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Special article

[Translated article] Recommendations for the safe use of high-risk medications in pediatrics☆

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ABSTRACT

Objective: The objectives of this consensus document were to establish a standardized list of high-risk medications for the pediatric population and to compile the recommended practices for their safe use with the aim of promoting the implementation of medication error prevention programs in health care centers.
Method: The Ministry of Health, the Spanish Institute for Safe Medication Practices, the Spanish Association of Pediatrics and the Spanish Society of Hospital Pharmacy and regional administration representatives participated in the project. The *Recommendations for the Safe Use of High-Risk Medications* was used as reference, and its contents adapted and expanded to address specific issues in the pediatric population based on the current evidence.
Results: The document provides a reference list of high-risk medicines in pediatric care. It recommends that health care centers, in addition to prioritizing interventions in relation to anticoagulants, insulins, opioids, neuromuscular blockers, IV potassium, oral methotrexate and cytostatic agents, also consider interventions for IV adrenergic agonists, aminoglycosides and vancomycin, drugs for moderate and minimal sedation, parenteral nutrition and IV paracetamol in pediatric patients. The document emphasizes the need to implement multiple safe practices at every stage of the medication use process, prioritizing those with the greatest effectiveness, and involving pediatricians, pharmacists and other healthcare professionals. It also highlights the importance of active involvement by patients and caregivers. Finally, it provides general guidelines common to all these medications, as well as specific practices for each prioritized pharmacological group or medication, which should be combined to enhance pediatric patient safety.
Conclusion: Developing programs to increase the safety of high-risk medications in pediatric patients is essential in order to reduce medication errors in this vulnerable population. The implementation of safe practices should be accompanied by continuous monitoring and periodic updates to guarantee effectiveness and strengthen the safety culture in health care centers.

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Recomendaciones para el uso seguro de los medicamentos de alto riesgo en pediatría

Palabras clave:
Errores de medicación
Seguridad del paciente
Gestión de riesgos
Pediatría

RESUMEN

Objetivo: los objetivos de este documento de consenso han sido establecer una lista estandarizada de medicamentos de alto riesgo en pediatría y recoger las prácticas recomendadas para su uso seguro, con el fin de promover la implementación de programas dirigidos a prevenir errores de medicación en los centros sanitarios.
Método: en su realización participaron el Ministerio de Sanidad, el Instituto para el Uso Seguro de los Medicamentos, la Asociación Española de Pediatría y la Sociedad Española de Farmacia Hospitalaria, así como representantes autonómicos. Se utilizó como referencia el documento de *Recomendaciones para el uso seguro de los medicamentos de alto riesgo*, cuyo contenido se adaptó y se amplió para abordar los problemas específicos de la población pediátrica, considerando la evidencia disponible.
Resultados: el documento proporciona una lista de referencia de medicamentos de alto riesgo en pediatría. Recomienda que los centros sanitarios, además de priorizar las intervenciones en anticoagulantes, insulinas, opiáceos, bloqueantes neuromusculares, potasio IV, metotrexato oral y citostáticos, en pediatría consideren agonistas adrenérgicos IV, aminoglucósidos y vancomicina, medicamentos para sedación moderada y mínima, nutrición parenteral y paracetamol IV. Incide en la necesidad de implementar múltiples prácticas seguras en todas las etapas del circuito de los medicamentos, priorizando aquellas de mayor efectividad y contando con la participación de pediatras, farmacéuticos y otros profesionales sanitarios. También resalta la importancia de la participación activa de pacientes y cuidadores. Finalmente, recoge prácticas generales comunes a todos estos medicamentos y prácticas específicas para cada grupo farmacológico o medicamento prioritario, que deben combinarse para mejorar la seguridad.
Conclusión: desarrollar programas de mejora de la seguridad de los medicamentos de alto riesgo en pediatría es esencial para reducir los errores de medicación en esta población vulnerable. La implantación de prácticas seguras debe ir acompañada de un seguimiento continuo y de una actualización periódica, para garantizar su efectividad y fortalecer la cultura de seguridad en los centros sanitarios.
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Introduction

