

Risk of Harm in Pediatrics: Adverse Events Associated with Medication Use

Risco de Danos em Pediatria: Eventos Adversos Associados ao Uso de Medicamentos
Riesgo de Daños en Pediatría: Eventos Adversos Asociados al Uso de Medicamentos

RESUMO

Objetivo: Identificar os medicamentos associados a eventos adversos no público pediátrico, assim como as principais reações envolvidas. **Metodologia:** Revisão integrativa de literatura, conduzido em março de 2024, utilizando bases de dados MEDLINE, LILACS e SciELO. A pergunta norteadora foi "Quais os medicamentos estão associados a eventos adversos no público pediátrico?". **Resultados:** Os estudos publicados entre 2019 e 2023 investigaram reações adversas a medicamentos em pacientes pediátricos. Os antibióticos foram os mais associados a reações adversas, destacando-se a ceftriaxona e a amoxicilina. As reações mais comuns incluíram rash, diarreia e náusea/vômito. Além disso, também foram relatados casos de reações mais graves, como necrólise epidérmica tóxica e insuficiência renal aguda. **Conclusão:** As reações medicamentosas em crianças representam um problema de saúde pública, podendo resultar em complicações graves. Logo, é essencial um monitoramento rigoroso, sistemas de notificação eficazes e mais pesquisas sobre a segurança dos medicamentos pediátricos.

DESCRIPTOR: Efeitos Colaterais e Reações Adversas Relacionados a Medicamentos; Pediatria.

ABSTRACT

Objective: To identify the medications associated with adverse events in the pediatric population, as well as the main reactions involved. **Methodology:** An integrative literature review conducted in March 2024, using the MEDLINE, LILACS, and SciELO databases. The guiding question was: "Which medications are associated with adverse events in the pediatric population?" **Results:** Studies published between 2019 and 2023 investigated adverse drug reactions in pediatric patients. Antibiotics were the most frequently associated with adverse reactions, with ceftriaxone and amoxicillin being the most notable. The most common reactions included rash, diarrhea, and nausea/vomiting. Additionally, more severe reactions such as toxic epidermal necrolysis and acute renal failure were also reported. **Conclusion:** Adverse drug reactions in children represent a public health concern, as they can lead to severe complications. Therefore, rigorous monitoring, effective reporting systems, and further research on pediatric drug safety are essential.

DESCRIPTOR: Drug-Related Side Effects and Adverse Reactions; Pediatric.

RESUMEN

Objetivo: Identificar los medicamentos asociados con eventos adversos en la población pediátrica, así como las principales reacciones involucradas. **Metodología:** Revisión integrativa de la literatura, realizada en marzo de 2024, utilizando las bases de datos MEDLINE, LILACS y SciELO. La pregunta orientadora fue: "¿Qué medicamentos están asociados con eventos adversos en la población pediátrica?" **Resultados:** Los estudios publicados entre 2019 y 2023 investigaron reacciones adversas a medicamentos en pacientes pediátricos. Los antibióticos fueron los más frecuentemente asociados con reacciones adversas, destacándose la ceftriaxona y la amoxicilina. Las reacciones más comunes incluyeron erupción cutánea, diarrea y náuseas/vómitos. Además, también se reportaron casos de reacciones más graves, como necrólisis epidérmica tóxica e insuficiencia renal aguda. **Conclusión:** Las reacciones adversas a medicamentos en niños representan un problema de salud pública, ya que pueden provocar complicaciones graves. Por lo tanto, es fundamental un monitoreo riguroso, sistemas de notificación eficaces y más investigaciones sobre la seguridad de los medicamentos pediátricos.

DESCRIPTOR: Efectos Colaterales y Reacciones Adversas Relacionados con Medicamentos; Pediatría

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Jamilly Souza Tavares
Medical Student at the Faculty of Medical Sciences of Pará
ORCID: <https://orcid.org/0000-0002-1068-291X>

Gilmara Rodrigues Lima Furlan
Medical Student at the Faculty of Medical Sciences of Pará
ORCID: <https://orcid.org/0000-0001-6606-2392>

Matheus Cade Coelho Soares
Medical Student at the Faculty of Medical Sciences of Pará
ORCID: <https://orcid.org/0000-0001-5772-2299>

