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EDUCATIONAL REVIEW

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The German guidelines for medication safety in pediatric emergencies

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Abstract

Medication errors are a significant threat to the safety of patients of all ages. These errors are more common in children than in adults due to age-specific drug dosages, drug dilutions, and individual dose calculation based on body weight. In addition, it may be necessary to rapidly administer several potentially harmful or even life-threatening drugs during the emergency situation. It is not possible to provide specialized pediatric emergency teams for every prehospital or intrahospital emergency and technical resources are frequently not identical to those of a specialized facility further increasing the risk of medication errors. This narrative review of the German Guidelines for Medication Safety in Pediatric Emergencies introduces the main principles for medication safety in pediatric emergencies and the highlights its most important pragmatic measures and recommendations.

KEYWORDS
medication safety, pediatric emergencies, safety culture

1 | INTRODUCTION

Medication errors are among the most significant threats to patient safety with an estimated 7000 deaths in adults per year in the United States alone.[1] Risks associated with injectable medications are ranked #1 among the five most significant safety issues in medicine ("High5s") by the World Health Organization (WHO) during its 2007 global campaign.[2] The situation is of considerably more concern in pediatric emergencies with appalling incidences and devastating outcomes.

One principle contributing factor for the increased risk is the requirement for individual drug dose calculation in children. Tenfold calculation errors are easily made and may prove fatal. One example is dosing epinephrine for resuscitation or anaphylaxis.[3,4]

Due to the wide range of pediatric body weights (newborns weighing less than 3 kg to obese adolescents weighing in excess of 100 kg), familiarity with a "typical" dose similar to adult practice is not achievable.[5] In addition, multiple doses can be taken from a single vial in children, further reducing the possibility of detecting and preventing a serious administration error in smaller children. Serious dosing errors, therefore, are not very obvious or immediately noticed as "unusual." Further, pediatric emergencies are commonly attended by staff with limited pediatric experience.[6]

Drug dosing errors were documented to be as high as one in three administrations of any drug and in 60% of epinephrine in prehospital care by Emergency Medical Teams (EMT).[7] The average error of recorded overdoses of epinephrine was 808% from the recommended dose and is life-threatening. Another study of

The Expert Group coordinated by the German "Association of the Scientific Medical Societies (AWMF)" members are listed under the Appendix A section.

prehospital emergencies in Germany showed a deviation of the recommended dose (DRD) of greater than 300% in 22% of all drug administrations. All epinephrine administrations were above this 3-fold deviation, with an average of 882% of DRD.[8] Moreover, even a specialized pediatric emergency department with appropriate expertise and trained staff, reported a tenfold error in 1 in 32 administrations during simulated resuscitation scenarios.[9] This further highlights, that children are at risk of harm from medication errors in prehospital and clinical environments.

Case report: The Emergency Medical Team was called to an 8-month-old infant at home, who was found lifeless in his bed by his parents. Bag-mask ventilation was successful, and peripheral pulses were palpable during chest compressions. An intraosseous needle was successfully inserted, and three doses of 2 mg of epinephrine were given. The child died. The emergency medical protocol did not provide the infant's body weight. A forensic pathology inquiry reported a measured weight of 8 kg.

2 | METHODS OF GUIDELINE DEVELOPMENT

The *German Society for Pediatric and Adolescent Medicine* (DGKJ) initiated a Guideline Project with participation of 15 medical societies, medical professional associations, and patient representatives,[†] with the aim to improve medication safety in pediatric emergencies. This was formally further endorsed by the *Association of the Scientific Medical Societies in Germany* (AWMF). During an initial web-based meeting, a group of 22 experts, mandated by their respective societies, agreed to develop a consensus-based guideline. A previously published guideline[10] and systematic review on medication safety in pediatric anesthesia[11] as well as pediatric emergencies[12] demonstrated that the majority of reasonable and pragmatic recommendations were not evidence-based. Therefore, the expert group agreed that a formal expert consensus was the most appropriate approach. A thorough, but nonsystematic search for evidence was performed by this expert group.

This following narrative review of the German Guidelines for Medication Safety in Pediatric Emergencies introduces the main principles for medication safety in pediatric emergencies and highlights its most important pragmatic measures and recommendations. The guidelines reached full consensus by the whole expert group, have formally been approved by all participating professional societies (partly after an additional external peer-review process), and were published in March 2021 on the homepage of *Association of the Scientific Medical Societies in Germany* (AWMF).[13] For ease of access, the exact translation of the consensus guideline is provided in the Appendix A.