According to the World Health Organization (WHO), medication errors continue to be one of the leading causes of preventable harm in health care systems worldwide. In fact, harm due to medicines may account for up to 50% of all preventable harm in medical care.[1] To address this issue, in 2017, the WHO launched the third Global Patient Safety Challenge, *Medication Without Harm*,[1] and subsequently adopted the *Global Patient Safety Action Plan 2021–2030*,[2] which includes a strategic objective aimed at implementing practices to improve medication safety based on the recommendations of the third challenge. The *Medication Without Harm* initiative defined a strategic framework with three priority areas for action, one of which addresses medication safety in high-risk situations, which include the use of high-risk medications and the management of patients who are more vulnerable to medication errors, such as pediatric patients.[3]

High-risk or high-alert medications are drugs that bear a heightened risk of causing significant patient harm or even death when they are used in error. This is a key concept in patient safety that was introduced by the Institute for Safe Medication Practices (ISMP) to identify medicines on which to target safety efforts and improvement interventions.[4] On the other hand, pediatric patients constitute a particularly vulnerable group on account of several factors that increase both the frequency of medication errors and the severity of the associated adverse events.[5,6] Therefore, for this patient group, it is particularly crucial to implement effective measures to prevent errors in the use of these medications and to minimize the severe or fatal consequences that may result.[1]

In Spain, the Ministry of Health, in the framework of the *Strategy for Patient Safety* of the National Health System,[7] has promoted the adoption of safety practices for high-risk medications and the development of specific interventions to reduce the incidence of medication errors in pediatric patients. In 2023, in collaboration with the ISMP-Spain, the Ministry of Health published the *Recommendations for the Safe Use of High-Risk Medications*,[8] a document intended to help providers manage these medications safely in health care settings. The document noted that certain settings, such as pediatric care units, should adapt the already existing list of high-risk medications and add other medicines considered to carry a high risk for pediatric patients as well as the corresponding safety practices.

The objectives of this consensus document were to provide a reference list of high-risk medications for the pediatric population and present the practices recommended for their safe use in order to promote the implementation of programs for the prevention of medication errors in pediatric patients in health care centers in Spain.

Methods

This document, which provides recommendations for the safe use of high-risk medications in pediatric patients, was developed through the collaboration of the Ministry of Health, the Instituto para el Uso Seguro de los Medicamentos (ISMP-Spain), the Asociación Española de Pediatría (AEP, Spanish Association of Pediatrics) and the Sociedad Española de Farmacia Hospitalaria (SEFH, Spanish Society of Hospital Pharmacists) as well as representatives from the autonomous communities of Spain. It began with the formation of a steering committee and a scientific committee composed of members of the participating institutions and societies. In addition, the AEP and the SEFH appointed a technical committee of drug safety experts composed of members of their respective working groups.

This document was developed using the *Recommendations for the Safe Use of High-Risk Medications*[8] as reference, adapting and expanding its contents in consideration of the specific safety issues in the pediatric population. The development of the document was organized in several steps.

– *Drafting the initial version of the document*

The members of the scientific committee developed an initial draft with a list of high-risk medications in pediatric care, providing directions for the management of these drugs in health care organizations and general safety practices, and specifying the high-risk individual medications or drug classes for which interventions should be prioritized.

To this end, the committee used the existing document that provides general recommendations as well as information obtained through the review of the evidence available in the PubMed database and the websites of governmental agencies, safety organizations and scientific societies. The committee also considered the serious patient safety incidents documented in the reporting system of the ISMP-Spain and the Patient Safety Reporting and Learning System (SiNASP) of the Ministry of Health.

In parallel, the members of the expert committee developed safety practice recommendations for the prioritized high-risk medications, which were revised by the scientific committee and then added to the document to complete the initial draft. Lastly, the draft was revised by the Ministry of Health.

– *Revision of the initial draft by the autonomous communities*

The Ministry of Health submitted the initial draft to the autonomous communities for review by Patient Safety Strategy representatives, health care professionals and/or experts in medication safety.

– *Development of the final version of the document*

The scientific and steering committees analyzed the comments and proposed changes to the initial draft formulated by professionals from the different autonomous communities to produce the final version of the document.

