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Improving Pediatric Drug Safety in Prehospital Emergency Care—10 Years on

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Objectives: The Pediatric Emergency Ruler (PaedER) is a height-based drug dose recommendation tool that was reported to reduce life-threatening medication errors by 90%. The PaedER was introduced into the Cologne Emergency Medical Service (EMS) in 2008 along with educational measures, publications, and lectures for pediatric drug safety. We reviewed the impact of these continuously ongoing measures on medication errors after 10 years.

Methods: The PaedER was introduced and distributed to all 14 emergency ambulances and 2 helicopters staffed with emergency physicians in the city of Cologne in November 2008. Electronic records and medical protocols of the Cologne EMS over two 20-month periods from March 2007 to October 2008 and March 2018 to October 2019 data sets were retrieved. The administered doses of either intravenous, intraosseous, intranasal, or buccal fentanyl, midazolam, ketamine, or epinephrine were recorded. Primary outcome measure was the rate of severe drug dosing errors with a deviation from the recommended dose of greater than 300%.

Results: A total of 59 and 443 drug administrations were analyzed for 2007/08 and 2018/19, respectively. The overall rate of drug dosing errors decreased from 22.0% to 9.9% ($P = 0.014$; relative risk reduction, 55%). Four of 5 severe dosing errors for epinephrine were avoided ($P < 0.021$; relative risk reduction, 78%). Documentation of patient's weight increased from 3.2% in 2007/08 to 30.5% in 2018/19 ($P < 0.001$).

Conclusions: The distribution of the PaedER combined by educational measures significantly reduced the rates of life-threatening medication errors in a large EMS. Those results should motivate further initiatives on pediatric drug safety in prehospital emergency care.

Key Words: pediatric drug safety, pediatric emergency care, medication errors, prehospital care

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Medication errors—especially with injectable drugs—are a major source of morbidity and mortality in adults and children and recognized by the World Health Organization in their "High 5s Project" for global patient safety.[1] Children with medical emergencies are particularly vulnerable to medication errors because of the need for individual drug dosing calculations and the lack of a familiarity with a "typical dose."[2] Most paramedics participating in a survey reported to be "very uncomfortable" with their ability to administer a drug dose to an infant.[3] High drug error rates during real preclinical pediatric emergencies are reported.[4] A recent trial reported high medication error rates also in simulated scenarios,[5] with a 10-fold error with epinephrine for resuscitation likely precluding patient survival.[6] Hence, life-threatening drug dosing errors are common in pediatric emergencies, and improvements are desperately needed.[7]

After 3 years of development, we introduced the height-based dose recommendation tool Pediatric Emergency Ruler (PaedER; Alpha 1 Werbedesign e.K., Falkenberg, Germany) into clinical practice in November 2008.[8] In the United States, the Broselow Pediatric Emergency Tape (Armstrong Medical Industries, Inc, Lincolnshire, IL) is a widely used comparable device, but this is neither available nor licensed for the European market. In addition, the major advantage of the PaedER compared with the Broselow Tape is that it provides all information about normal physiological values, size of equipment, preparation of the drugs, and recommended doses on the device itself, with no accompanying booklets to look up for details.

We conducted a pre-post interventional study in real-life prehospital pediatric emergencies to assess the impact of the PaedER on the correct administration of drug doses with emphasis on life-threatening medication errors.[8] When the PaedER was used in the postinterventional group with federal statewide prospective recruitment between 2010 and 2015, 9 of 10 cases with deviations of the recommended dose (DRD) of greater than 300% (<33% or >300% of the recommended dose) of all observed medications (midazolam, fentanyl, ketamine, and epinephrine) were prevented. Subsequently, a prospective randomized controlled trial was considered unethical because of the expected positive impact of the PaedER necessitating a retrospective control group of all electronic data sets and medical protocols of all children (<18 years) who were treated by Cologne Emergency Medical Service (EMS) during a 20-month period from March 2007 to October 2008.