Paula Gabrielle Gomes Candido
Nurse, Master's Degree in Health and Technology from the Federal University of Maranhão
ORCID: <https://orcid.org/0000-0002-2759-1408>

Wherveson de Araújo Ramos
Nurse, Master's Degree in Health and Technology from the Federal University of Maranhão
ORCID: <https://orcid.org/0000-0002-8741-2686>

INTRODUCTION

The administration of medications always entails a potential risk of harm to the body during a therapeutic regimen⁽¹⁾. These harms, identified as adverse reactions, are defined by the World Health Organization (WHO) as undesirable manifestations resulting from the use of medications in therapeutic doses⁽²⁾, morbidity, mortality, prolonged hospitalization time for patients, and financial burden on health systems⁽³⁾.

From a global perspective, this problem impacts individuals in all age groups; however, its incidence is notably higher in children⁽¹⁾. The increased risk of adverse events in pediatric patients may be intrinsically linked to the immaturity of the organic systems responsible for the absorption, metabolism, distribution, and excretion of these drugs⁽³⁾. In addition, there is widespread use of medications outside of their approved indications (off-label) in children, considerably exacerbating the risk of adverse reactions⁽³⁾.

In Brazil, the National Drug Policy (PNM) and the National Pharmaceutical Assistance Policy (PNAF) were implemented with the aim of ensuring therapeutic safety for the population, as well as promoting access, production and quality of drugs available in the country⁽⁴⁾. However, with the scarcity of scientific studies related to

the formulation and administration of drugs in the pediatric population, there is an impasse related to the safety and quality of care in the child population targeted by the PNAF⁽⁵⁾.

Considering the scarcity of evidence to guide the prescription of drugs in children, it is imperative to establish strict monitoring and follow-up of the use of these pharmaceutical agents⁽⁶⁾. In addition, it is essential to identify possible adverse events through active surveillance, as well as to ensure the importance of direct patient reporting systems⁽⁷⁾.

In this sense, the Pharmaceutical Assistance in Pediatrics in Brazil, with the aim of promoting the safe administration of drugs in the pediatric population, includes a series of recommendations and data associated with the use of drugs in children. However, despite highlighting the various issues related to therapeutic management in children, there is a lack of specific topics focused on the occurrence of adverse drug reactions⁽⁸⁾. Thus, the objective of this study was to identify the medications associated with adverse events in children, as well as the main reactions involved.

METHOD

To prepare the review, the steps proposed by Souza; Silva and Carvalho, 2010, were adopted, which con-

sist of an integrative literature review study⁽⁹⁾. This method aims to synthesize information relevant to the topic in question, through a scientific and critical approach, with the aim of providing an in-depth contextualization of the problem under analysis.

The guiding question was developed based on the acronym PICo, in which the pediatric population was defined as the public (P), the interest of the study was related to adverse drug events (I), and the context of the analysis was directed to children using medication (Co). The guiding question developed was "Which medications are associated with adverse events in the pediatric population?"

The research was carried out in March 2024, and the databases used were Medical Literature Analysis and Retrieval System Online (MEDLINE), Latin American and Caribbean Literature in Health Sciences (LILACS) and Scientific Electronic Library Online (SciELO). The descriptors used to search for articles were selected through the Health Sciences Descriptors (DeCS) keyword system and were interconnected by the Boolean operator "AND". The descriptors were "PEDIATRIC" and "ADVERSE DRUG REACTION", written in English in order to expand the available articles. In addition, a time interval was defined from 2018 to 2024, the period since the preparation of the recommendations estab-

lished by the strategy “Pharmaceutical Assistance in Pediatrics in Brazil”.

The search and selection of articles was conducted independently by two researchers, following the established criteria. Any disagreements were discussed and reassessed to include studies that were relevant to the topic. Studies involving an age group of under 15 years old, addressing drug classes and their adverse effects, and in English, Portuguese, and Spanish were included. The exclusion criteria were literature reviews and case reports, protocols, guidelines, and editorial letters.

The analysis of the articles was conducted in distinct stages, characterized by a careful and systematic process. Initially, the first stage consisted of correlating the titles of the articles with the research objectives in order to identify their relevance to the scope of the study. Next, the articles were selected based on the evaluation of the abstracts, which were pre-selected based on the titles considered relevant. Subsequently, after a detailed reading of the abstracts, the articles that showed signs of containing the content of interest were selected for full reading. Finally, those that met the pre-established inclusion criteria for conducting the study were chosen. This systematic process of analysis and selection guaranteed the relevance of the articles included in the integrative literature review in question.