Results

This article presents a summary of the resulting document, *Recomendaciones para el Uso Seguro de los Medicamentos de Alto Riesgo en Pediatría*, whose full text is available for consultation online.[9]

Section I. High-risk medication reference list for pediatric care

This document provides a high-risk medication reference list for pediatric patients (Table 1), which was developed taking into account the medications used in children featured in the high-risk medication reference lists for hospitals and chronic patients of the *Recommendations for the Safe Use of High-Risk Medications* document[8] as well as specific lists for pediatric patients compiled through the review of the literature.[10–15]

This list should be used as a reference by health care organizations to produce their own high-risk medication lists for the pediatric population, which they will use for developing, prioritizing and implementing preventive measures (see Section II).

Section II. Recommendations for the management of high-risk medications in health care organizations

The WHO and patient safety organizations emphasize the need for health care organizations to develop and implement programs to improve high-risk medication safety aimed at reducing errors at every stage of the medication use process.[3,8,16–25] These programs must be an organizational priority and be supported and led at the institutional level in order to convey their importance to the entire organization.

The organization's high-risk medication management program should be strengthened and expanded by taking into account the specific safety concerns associated with the pediatric population. This requires the engagement of pediatricians, pharmacists and other professionals involved in the care of this population, whose role is to develop initiatives that specifically target pediatric patients to be integrated in the general safety practices implemented by the organization and to ensure their implementation in clinical practice.

The measures that organizations need to take to develop a program to reduce errors involving high-risk medications are:

Table 1
High-risk medication list for pediatric patients.

Therapeutic classes
– Inotropic medications, IV *(e.g., digoxin, milrinone, levosimendan)*
– Adrenergic agonists, IV *(e.g., DOPamine, DOBUTamine, EPINephrine, PHENILephrine, isoprenaline, norepinephrine)*
– Anesthetic agents, general, inhaled and IV *(e.g., ketamine, propofol, sevoflurane, isoflurane)*
– Antiarrhythmics, IV *(e.g., adenosine, amiodarone, flecainide, lidocaine)*
– **Aminoglycoside antibiotics *(e.g., amikacin, gentamicin)***
– **Antivirals *(e.g., acyclovir, ganciclovir)***
– Oral anticoagulants *(e.g., acenocoumarol, dabigatran, rivaroxaban)*
– Anticonvulsants with narrow therapeutic range *(e.g., phenytoin, phenobarbital, valproic acid)*
– Antipsychotics *(e.g., chlorpromazine, haloperidol, risperidone, levomepromazine)*
– Beta blockers *(e.g., propranolol, carvedilol, esmolol, labetalol, etc.)*
– Benzodiazepines and analogues *(eg, clobazam, clonazepam, diazepam, zolpidem)*
– Neuromuscular blockers *(e.g., suxamethonium, rocuronium)*
– Cytostatic agents, parenteral and oral
– Loop diuretics *(e.g., furosemide)*
– Heparin and other parenteral anticoagulants *(e.g., sodium heparin, low-molecular-weight heparin)*
– Oral hypoglycemic agents *(e.g., gliBURIDE, liraglutide, metformin, semaglutide)*
– Direct thrombin inhibitors *(e.g., argatroban, bivalirudin)*
– Immunosuppressants *(e.g., ciclosporin, tacrolimus, mycophenolate)*
– Insulin, subcutaneous and IV
– Moderate and **minimal sedation** agents *(e.g., midazolam, ketamine, propofol, dexmedetomidine, chloral hydrate)*
– Epidural and intrathecal medications
– Parenteral nutrition
– Opioids, IV, transdermal and oral (all presentations)
– **Prostanoids, IV and inhaled**
– Cardioplegic solutions
– Hypertonic dextrose solutions (≥20%)
– Thrombolytics *(e.g., alteplase, urokinase)*
– Vasopressin and analogues *(e.g., desmopressin, terlipressin)*
Specific medications
– Liposomal amphotericin B
– **Calcium, IV (gluconate, chloride)**
– **Clonidine**
– Potassium chloride, IV (concentrate)
– Hypertonic sodium chloride solution (>0.9%)
– EPINephrine, IM and SC
– Potassium phosphates, IV
– Nitroprusside sodium, IV
– **Paracetamol, IV**
– Magnesium sulfate, IV
– **Vancomycin**