3 | INDIVIDUAL AND INSTITUTIONAL SAFETY CULTURE

The above reported case description was reported in an interventional trial on medication safety in pediatric emergencies.[8] Successful ventilation, palpable pulses, and a vascular access should aid the resuscitation of an infant, if survival is possible. However, three epinephrine boluses of 250 μg/kg, instead of 10 μg/kg that would have been the recommended dose for resuscitation,[6] proved fatal far exceeding the 100 μg/kg threshold reportedly leading to death.[3,4]

It is not sufficient to agree with the general principle "To err is human" but every single practitioner must accept the very own fallibility, regardless of education, rank, or experience. Evidence suggests that some medical providers are more enthusiastic about safety issues than others, and acceptance of personal susceptibility for errors also varies.[14] Seniority may contribute to overestimation of one's own capabilities and may lead to reduced awareness of individual fallibility.[15–17] Seniority can also reduce the ability of others to challenge errors and voice their concerns because of hierarchical barriers.[18] Seniority is not a burden per se because knowledge and experience of the practitioner can contribute to better medication safety. This superior knowledge and experience must be shared with younger personnel through teaching and supervision. Every health care provider is responsible for vigilance and adherence to safety while senior staff have additional responsibilities toward supporting the institutional safety structures and the error prevention culture.

Standard operating procedures (SOPs), checklists, and tables help to standardize processes and make critical pharmacotherapy information visible for the entire team. Regular simulations including such aids will improve their adherence and competence of the team. Users must be granted the opportunity to initiate reasonable modifications and optimizations of safety structures.[11] Each medical facility should establish a "living" safety and error prevention culture. Nonblaming critical incident reporting as well as morbidity and mortality meetings should be implemented. Every team member should cocheck every medication and have the opportunity to express doubts at any time even in a strict hierarchical structure ("speaking up").

†Professional Association of Pediatricians and Adolescents e. V. (BVKJ), Professional Association of Pediatric Nurses Germany e.V. (BeKD), Federal Association of Medical Directors of Rescue Services Germany e.V. (BV-ÄLRD), Federal Association of the Working Groups of Emergency Physicians Germany e.V. (BAND), German Society for General and Visceral Surgery e.V. (DGAV), German Society for Anesthesiology and Intensive Care Medicine e.V. (DGAI), German Society for Specialist Nursing and Functional Services e.V. (DGF), German Society for Interdisciplinary Emergency and Acute Medicine e.V. (DGINA), German Society for Pediatric and Adolescent Medicine e.V. (DGKJ), German Society for Pediatric Surgery e.V. (DGKCH), German Interdisciplinary Association for Intensive Care and Emergency Medicine e.V. (DIVI), German Foundation for Acute and Emergency Medicine gGmbH (DSAN), German Professional Association of Rescue Services e.V. (DBRD), Society for Neonatology and Pediatric Intensive Care Medicine e.V. (GNPI), Children's Network e.V. (KNW); e.V. = Registered Association; GmbH = limited liability company.

NOTE Acceptance of fallibility by all members of the health care team is critical for improved patient safety. No personal blame should be assigned when reporting errors.

4 | THE IMPORTANCE OF THE CHILD'S BODY WEIGHT AND ESTIMATION METHODS

The case presented emphasizes the importance of the body weight to be known for treatment and in prehospital pediatric emergency care. Only 0.5% of all emergency physician protocols in a German study documented the body weight of children who had received intravenous medication.[8] This was partially due to the fact that, until recently, the nationwide emergency physician protocols did not universally offer an entry field to document the body weight. This was rectified along with other measures 10 years ago, when the documentation rate rose to 30% with an overall reduction of severe dosing errors by 55% and by 78% for epinephrine.[19]

NOTE Actual or height-related estimation of the body weight is critical for medication safety in pediatric emergencies.

Parental reported weight should be used, otherwise, height-related estimations are better than age-related estimations[20] with appropriate systems available.[6] Obesity can cause drug overdose if the total body weight is used for drug calculations. The doses of drugs with a narrow therapeutic range and big impact on vital functions should be calculated using the average weight for height. Height-related weight estimation have the advantage of estimating the average weight for any given height. This had the added benefit of being a reasonable approximation of the "ideal" weight, which is used preferentially for emergency medications, but difficult to calculate. It is recommended to use a height-based system for weight estimation that simultaneously offers weight-related drug doses.[6]

5 | PREVENTION OF DRUG OVERDOSING

Drug overdosing is especially hazardous in prehospital emergencies as resources, equipment, and expertise are limited. Apart from accidental overdoses, several situations can lead to medication errors. A nonchild-friendly environment exacerbates provider and patient agitation and anxiety and may lead to attempts to sedate a child. An extreme example is the "preemptive intubation" for transport in challenging conditions such as a helicopter transfer and may result in severe harm or death if complications occur. This can in some cases be mitigated by parental presence to decrease situational stress and avoid the administration of sedatives.