Using the GRADE system to assess the quality of evidence, this study achieved a level of evidence classified as high, based on the consistent findings obtained. This classification reinforces the robustness and reliability of the conclusions derived from the critical analysis of the scientific literature available on the topic under analysis.

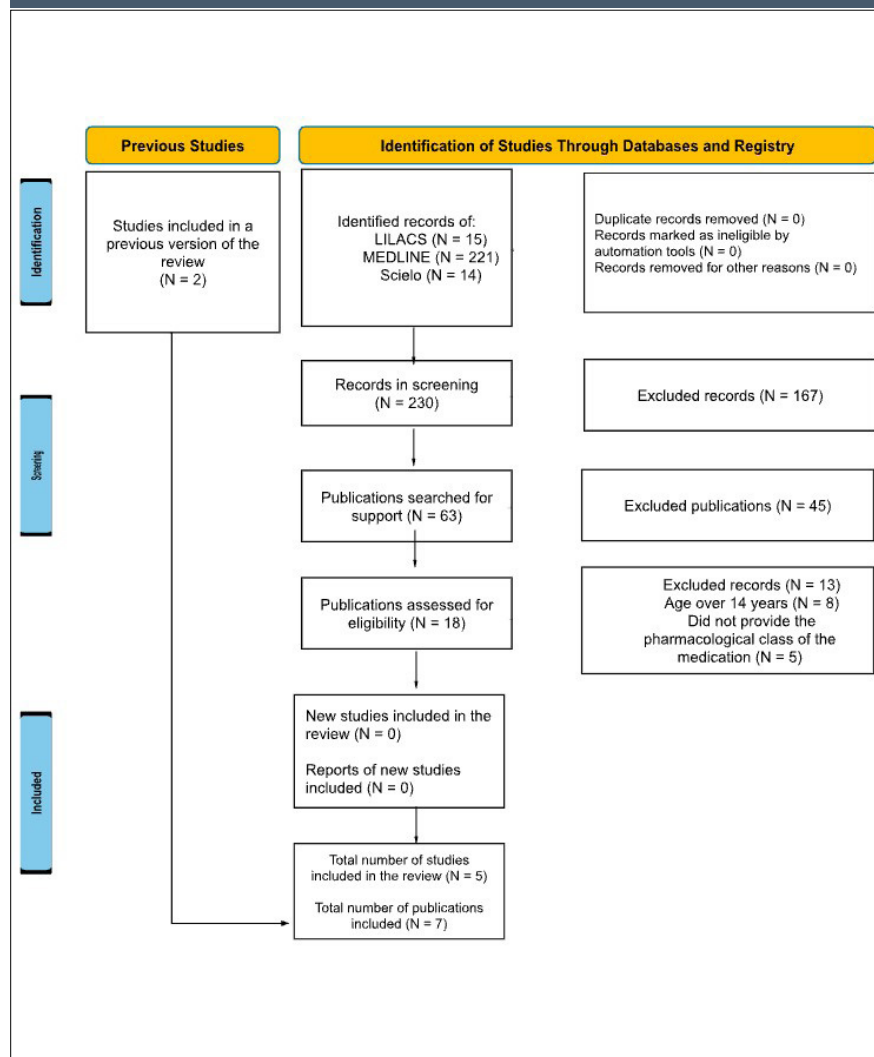
RESULTS

During the study collection phase, 230 articles were distributed among

the MEDLINE (n=211), LILACS (n=15) and SciELO (n=4) databases. First, 167 articles were excluded after reading their titles. In the second stage of analysis, 45 studies were excluded after reading their abstracts. In the third stage of analysis, the remaining studies were fully reviewed, resulting in the selection of 5 articles,

according to the established eligibility criteria. The exclusion of 13 articles after full reading was due to the lack of thematic alignment with the research objectives. In addition, 2 previously analyzed studies were included due to their suitability for the research objective.

Flowchart 1: Article selection



Source: The Authors

Within the scope of this study, seven articles were selected, all published in English, between 2019 and 2023. Regarding nationality, three studies were conducted in India, two

in Brazil, one in Japan and one in the United States. In addition, it is worth noting that the predominant types of studies were cross-sectional and cohort, constituting more than half of the studies presented.