A potential limitation of this prior study was a selection and reporting bias with only enthusiastic emergency physicians with a special interest in drug safety in pediatric emergencies participating in the postinterventional prospective recruitment. Simultaneously, we also introduced and, since then, have continuously maintained multiple educational and training measures for pediatric drug safety for the Cologne EMS. We re-examined the impact of those educational measures in combination with the PaedER after 10 years using the identical method over an identical period focusing severe drug errors (DRD > 300%) in prehospital care.

METHODS

We conducted a pre-post interventional study in prehospital pediatric emergencies to assess the impact of multiple measures over a period of 10 years on the correct administration of drug doses with emphasis on life-threatening medication errors. All doses of the investigated drugs were evaluated as percentage with respect to the recommended dose (defined in Table 2). Primary outcome was the rate of errors with respect to the medications fentanyl, ketamine/esketamine, midazolam, or epinephrine. Deviation from the recommended dose of greater than 20% (<80% or >120% of the recommended dose) were classified as errors and of greater than 300% (<33% or >300% of the recommended dose) as life-threatening errors.

Intervention: Additional measures for pediatric drug safety introduced and maintained since 2008 are as follows:

1) We developed the PaedER, a height-based dose recommendation tool that was registered as medical product and certificated by a notified body of the European Union in 2008 as described elsewhere.[8] The PaedER is made of durable plastic with a sterilizable surface in the manner of a wide folding ruler. After analyzing the decelerating proportional weight gain related to the absolute length gain of children, optimal segments on the PaedER were chosen under support of a medical statistician. While placing the unfolded ruler next to a supine child (Fig. 1), at the segment positioned next to the tip of the head, all information about normal values for weight, intubation material, and weight-adjusted doses for emergency drugs is provided with no further calculation steps required. The PaedER was distributed to all 14 emergency ambulances and 2 emergency rescue helicopters staffed with an emergency physician of the Fire Department, Center of Emergency Medicine, City of Cologne, Germany. Every member of EMS in cologne was instructed on how to use the PaedER by emergency physicians without a formal special certification. During the years 2010–2015, a prospective federal statewide evaluation was conducted and published in 2016.[8]
2) We have added a field for specifying the weight into the standardized EMS protocol sheets.
3) Before their first preclinical assignments, all emergency physicians of the Cologne EMS undergo training and have to pass a final exam. The included curriculum has been expanded with patient safety and lessons on pediatric drug safety since 2008. In addition, regular continuing medical education courses on this topic were held for the Cologne EMS staff.
4) We since published an evidence-based guideline,[9] 2 systematic reviews,[2,10] 2 clinical studies,[8,11] 2 editorials[7,12] and 22 narrative reviews or book chapters on the topic of pediatric medication safety.[a] In addition, between 2008 and 2018 we gave numerous invited lectures on all relevant congresses, symposia, and continuous medical education courses on this topic in Germany.

Data Collection and Statistical Analysis

Identical to the PaedER trial from March 2007 to October 2008, a complete record of all children (<18 years) who were treated by the Cologne EMS from March 2018 to October 2019 was obtained by screening of the electronical emergency records and collection and review of the associated medical protocols. All medical information was transferred into an electronical spreadsheet by 1 person (E.S.) and verified (J.K.), both staff of the Cologne EMS. Weights documented in the medical record provided by the EMS were used, if available. Missing patient's weights were retrieved from hospital records and the subsequent data set fully anonymized. In both cases, the source of the weight

