factors; ISF, individual staff factors; PF, patient factors; TF, task-related factors; TSF, team and social factors; WE, working environment.

ducted in single centers and assessed risks from a local perspective, based on their specific circumstances, and their main limitation is the difficulty of generalizing their results

to other PEDs. The aim of our study, building on the previous experience of the SEMES Risk Mapping Group, was to develop and validate a risk map for pediatric emergency care that

**Table 4** Contributory or causal factors identified for each process.

Process	Registration/ Admission	Triage	Patient care I-II	Patient care III-IV	Observation	Diagnostic tests	Treatment	Discharge	Total
<b>Number of risks</b>									
Working environment	3	10	9	10	12	22	22	16	104
Communication factors	3	9	4	7	10	19	20	15	87
Equipment and resource factors	1	3	2	3	7	7	8	7	38
Team and social factors	3	5	3	5	6	10	5	5	42
Education and training factors	0	0	5	3	3	2	4	4	21
Patient factors	0	6	6	5	3	11	12	3	46
Individual staff factors	3	6	6	4	7	8	7	9	50
Task-related factors	1	6	4	6	6	16	20	5	64
Organizational and strategic factors	1	8	4	7	8	12	18	7	65
	1	1	0	8	0	0	1	5	16

could be applied in any PED in Spain with adaptation to the particular circumstances of each setting.

There is considerable variability in the implementation of patient safety measures in the PEDs affiliated to the SEUP, and this heterogeneity will probably only increase if we extend our purview beyond our scientific society. Our ultimate goal was to provide a tool that can serve as a reference for both PEDs that want to start implementing patient safety measures and those with established risk management systems (available in <https://seup.org/gtcalidad/>). To this end, we present three versions of the risk map. The complete risk map is a comprehensive and detailed document resulting from a thorough review of each process, and it offers a global perspective on potential risks for patient safety in the PED setting. This option is particularly useful for PEDs with prior experience in risk management, self-assessment, or internal audit processes, as well as for the design and planning of new PEDs. It is essential to recognize that, given their extent and complexity, it may not be feasible to simultaneously address all 104 risks included in this document. By means of the RPNs, the FMEA tool allowed us to prioritize the risks with the greatest potential impact on patient safety. Based on this criterion, we propose a core risk map, which includes the 13 highest-priority risks (RPN > P90) and serves as a 'basic' model for PEDs beginning their efforts on patient safety. In addition, we propose a recommended risk map, which includes the 45 risks with RPN scores above the median (RPN > P50), which offers an intermediate model. The choice between these models should be individualized for each PED taking into account the previous training and experience of its staff, the available resources, and its specific goals.

After selecting the most suitable model, it is crucial to consider when and how a risk map should be applied within a pediatric emergency department to maximize patient safety benefits. In the pediatric care setting, risk maps should be used as strategic tools to enhance patient safety and support quality improvement initiatives. Risk maps are particularly useful during the initial planning or redesign of a PED, prior to audits or accreditations, following adverse events or near-misses, and as part of routine risk management efforts. Additionally, their use is recommended when introducing new procedures, technologies, or medications, or in situations involving high staff turnover or increased workloads. By identifying critical points in the care process—such as triage, the administration of medication, or patient transfers—a risk map enables the prioritization of risks based on their likelihood and severity, facilitates evidence-based decision-making, and fosters a culture of safety within the health care team. Numerous publications support the usefulness of FMEA as a systematic instrument for evaluating complex health care processes, allowing identification of risk areas for the purpose of designing interventions to minimize the probability of adverse events, thus contributing to the improvement of patient safety in hospital emergency care settings.<sup>9,13,18,19</sup>

Using the FMEA approach, we identified the distribution of risks across processes. Examining the risk distribution, we found that the most critical points for patient safety in the care episode were the 'treatment' and 'diagnostic tests' processes, which together account for the largest number of risks in the complete risk map. This risk distribution is similar to the distribution described in other studies of risk

**Table 5** Number of risks in the complete, recommended, and core risk maps.

Process	Complete risk map	Recommended risk map	Core risk map
Registration/Admission	3	1	0
Triage	10	2	1
Patient care I–II	9	6	3
Patient care III–IV	10	4	2
Observation	12	3	1
Diagnostic tests	22	12	1
Treatment	22	15	5
Discharge	16	2	0
Total	104	45	13