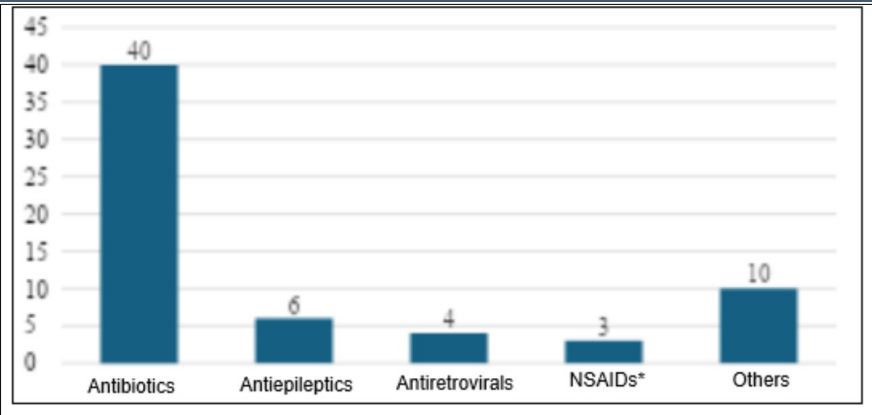
Table 1: Characteristics of the articles included in the integrative review. Marabá - PA, Brazil, 2024.

Nº	TÍTULO	AUTORES	COUNTRY	TYPE OF STUDY	SAMPLE No.	LANGUAGE	YEAR
1	Adverse events associated with diphenhydramine in children, 2008–2015	Robert B. Palmer, Kate M. Reynolds, William Banner, G. Randall Bond, Ralph E. Kauffman, Ian M. Paul, Jody L. Green e Richard C. Dart.	USA	Cross-sectional	6.618	English	2019
2	Assessment of Causality in Hospitalized Children with Aminoglycoside Related Nephrotoxicity	Madhileti Sravani; Sriram Krishnamurthy; Narayanan Parameswaran; Medha Rajappa	India	Cohort	110	English	2021
3	Adverse Drug Reactions in the Pediatric Population: Findings From the Adverse Drug Reaction Monitoring Center of a Teaching Hospital in Odisha (2015-2020)	Tripathy Ratikanta; Swarnalata Das; Palash Das; Nirmal K; Mohakud; Mangalacharan Das.	India	Cross-sectional	105	English	2021
4	Active Extraction of Experience of Adverse Drug Reactions in Children	Aoi Noda; Taku Obara; Michihiro Satoh; Naoto Yagi; Nariyasu Mano; Kenji Kaneko	Japan	Cross-sectional	15.076	English	2021
5	Causality and avoidability of adverse drug reactions of antibiotics in hospitalized children: a cohort study	Sheila Feitosa Ramos; Fernando de Castro Araújo-Neto; Giulyane Targino Aires-Moreno; Dyego Carlos Souza Anacleto de Araújo; Elisângela da Costa Lima; Divaldo Pereira de Lyra Jr.	Brazil	Cohort	183	English	2021
6	Adverse Drug Reactions to Anti-infectives in Hospitalized Children: A Multicenter Study in Brazil	Sheila Feitosa Ramos; Thais de Barros Fernandes; Dyego Carlos Araújo; Luísa Rodrigues Furtado Leitzke; Ronaldo Gomes Alexandre Júnior; Janaína Moraes de Araújo; Alcidésio Sales de Souza Júnior; Isabela Heineck; Marta Maria de França Fonteles; Claudia G. S. Osorio-de-Castro; Louise E. Bracken; Matthew Peak; Divaldo Pereira de Lyra Junior; Elisangela Costa Lima.	Brazil	Cohort	1.020	English	2022
7	Causality, Severity, and Avoidability of Adverse Drug Reactions in Hospitalized Children: A Prospective Cohort Study	Saurabh Gupta; Syed A. Zaki; Sanjeevani Masavkar; Preeti Shanbag.	India	Cohort	6.026	English	2023

Source: The Authors

During the analysis, a total of 11 drug classes were identified, covering 63 evaluated drugs. The antibiotic class presented the largest number of medications, with 40 types of drugs, followed by antiepileptics, antiretrovirals and Non-Steroidal Anti-Inflammatory Drugs (NSAIDs). Bronchodilators, muscle relaxants and antimalarials presented two respectively, while corticosteroids, antiallergics, anesthetics and membrane stabilizers presented 1 drug per class.