Abbreviations: IM, intramuscular; IV, intravenous; SC, subcutaneous.
High-risk medications specific to the pediatric population that are not included in the reference lists provided in the *Recommendations for the Safe Use of High-Risk Medications* document are indicated in bold.[8]

(1) Develop an organization-specific list of high-risk medications to prioritize in the implementation of safety practices

An organization-specific high-risk medication list for pediatric patients should be developed using the general high-risk medication list presented in the previous section as a reference and taking into consideration the characteristics of the pediatric population served. The list should include, at a minimum, the following medications which are deemed high priority for all patient groups, including both adult and pediatric patients:

– Anticoagulants, insulins, opioids, neuromuscular blockers, IV potassium, oral methotrexate (non-oncologic use) and cytostatic drugs (unless they are not used at the facility).

In addition, the following should be included specifically for pediatric patients:

– IV adrenergic agonists, aminoglycosides and vancomycin, medications used for moderate and minimal sedation, parenteral nutrition and IV paracetamol.

Additional medications from the general reference list may be included, taking into account the most serious incidents recorded in the specific organization or identified in medication and patient safety publications. A key consideration is that the list should not be too long to ensure the feasibility of implementing the necessary safety practices in the organizations, as a list in itself is of little value if the health care staff is unaware of its existence or is not accompanied by effective risk-reduction strategies.[16]

(2) Select and implement multiple safety practices at the various stages of the medication use process for each therapeutic class or specific medication included in the health care organization's high-risk list

Each organization must select and implement multiple general and specific safety practices (see section III) for each and every stage of the medication use process, aimed at reducing the incidence of errors associated with the use of medications included in its high-risk list. It is important to keep in mind that a single risk-reduction practice rarely suffices to prevent all possible incidents involving a high-risk medication.

The following recommendations should be taken into account in selecting safety practices for implementation:

- Safety practices should be implemented at every stage of the medication process (procurement, storage, prescribing, reviewing, dispensing, preparation, administration, monitoring, patient and caregiver education and care transitions) with engagement of all professionals involved.
- The "hierarchy of effectiveness" of error prevention practices should be taken into consideration (Fig. 1).[26] It is recommended to prioritize highly effective practices, such as those involving automation and/or the use of technology, constraints or computerized alerts, or moderately effective ones, such as standardization and simplification. These should be combined with less effective practices requiring health care professionals to adhere to rules, protocols or procedures to avoid errors or those that may rely on memorization.[26,27] It is important to note that improvement is more likely with the implementation of few but highly effective practices aimed at preventing the most frequent errors involving each high-risk medication compared to the implementation of a large number of less-effective practices.
- Ensure that error prevention does not rely solely on low-effectiveness practices, such as labeling the drawers or boxes containing high-risk medications or disseminating the organization's high-risk medication list or information on these medications.
- Limit the use of double-checking to specific critical points in the medication process and certain high-risk medications (*e.g.*, chemotherapy or opioid infusions).
- Consider the root causes and factors that increase the likelihood of errors in pediatric patients. For instance, given that errors in pediatric patients frequently result from the need to perform calculations to adjust the dose based on age and/or body weight, or to manipulate commercial presentations by splitting or diluting due to the unavailability of pediatric formulations, specific safe practices aimed at detecting and reducing errors at these critical steps should be selected.