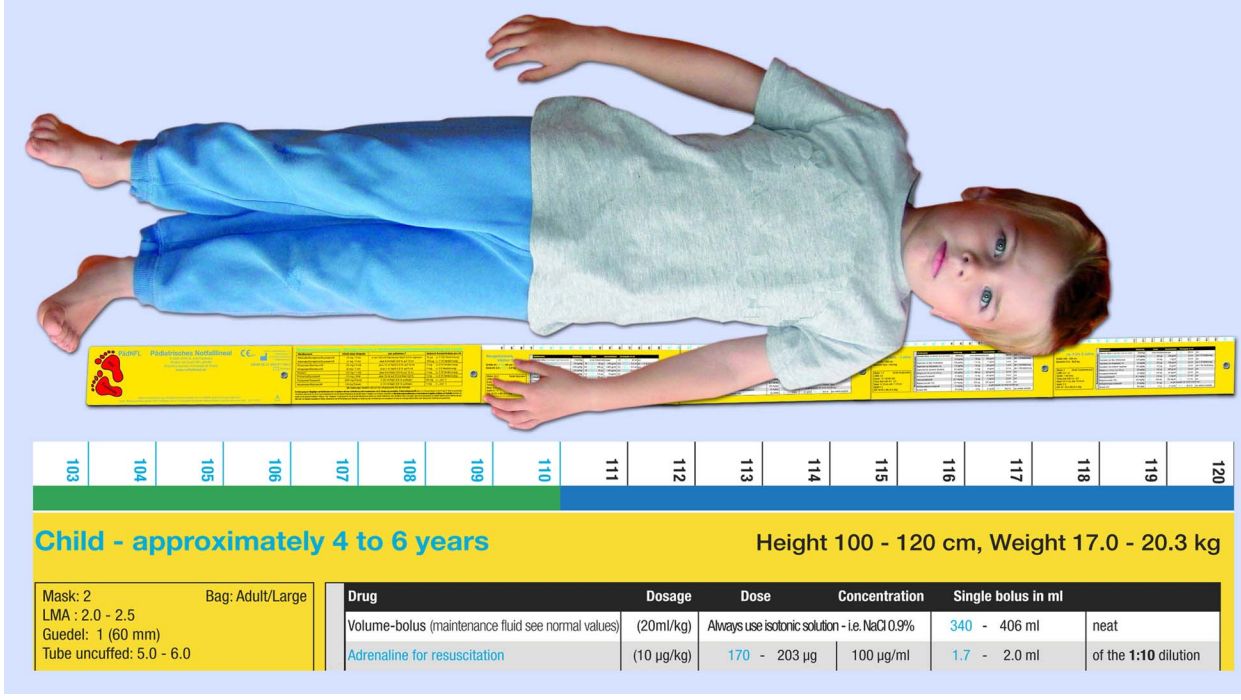

FIGURE 1. Illustration for the use of the PaedER. The supine child is measured with the unfolded ruler from the heel over the straightened leg to the head, where the height is displayed. Normal values for age, size to tracheal tubes, and weight-adjusted doses for the emergency drugs are provided at the head end. The lower part of the figure contains a translated excerpt from the table.