Gráfico 1: Classe e quantidade dos medicamentos em análise.



* Non-Steroidal Anti-Inflammatory Drugs
Source: The Authors

The drugs that were most frequently listed and related to adverse reactions were ceftriaxone (3, 4, 5 and

7); amoxicillin (4 and 7); amoxicillin + clavulanate; azithromycin and meropenem (5 and 7); paracetamol (3

and 4); diphenhydramine (1); carbamazepine (7); phenytoin sodium (7).

Tabela 3: Reações adversas registradas dos medicamentos identificadas na revisão integrativa.

DRUG	NO.	REAÇÃO ADVERSA	ORGANIC SYSTEM
CEFTRIAXONA	3 and 5	Síndrome de Stevens-Johnson	Tegumentary
	4, 5 and 7	Rash	
	5	Diarreia	Gastrointestinal
	4	Vômito	
	5	Náusea e vômito	
	7	Pseudo-litíase biliar	
	7	Anafilaxia	Global
AMOXICILINA	4 and 7	Rash cutâneo	Tegumentary
AMOXICILINA + CLAVULANATO	7	Diarreia	Gastrointestinal
	5	Vômito	
	7 and 4	Rash	Tegumentary
	7	Edema angio-neurótico	
	5	Diarreia	
AZITROMICINA	4	Vômito	Gastrointestinal
	5	Náusea e vômito	
	5	Diarreia	
MEROPENEM	7	Distúrbios metabólicos	Global
	3 and 4	Rash	
PARACETAMOL	2	Distúrbios metabólicos	Tegumentary
AMINOGLICOSÍDEOS	7	Síndrome do homem vermelho	Gastrointestinal
	7	Insuficiência Renal Aguda.	
	1	Taquicardia	Renal
DIFENIDRAMINA	1	Alucinação; sonolência e agitação	Cardiovascular
	7	Distúrbios metabólicos	Neurological
CARBAMAZEPINA	7	Ataxia; Nistagmo	Global
FENITOÍNA SÓDICA			Neurological

Source: The Authors

The most cited drugs were amoxicillin and ceftriaxone (3, 4, 5 and 7). The most analyzed NSAID was paracetamol (3 and 4). Children aged 2 years were the most related to the occurrence of adverse drug events (1, 2, 5 and 6). The most affected gender was male (1, 2, 3 and 7).

Four articles indicated Ceftriaxone as the drug with the highest number of occurrences of adverse reactions (3, 5, 6 and 7). Two articles highlighted amoxicillin as the drug with the highest number of adverse

events (2 and 30). Two articles highlighted paracetamol as an important causative agent of adverse manifestations (3 and 4). Vancomycin was related to the occurrence of Red Man Syndrome in two studies (3 and 7).

Skin rash was the most common dermatological manifestation (3, 4, 5, 6 and 7). Furthermore, two studies identified that the most common types of adverse reactions were related to the cutaneous system (3 and 5). Two studies associated the occurrence of toxic epidermal necrolysis, a

serious condition, with the use of antibiotics (3 and 7). Regarding the gastrointestinal system, diarrhea was the most cited symptom (4, 5, 6 and 7), and two studies classified the gastrointestinal system as the most affected (5 and 6). Acute kidney injury was identified in two studies, associated with the use of aminoglycosides⁽²⁾ and amphotericin B⁽⁷⁾.

DISCUSSION

In the pharmacological context, there are a variety of drug classes related to the

occurrence of adverse reactions in pediatric patients. In Brazil, the age group most affected by drug poisoning is up to 4 years of age, which is related to the administration of overdoses, storage conditions and parental self-medication⁽¹⁰⁾. Such conditions reflect the scarcity of research related to the development of medications and safe doses for pediatric patients, which limits the understanding of the pharmacology of drugs in children's bodies and favors the occurrence of adverse effects during drug therapy in children⁽¹¹⁾.