Recommended risk map (risk profile number [RPN] > 50th percentile); Core Risk Map (RPN > 90th percentile).

maps designed in single PEDs in Spain.<sup>10,12,13</sup> Considering that these are complementary strategies, we can also draw a parallel with reactive management approaches. The proactive identification of risks using FMEA was consistent with the previous literature, showing that medication errors are the most frequent adverse events/incidents in pediatric care settings.<sup>20–23</sup>

Understanding the contributory factors for each identified failure mode is key for designing targeted strategies that effectively mitigate these risks. The working environment, including factors such as human resource allocation, workload, staff turnover, fatigue, time constraints, the physical environment, or administrative factors, was found to contribute to 87 of the 104 risks (83.7%) included in the complete risk map. In addition, task-related factors, such as the availability, accessibility, and adherence to guidelines, protocols, and procedures, which concern the safe and effective performance of health care processes, were involved in 65 of the 104 risks (62.5%). Furthermore, factors related to individual staff members, including unique physical, psychological (e.g., stress, mental health issues, lack of motivation), cognitive (e.g., inattention, interruptions), and family-related aspects, along with interpersonal relationships at work, contributed to 64 of the 104 risks (61.5%).

Planning efforts seeking to develop efficient safe practices to reduce risk should focus on addressing the contributory factors with the greatest impact on patient safety. This involves adjusting the staff-to-patient ratio, promoting staff retention, designing work settings that are safe for both patients and providers, ensuring the availability and accessibility of guidelines, protocols, procedures, and decision-making aids, and designing strategies to promote compliance with these tools. These factors are closely linked to the individual staff-related factors, which are, without question, the most challenging to address. Addressing these requires implementing strategies to improve the working environment, reduce burnout and increase engagement among professionals, and minimize unnecessary interruptions during task performance.

While these strategies rely on structured methodological approaches like FMEA, it is important to recognize that these analyses should not become the core of an organization's patient safety strategy. As Orrego Villagran points out, their true value resides in the translation of identi-

fied risks into actionable safe practices and the redesign of processes to reduce potential hazards. In this context, FMEA serves as a valuable follow-up tool,<sup>24–26</sup> as it allows assessment of the effectiveness of implemented improvement strategies and ongoing monitoring of patient safety risks in complex clinical settings such as pediatric emergency departments.<sup>13</sup>

The main strength of this study lies in its multidisciplinary approach, with participation of nurses, pediatricians, and department and section chiefs employed in the PEDs of 22 hospitals with varying levels of care complexity and patient safety strategy implementation. This diversity allowed for the development of a generic 'diagnostic' tool for a proactive patient safety approach, which can be applied to any PED, adapting the risk map to their specific circumstances. Additionally, we believe that analyzing the contributory factors with the greatest impact on the identified risks can be useful for establishing priorities in the planning and implementation of improvement strategies, thereby optimizing the use of the available resources.

Nevertheless, the study has some limitations. The FMEA tool is a theoretical exercise that relies on reports with a degree of subjectivity, which may influence the root-cause analysis and risk level assessment.<sup>25</sup> The complete risk map is a lengthy and exhaustive document, and its application can be challenging without prior knowledge and training in FMEA. We believe that the different risk map models yielded by this study will facilitate the implementation of a proactive patient safety management system in any PED.<sup>21</sup> However, the development or adaptation of the risk map at the local level requires a considerable investment of time and resources. Its success largely depends on the commitment of risk mapping group members and of the organization to hold regular and productive meetings.<sup>23</sup>

In conclusion, we believe that the risk map developed by the SEUP can be a useful tool to facilitate the implementation of proactive risk management patient safety models in PEDs. In addition, identifying contributory factors allows for the prioritization of strategies with the greatest potential impact on improving patient safety.

### Declaration of competing interest

The authors declare having no conflicts of interest.

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## Appendix A. Supplementary data

Supplementary material related to this article can be found, in the online version, at doi:<https://doi.org/10.1016/j.anpede.2026.504137>.

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