Children with severe respiratory compromise, limited muscle strength, or serious neurological impairments are at high risk of critical complications. In general, medications that potentially impact vital functions mandate close monitoring of vital signs using pulse oximetry and an electrocardiogram. It may be safer in difficult situations with a rapidly deteriorating patient to limit the drug treatment and transport the child to a more appropriate pediatric facility as expeditiously as possible. This recommendation must not be misinterpreted as an invitation to omit life-saving measures but rather as an encouragement to explore other available options and supportive measures under the given circumstances. It is important in general and even more in such cases to document what is done or what is omitted and why. The assumed clinical diagnosis, initial treatment, the rationale and decision for safe transfer, and telephonic contact with reference center if this had taken place must be recorded.

NOTE Sometimes, "doing as little as possible" might be the best option ("primum non nocere").

6 | CALCULATIONS

Generally, the weight-related drug dosages are rarely directly comparable with adults and often also change significantly during growth. For example, neonates and young toddlers have a larger fraction of total body water and require larger amounts of hydrophilic drugs in relation to bodyweight in order to achieve comparable plasma concentrations. In addition, hepatic and renal drug clearances are often lower in neonates compared to older infants and children, which affects duration of drug action.

The caregiver must reliably be able to determine the correct drug dosage for each individual patient. To facilitate such information, a tabular compilation of data from pediatric formularies is recommended. The individual weight-related calculation is the most error-prone step during emergency medication administration and may lead to harm. However, other simple measures that reduce the cognitive requirements by supporting or replacing calculations (like the "Pediatric Emergency Ruler") are also effective to reduce the frequency and the severity of such errors.[8,12,17,19]

NOTE Potentially harmful medications must never be given without prior verification by a cognitive aid.

7 | PREPARATION

Drug dilution is a source of errors and contamination and should be avoided, whenever possible. Most drugs can be given undiluted using

a 1-ml syringe (with 0.01 ml markings) and effective rinsing with normal saline. The smallest precise volume to be administered with such a syringe is probably 0.05 ml or even better 0.1 ml. When this is not possible due to the weight of the patient, commercially or "in house (pharmacy)" prediluted "ready-to-use" syringes should be used. In the absence of these critical preparations and if dilution is inevitable, clear preparation instructions must be provided. The intended target dilutions must enable simple further calculations (e.g., 1, 10, or 100 units per ml). The target syringe containing the medication must immediately be labeled to conform with International Organization for Standardization (www.iso.org, ISO standard: 26825), and indicate the drug concentration and visible syringe markings. The person preparing the syringe should not be distracted during his or her work.

8 | ADMINISTRATION

5-R rule **Right patient?**
Right medication?
Right dose?
Right time?
Right route?

Prior to every drug administration, every staff member involved in drug administration must verify that the 5-R rules are met. A brief pause prior to injection ("stop-check-inject") should be routine, even if the experienced staff is familiar with the current medical situation and administering a "harmless" drug. The person in charge of the treatment should state the name of the drug and the dose intended, the person in charge of administration repeats the name, the dose, and the amount to be injected. It is critical to recognize that cognitive fatigue must be avoided, and such "drills" must correspond to the threat of the individual situation. These pauses can be short in "safe situations," if an experienced staff is familiar with the current medical situation administering a harmless drug. For drugs with potential harm such as epinephrine for resuscitation, this check but must be performed in full extension and also the patient's weight, dosage per kg, total dose calculated, concentration of the preparation, and amount to be given should be stated.

NOTE Only after all team members have verified the information ("closed-loop communication"), a medication with potential harm should be administered.

This pause takes only seconds with no or negligible cost or delay but improves safety. It is recognized that even such a small step may be opposed by some staff members. The experts group recommends small initial steps involving few staff members to implement this culture change and convince others. This small but essential step before each drug administration reminds every single staff of the importance of drug safety. It contributes to the increase of vigilance, which is fundamental for any drug safety initiative.