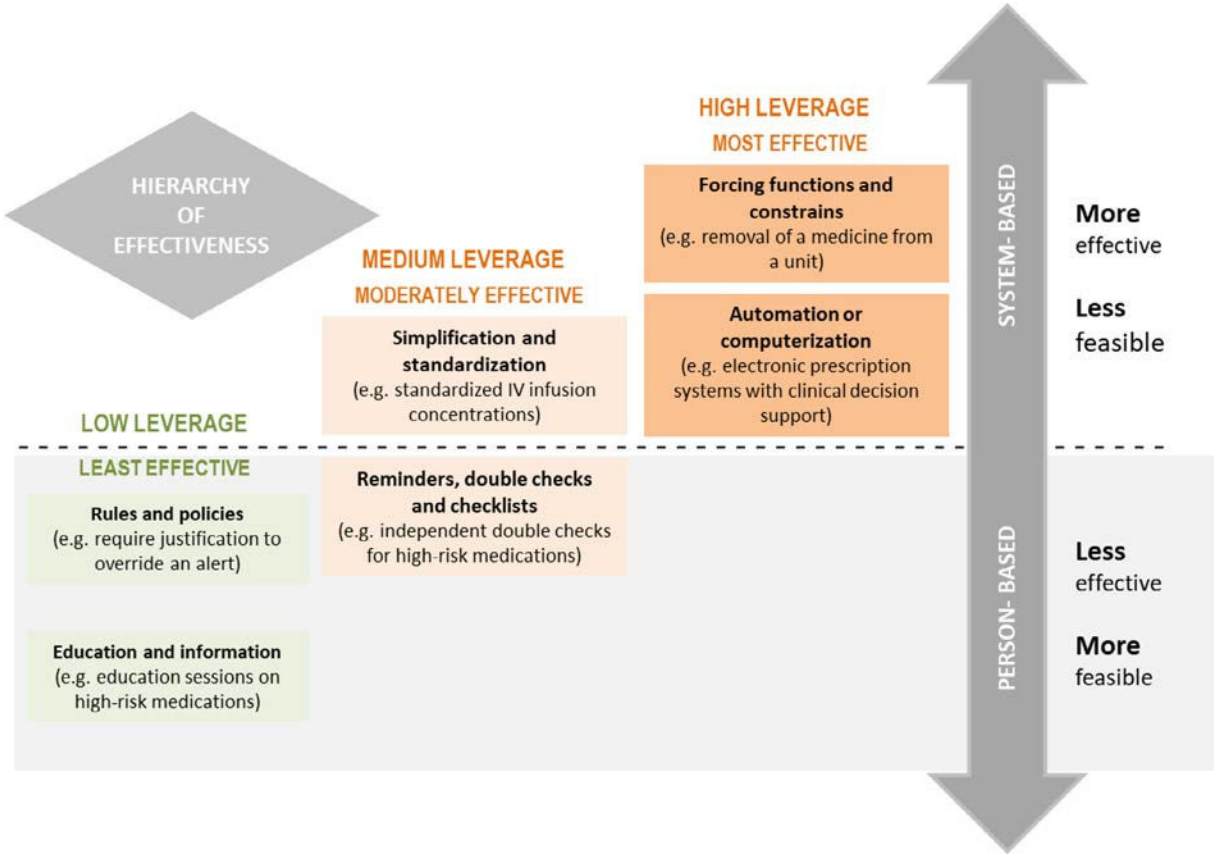

Fig. 1. Hierarchy of effectiveness of medication error prevention practices[26] (reproduced with the approval of ISMP-Canada). *The most effective practices are those involving systemic changes and that do not rely on memory, attention or human behavior, although their implementation is usually more complex. Medium-leverage practices reduce the probability of errors occurring. They are relatively quick and easy to implement, but they need constant reinforcement and updating. The least effective measures are those that are person-based. They are quicker and easier to implement, but they must be accompanied by other measures to achieve a safe system.*

Table 2
General safety practices to reduce errors involving high-risk medications in pediatrics.[3,4,8,20,22,28–39]