The fact that antibiotics constituted the class of drugs that presented the most adverse reactions may be related to the widespread use of these medications in pediatrics, since acute infections are the main cause of childhood illness, especially in younger age groups, as described in the study by Bell, Wilson and Harris⁽¹²⁾. These results converge with the national literature, which indicates antimicrobials as the most prescribed drug class in pediatrics⁽¹³⁾. Such conditions seem to contribute to the predominance of ceftriaxone and amoxicillin as the drugs that appeared most in the studies, which implies the need for strict monitoring, as well as follow-up during administration.

In addition to the indiscriminate prescription of antibiotics, self-medication, in this case in children — characterized by the purchase and use of medications without medical advice, as well as the storage and reuse of previously prescribed antibiotics — increases exposure to these drugs. Self-medication with antibiotics is statistically associated with low- and middle-income families, while a medium or high level of education acts as a protective factor. Young parents tend to administer antibiotics without consulting a doctor more frequently, especially in places where over-the-counter acquisition is easy⁽¹⁴⁾.

In view of this, the use of this pharmacological class in the pediatric age group is associated with long-term adverse effects. Studies by Duong et al. report that this exposure is related to autoimmune, metabolic and neurodevelopmental alterations. These associations demonstrate that the indis-

criminate use of antibiotics also triggers comorbidities of chronic courses, in addition to the repercussions of an acute nature⁽¹⁵⁾.

It is worth mentioning that paracetamol, widely used to manage pain and fever, is one of the most commonly used drugs by children, with high rates of poisoning⁽¹⁰⁾. This drug was responsible for a significant proportion of adverse reactions in children. Excessive or inappropriate use of paracetamol is associated with its wide availability without a prescription, which contributes to self-medication of this drug and the consequent occurrence of complications in pediatric patients^(16,17).

In this sense, given the toxicity of paracetamol, several European countries have adopted strategies to reduce its consumption, such as reducing the size of the packaging used in sales⁽¹⁸⁾. In addition, countries such as Ireland, the Netherlands and Sweden have established measures to quantitatively limit the sale of this drug⁽¹⁹⁾. Despite this, in Brazil, the sale of this drug is free of restrictions, being widely authorized and approved by the National Health Surveillance Agency (ANVISA), in accordance with Technical Note No. 346/2013⁽²⁰⁾.

The analysis of adverse drug reactions in pediatrics reveals significant limitations related to the lack of studies in pediatric patients, as well as doses, duration of treatments, route of administration and physical presentation of drugs. These information deficits hinder the ability to perform an accurate analysis of adverse reactions and, consequently, affect the quality of clinical interventions and patient safety⁽²¹⁾.

Mota, Vigo and Kuchenbecker highlight that the pharmacovigilance system in Brazil faces substantial problems, including incompleteness, inconsistency and inaccessibility of data, as well as lack of comprehensiveness and frequency in adverse event reporting⁽²²⁾. The lack of specific and detailed records on the use of medicines in children prevents an in-depth understanding of the associated risks and hinders the implementation of effective preventive measures. Therefore, to improve the analysis and management of adverse reactions, it is crucial to promote more detailed report-

ing and recording of adverse events⁽²³⁾.

In this sense, it is important to highlight the importance of providing guidance to healthcare professionals on reporting adverse reactions. Furthermore, developing awareness campaigns aimed at children's guardians can also contribute to the early identification of these effects. Therefore, implementing stricter guidelines for collecting data on pediatric medication use and expanding access to public databases can facilitate more accurate analyses, allowing the adoption of preventive and effective measures to improve the safety of drug use in this population.

CONCLUSION

The occurrence of drug reactions in pediatric patients is a public health problem and reveals that different pharmacological groups are associated with episodes of organic poisoning, from gastrointestinal and skin conditions to serious and potentially lethal reactions, such as toxic epidermal necrolysis. To minimize these risks, continuous medical monitoring of children undergoing treatment should be prioritized, as well as combating the practice of parental self-medication.

In addition, it is crucial that more research be conducted to deepen knowledge about the safety profiles of medications in children, in order to ensure safer and more effective pharmaceutical care for this population. This highlights the importance of specific clinical trials aimed at developing medications suitable for pediatrics, with the aim of avoiding the empirical application of therapies intended for adults, and, consequently, reducing the risks of associated complications.

It is also important to have rigorous monitoring and effective reporting systems for adverse drug reactions, especially among children. There is a clear need for detailed and available records of drug reactions in pediatric patients. An adequate pharmacovigilance system can promote improvements in situational diagnosis and contribute to the formulation of specific interventions in these cases.

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