9 | ARRANGEMENT AND STORAGE OF MEDICATIONS

Medication mix-ups occur when drug names sound similar, ampoules look alike, or syringes are not clearly labeled. This is exacerbated when drugs are stored close to each other. If at all possible, similar sounding or similar looking drugs should be avoided or, at least, be kept distinctly separated and clearly marked. Following the same principles, storing different concentrations of drugs and drugs with or without additives in close proximity should be avoided if and whenever possible.

10 | OFF-LABEL-USE IN PEDIATRICS

Despite continuing national and international efforts, a large number of critical drugs in pediatrics have no formal legislative approval and are used "off-label." This applies even to drugs with longstanding clinical use and with scientific evidence, demonstrating their effectiveness and safety in children. Such "off-label" drugs are commonly the first choice in certain indications and patient groups. Therefore, the guidelines expert group considered it essential to issue a clear statement on "off-label use" in pediatric emergency medicine.

Therapy decisions must be based on scientific evidence and experience and not depend on the administrative authorization status alone. An "off-label use" is neither improper, illegal nor contraindicated, but may represent the best possible therapy in children.

NOTE Avoiding "off-label" drugs may put children at risk and prevent effective and appropriate treatment.

Nevertheless, the "off-label" use of drugs in children should be addressed with parents as soon as possible, usually after the emergency treatment, and with legislative bodies through key medical societies. The above given statement is supported by the key medical societies responsible for pediatric emergency medicine in Germany. However, those who administer emergency medication to children and adolescents, especially for "off-label" use, must maintain their and constantly and keep up-to-date with the safety notices.

11 | REFLECTIVE QUESTIONS

- Is all information required for safe medication of children of all ages readily available at my work place?

- Do we have supportive aids for quick and safe determination of the correct dose available and are we trained to use them?
- Has our institution established routine protocols and benchmarked measurements to improve medication safety during pediatric emergencies (e.g., "stop-check-inject," "closed-loop communication," and "speaking up")?
- How can we improve medication safety in pediatric emergencies in our institution?

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CONFLICT OF INTEREST

Jost Kaufmann holds a Europe-wide registered design-patent for the "Pediatric emergency Ruler – PaedER" (OHIM No 002909382–001). He currently has no licensing arrangements and receives no royalties from this patent. During the discussion moderated by AWMF at the formal consensus conference, the conflict of interest was classified as low. Mr. Kaufmann abstained from voting on the corresponding recommendations. All other authors declare that they have no conflict of interests.

DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article as no new data were created or analyzed in this educational review.

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APPENDIX A

In alphabetical order: Sebastian Bittner, Prof. Dr. Christoph Eich, Frank Flake, Priv.-Doz. Dr. med. Florian Hoffmann, Prof. Dr. med. Karl-Peter Ittner, Dr. med. Phillip Jung, Dr. Tobias Klein, Marco K. König, Dr. med. Martin Krebs, Dr. Reinhold Merbs, Dr. Annette Mund, Prof. Dr. rer. nat. Ante Neubert, Dr. med. Hubert Radinger, Prof. Dr. med. Wolfgang Rascher, Julia Rebbert, Dr. med. Florian Reifferscheid, Bianka Rösner, Prof. Dr. med. Robert Schwab, Lothar Ullrich, Prof. Dr. med. Johannes Winning.

Exact translation of the entire recommendations of the guidelines "Medication safety in pediatric emergencies" by the German Society for Pediatric and Adolescent Medicine (DGKJ) under participation of 15 medical societies, medical professional associations, and patient representatives, which was formally supervised by the Association of the Scientific Medical Societies in Germany (AWMF; S2k-level, Reg-Nr. 027–071). The group of 22 experts

formally designated by their societies agreed to all those rules with 100% consent.

1 Clear indication, age-specific contraindications, underlying disease-related aspects, avoid overtreatment

- The indication should be questioned and checked before each therapy.
- The potential positive effect of the reassuring influence of a caregiver should be exploited as far as possible.
- Whenever possible, child-friendly positioning and child-friendly interactions should be used.
- Age group-specific dosages should be known and can be reassured/quested at any time.
- Children should be cared for in a thermoregulatory neutral environment.
- Sedatives and opioids should be dosed at average weight for height in children with significant obesity.
- Drugs with low distribution volume and low therapeutic range should be dosed at average weight for height in children with significant obesity.
- Non-nutritive sucking should be allowed whenever possible for calming.
- Only when other therapeutic measures are inadequate, sedatives and opioids should be used.
- "Overtreatment" should be avoided (as less as possible and as much as necessary).