Throughout the medication use process
• Ensure that health care professionals can access essential patient information (such as age and weight), a complete and up-to-date medication history and laboratory results from their respective care settings to enable the appropriate use of high-risk medications. • Implement measures to facilitate the identification of high-risk medications, either through visual identifiers or electronic alerts: • For visual identification, use a symbol to mark high-risk medications in their storage locations (e.g., drawers) or in databases that contain information about medications. For medications classified as high-risk exclusively for pediatric patients, use a specific symbol (see Fig. 2). • Configure available technological tools to assist in the identification of high-risk medications. For example, include alerts in electronic prescribing or automated dispensing systems so that a warning is issued whenever a high-risk medication is being prescribed or dispensed. These alerts must be reviewed, validated and updated periodically to prevent "alert fatigue", a phenomenon that limits their effectiveness. • Have protocols for use and guidelines for the prescribing, preparation and administration of high-risk medications, which are accessible and known to health care professionals. • Establish independent double-check procedures at the most vulnerable points. If possible, integrate barcode-based automated verification systems for the preparation, dispensing and administration of these medications. • Ensure that professionals involved in the management of high-risk medications in pediatric patients have the necessary knowledge and skills through the implementation of a training and skill assessment program.
Selection and procurement
• Standardize and limit the number of dosage forms containing different doses, concentrations or volumes to be stocked in the facility. • Include specific technical criteria for pediatric patients when selecting/procuring medications (e.g., dose, concentration, administration devices adapted to the needs of pediatric patients, excipients, palatability). • Select, whenever possible, medications that do not have packaging or names similar to other medications already available in the facility, in order to avoid confusion. • To the extent allowed by electronic prescribing systems, when the medication formulary of the facility includes several presentations of a single active ingredient and dosage form, restrict those with the lowest doses to pediatric use.
Storage
• Review high-risk medications with look-alike names or packaging and implement several strategies to prevent mix-ups (e.g., barcode readers, tall man lettering, separate storage). • In pediatric care units or within general units where pediatric medications are stored, include the presentations with the lowest dose or concentration. • Mark the containers or bins used to store high-risk medications with the appropriate symbol. • In clinical units, ensure the availability of antidotes to reverse the toxicity of these medications, along with usage guidelines.
Prescribing
• Establish consensus-based prescribing protocols to minimize variability in the use of medications in the pediatric population. • Consult available genetic information from neonatal or antenatal screenings to identify patients genetically predisposed to serious adverse events associated with certain high-risk medications (e.g., the m.1555A > G mutation in mitochondrial gene MT-RNR1 to assess the susceptibility to aminoglycoside ototoxicity in neonates). • Confirm and document the patient's actual body weight in the health record before prescribing. • Include in the prescription the specific dose calculated for the patient in units of mass (e.g., mg) and the dose based on weight (e.g., mg/kg) or another index used for calculation (e.g., body surface area), to allow for subsequent verification. • Prescriptions for oral liquid medications to be administered at home by parents or caregivers may also include the dose expressed in terms of volume. In such cases, the volume must be expressed in milliliters or with the abbreviation "mL" (never using the abbreviation "cc"). • Verify that the weight-adjusted dose does not exceed the maximum recommended dose and in no case exceeds the maximum recommended dose for adult patients, especially in obese patients. • Implement an electronic prescribing system with clinical decision support that includes dose limits (based on age and weight) and provides alerts when potentially incorrect doses are prescribed. • Integrate additional alerts in electronic prescribing systems to warn of potential interactions, duplications, excipients contraindicated in neonates, etc. • When electronic prescribing is not available, use alternative electronic resources with predefined order sets to aid in prescribing high-risk medications in specific situations (e.g., critical patients, neonates) or in complex treatment regimens (e.g., antineoplastics). • In protocols and prescriptions (whether electronic or preprinted), express the dose and rate of IV infusions for high-risk medications using the same format (e.g., mg, mmol, mEq, mg/kg, mcg/kg/min) and sequence as those used in nursing administration records, labeling, and infusion pumps.
Reviewing/dispensing
• In hospitals, ensure that pharmaceutical reviewing of high-risk medication prescriptions is carried out before their dispensation and administration, except in life-threatening emergencies. • Whenever possible, implement barcoding technology to assist restocking of high-risk medications in automated dispensing systems.
Preparation
• Standardize and limit the concentrations of IV infusion solutions for high-risk medications used in pediatric patients. • Promote the centralized preparation in the hospital pharmacy of standardized parenteral solutions of high-risk medications that are not commercially available, except in the case of life-threatening emergencies. • In the pharmacy department, use available traceability technologies to verify the accurate compounding of high-risk medications (e.g., image-based quality control, gravimetric control, etc.). • In clinical units, emergency departments, etc., have protocols in place that standardize the preparation of high-risk medications, both parenteral and oral. • In clinical units, establish procedures to standardize and assist in the preparation of low doses from available formulations that require dilution prior to administration, especially for neonatal patients. These procedures should also avoid the reuse of single-dose injectable vials by ensuring any remaining contents are discarded after the first opening. • When preparing liquid medications to be administered by the oral or enteral route, use specific syringes that are physically incompatible with intravenous infusion systems. • Develop training programs for health care professionals to ensure the implementation of correct techniques in the preparation of parenteral medications for pediatric patients and assess their competence.
Administration
• Train and educate health care personnel in verifying, at least, the "five rights" (right patient, drug, dose, route and time) before administering any type of medication. • Whenever possible, implement a barcode scanning system to verify both the medication and the patient prior to administering high-risk medications. • Minimize interruptions during the preparation and administration of IV medication and/or infusion pump programming to reduce human errors resulting from distraction.

Table 2 (*continued*)

Throughout the medication use process
• Use smart infusion pumps with dose-error reduction software to administer parenteral high-risk medications. These pumps should include a standardized drug library specifically designed for pediatric use. • Keep the drug library updated and ensure that data are retrieved for performance of periodic quality controls. • Integrate smart infusion pumps with the electronic prescribing system and the electronic health record so that high-risk medication infusions are programmed directly at the time of prescription.
Monitoring
• Ensure that pediatric patients with complex chronic conditions receiving high-risk medications, as well as patients with oncohematologic diseases, undergo periodic reviews to assess the appropriateness of their pharmacological treatment.
Care transitions
• In hospitals, establish a procedure for medication reconciliation upon admission, during care transitions and at discharge, as well as for different care settings (emergency department, outpatient clinics, etc.), giving priority to patients whose treatment includes high-risk medications. • Inform patients and their families that they must not take any medications on their own during the hospital stay. Ensure that any medication exceptionally brought in by the patient for in-hospital use is stored in the nursing unit, prescribed by a physician, and administered and recorded by the nursing staff. • When a patient is transferred within the hospital, ensure that any changes in treatment are explicitly communicated to the next health care professionals involved, following safe handover protocols. • In primary care, implement a medication reconciliation procedure following hospital admissions, emergency visits, outpatient consultations, etc., giving priority to patients treated with high-risk medications. • The reconciliation procedure must include providing the patient/caregiver with an updated medication list reflecting any treatment changes and reviewing those changes with them to ensure understanding.
Education of patients and caregivers
• Inform patients or caregivers who are prescribed high-risk medications about the potential errors in their use and subsequent consequences that may occur, and provide them with the necessary resources to help them use the medication safely at home. • Help and encourage parents or caregivers to take an active role in treatment and to ask any questions they may have about the medication. Provide access to resources such as the *5 Moments for Medication Safety*.[40] • Educate and involve caregivers in storing medications out of the reach of pediatric patients to prevent situations such as accidental poisoning or self-harm attempts. • Explain to caregivers how to properly use high-risk medications that require complex preparation or administration, whether due to the need for prior manipulation (*e.g.*, extemporaneous suspensions), use of a device, or complex administration techniques (*e.g.*, autoinjectors). Whenever possible, provide written instructions. • For high-risk oral liquid medications, verify that caregivers know which device to use for measurement and how to dose them correctly to ensure the prescribed dose is administered. Explain that they must always use the provided device, as dosing errors can occur if other devices are used. • Train caregivers to collaborate in the safe use of medications, including identifying and reporting suspected adverse drug reactions.

It is important to emphasize that each center must define and adapt these safety practices according to its available processes, workflows, and technologies, and that it must carry out strategic reflection and planning with a view to both the functional and structural evolution of the organization.

(3) Include practices promoting active involvement of patients, family members and caregivers in the safe use of high-risk medications

Patients, parents and/or caregivers should be educated and informed about any prescribed high-risk medications and the possible errors and adverse effects that may occur. They should also be encouraged to take an active role in treatment and to ask any questions they may have about the medication. Special emphasis should be placed on the importance of proper storage to prevent accidental poisoning or misuse of these medications.