2 Children at special risk for respiratory depression

- Opioids and sedatives should be dosed cautiously.
- Children should be monitored closely and thoroughly (pulse oximetry and electrocardiogram).
- The practitioner should reliably be able to perform all escalation levels of airway management (noninvasive and invasive airway management).
- Inexperienced practitioners should consider single dose intranasal/buccal administration and avoid intravenous administration of opioids and sedatives and allow rapid takeover by experienced practitioners in pediatric intensive care or emergency medicine.

3 Cognitive aids, weight estimation, length-related systems

- Emergency medications should be prescribed with knowledge and use of pediatric pharmacologic references or cognitive aids.
- Prior to any drug therapy, the child's weight should be determined and documented.
- If weighing is not possible, the weight should be asked from the parents or from the child himself ("Do you know your child's weight is?" or "Do you know what your weight is?").
- If no named weight is available, a length-based weight estimate should be performed.
- The use of age-related formulas may only be considered if the above superior options are not available.

4 Calculation of the dose and preparation. **CPOE = computerized physician order entry.*

- The weight-related dose to be administered be determined under use of a supportive system (e.g., chart, rulers, CPOE*).
- Administration of drugs that have a narrow therapeutic range or can cause great harm if dosed incorrectly (e.g., epinephrine, analgesics) should NOT be done without prior verification by a supportive system (e.g., table, rulers).
- Length-based systems for weight estimation with dose recommendation should be preferred, especially in prehospital care.
- In case of own calculation of dose, this should be supported by electronical calculators.
- The supporting system used (table, rulers, CPOE*) should be known by the physician in charge and regularly be trained.

5 Prescription, transmission of the prescription

- The drug dosage recommendation should be taken from the producer's information or, in case of off-label use, from sources including the latest scientifically research.
- The team leader should direct the team's attention to drug application in case of emergency (high-risk therapy).
- Verbal prescriptions should have a clear structure, be unambiguous and complete, and be documented in writing as soon as possible; whenever possible, prescriptions should be primarily in writing.
- Each prescription should be repeated aloud and confirmed by all involved.
- Medication should only be administered when all team members have signaled agreement ("closed-loop" communication) or have confirmed that everything is correct.
- Closed-loop communication should be shortened or extended depending on routine and risk (case-sensitive).
- Employees should actively provide feedback, because every team member should have a recognizable influence on required safety measures.

6 Preparation and administration - mix-ups, storage location

- The stocking of similar sounding trade names and similar looking ampoules/packaging should be avoided.
- Medications should be stored in a unique and known location.
- Changes in storage location, appearance, and trade names should be promptly and reliably communicated to all employees, for example, using a warning sign at the storage location.
- When possible, medications with potential hazards should be separated to enforce conscious "reaching for it."

- Dissolving and drawing up medications should be done immediately prior to administration according to the manufacturer's instructions, without contamination, and with compatible solvent solutions.
- Dilutions should be avoided wherever practical and appropriate. The use of sufficiently small syringes (1 and 2 ml) is recommended.
- Adequate flushing should follow each drug administration.
- Infusion lines should be short, thin, and kink-free, and the point of injection should be chosen close to the patient.
- There should be a standardized procedure for preparing medications, using the four-eyes principle if possible.
- The person preparing the syringe should NOT be distracted during his or her work.
- Each drawn up syringe should preferably have a label according to ISO 26852 affixed longitudinally in such a way that the scaling remains legible.
- If labels are not available, syringes should be clearly and non-wipeable identified by other means.
- Preference should be given to pharmaceutically prefilled syringes ("ready-to-use syringes").
- For i.m. application, only the dose to be administered should be drawn up in a syringe.

7 Quality assurance, critical incident reporting system (CIRS), speaking up

- Health care providers in charge of vital threatening pediatric emergencies should be experienced, less experienced should be provided supervision.
- Regular training on medication safety, medication errors, AND pediatric pharmacology should be conducted (e.g.,, once a year).
- With the knowledge of the prescribers, a control of the prescriptions by experienced persons (e.g., four-eyes principle) and a feedback to the prescribers should be provided.
- Each care structure should establish a living safety and error culture.
- Every team member should have the opportunity to express doubts about orders at any time ("speaking up").
- Each care area should have standards of care (e.g., standard operating procedures, standard operating procedures) and constantly update them.
- The nontechnical skills and content of standards of care should be trained (e.g., simulation training).
- Each medication administration should be communicated clearly and cohesively.