They should also be provided with written information and materials to help ensure safe use, in easily understandable language. To this end, it is recommended that original documents be used, preferably documents that are also available in electronic format and can not only be downloaded directly but also be integrated into electronic support, management, monitoring and educational resources. The recommendation document includes the information leaflet *10 Tips for Safely Administering Medication to Children*, developed specifically for parents and family members.[9]

(4) Disseminate the high-risk medication risk and established safety practices and train health care professionals

All professionals involved in the use of medicines should be informed of the list of high-risk medications and error-reduction practices. The following actions, among others, are recommended to this end:

- Designate specific staff to coordinate all the activities related to safety programs in pediatric care settings with the support and recognition of the management of the facility.
- Organize informational sessions or trainings to discuss the reasons for selecting the medications, medication errors and the harm to patients that could be prevented, as well as the importance of implementing each risk-reduction practice.
- Include a practical component in educational interventions, for instance, simulation-based learning, to train clinicians and care teams on the use of high-risk medications and early response to adverse drug events.
- Create incentives for reporting incidents involving high-risk medications, including medication errors and adverse drug reactions (for instance, by including them among the objectives and targets of the departments or units) so as to promote a safety culture among the health care staff.
- Promote multidisciplinary analysis of incidents occurring at the center and provide feedback on these incidents at regular intervals for learning purposes, including the measures adopted by the center.

(5) Monitor the implementation of safety practices and evaluate their effectiveness

Health care organizations must establish medication process and outcome indicators to monitor the implementation and to evaluate the effectiveness of established safety practices. Evaluations should be conducted at regular intervals to measure and analyze outcomes with the Risk Management Committee, the Pharmacy and Therapeutics Committee, and the center's management team.

Fig. 2. Recommended symbols to identify high-risk medications.

In this regard, it is advisable to monitor the actions undertaken at the center through periodic analysis of reported incidents.

Finally, it should be noted that safety management in healthcare centers must be a dynamic process. Therefore, organizations should regularly review and update their list of high-risk medications and established safe practices, taking into account the causes of errors involving these medications at their own facility, their healthcare activity, and published strategies for improving the use of high-risk medications.

Section III. Safety practices to reduce errors in the use of high-risk medications in pediatric care

The document presents a series of general safety practices applicable to all high-risk medications (Table 2).[3,4,8,20,22,28–39] These practices target each of the stages of the medication use process, from medication selection and procurement, through medication storage, prescribing, transcribing and reviewing, preparation, administration and monitoring to care transitions and patient and caregiver education. Although they focus on the safe use of high-risk medications in pediatric patients, many of them are also applicable to any type of medication or patient. (Fig. 2).

In addition to these recommendations, the full version of the document describes the most frequent errors and specific safety practices for the following high-risk therapeutic classes or medications: IV adrenergic agonists, aminoglycosides, oral anticoagulants, heparin and other parenteral anticoagulants, neuromuscular blockers, insulin, medications for minimal and moderate sedation, parenteral nutrition, opioids, methotrexate (non-oncologic use), IV paracetamol, IV potassium and vancomycin. Due to length constraints, we were unable to summarize this information in the present article, so we recommend consulting the full version of the document.[9]

Health care centers should implement specific pediatric practices combined with general practices to improve safety, bearing in mind the criteria presented in Section II and the characteristics of the patients and care settings of the center. In pediatric care, in particular, it is important to consider that certain subsets of patients, such as neonates, patients with complex chronic conditions, oncological patients and obese patients, and certain care settings, such as emergency departments, intensive care units, day hospitals, and hospital-at-home units, call for special considerations that are key to ensuring safe medication use.

In conclusion, safety in the use of high-risk medications in pediatric care is a crucial challenge that requires a comprehensive and multidisciplinary approach adapted to the specific characteristics of this vulnerable population. The development of programs for high-risk medication safety in health care organizations, with implementation of effective safety strategies at every stage of the medication process and promoting the education of health care professionals, patients and caregivers, is an essential step toward reducing medication errors and their adverse consequences. To succeed, this joint effort requires institutional commitment and ongoing evaluation of implemented interventions, thereby ensuring sustained improvement in pediatric patient safety and enhancing the safety culture of health care organizations.

Ethical considerations

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Declaration of competing interest

The authors have no conflicts of interest to declare.

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