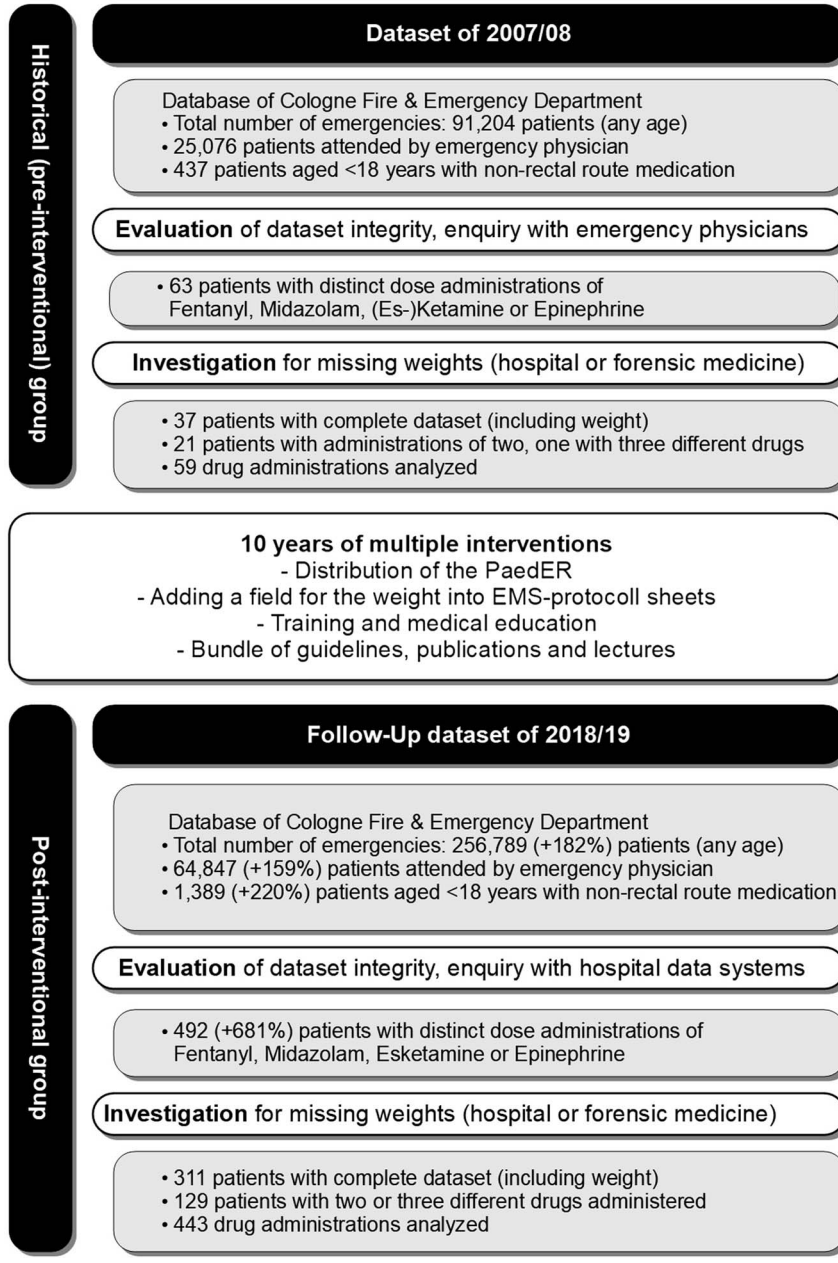

FIGURE 2. Study flow chart (PaedER).

specification was not further defined and, for example, could have been given by the parents or estimated by the health care providers using the PaedER (Fig. 2). Qualitative data were summarized by count and percentage, quantitative data by mean (standard deviation) or median (minimum to maximum), contingent on apparent skewness. Differences concerning demographic data were evaluated by 2-sample *t* test. Group differences between rates of drug deviations were evaluated by 2-tailed Fisher exact test and for significant differences regarding a DRD of greater than 300%, the relative risk reduction (RRR) with 95% confidence interval (CI) was calculated. If repeated administrations of the same drug were documented in the same patient, only the initial dose was included. When a patient received different drugs, each of the drug was analyzed separately. Analyses were performed using SPSS 21 (IBM Corp, Armonk, NY) and Stata/SE 12.1 (StataCorp LP, College Station, TX).

[a][1] *Deutsches Ärzteblatt*. 2010;107:A873. [2] *Anästh Intensivmed*. 2011;52:S570. [3] *Refresher Course der DAAF*. 2011;37:217–227. [4] *Qualitätsmanagement im Gesundheitswesen*. Köln: TÜV Media GmbH; 2012:1–25. [5] *Notfallmedizin up2-date*. 2012;7: 17–27. [6] *Anaesth Intensivmed*. 2012;53:254–267. [7] *Refresher Course der DAAF*. 2012;38:163–170. [8] *Der Anaesthesist*. 2013;62:143–145. [9] *Anaesth Intensivmed*. 2013;54:286–294. [10] *Rettungsdienst*. 2013;36:956–961. [11] *Monatsschr Kinderheilkd*. 2015;163:107. [12] *Anaesth Intensivmed*. 2015;56:S575. [13] *Notfall Kompakt*. Leverkusen; 2015:103–113. [14] *Intensiv- und Notfallbehandlung*. 2015;40:2–10. [15] *Der Allgemeinarzt*. 2015;37:16–20. [16] *Notfall + Rettungsmedizin*. 2016;19:221–223. [17] *Päd-Praktische Pädiatrie*. 2016;22:142–148. [18] *Monatsschrift Kinderheilkunde*. 2017;165:171–181. [19] *Der Anaesthesist*. 2017;66:340–346. [20] *Journal für Anästhesie und Intensivbehandlung*. 2018:63–66. [21] *Jahrbuch Intensivmedizin 2019*. Lengerich: Pabst Science Publishers; 2018:409–417. [22] *Refresher Course der DAAF*. 2018;44:299–311.

Ethical Issues

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional ethics committee and with the 1964 Helsinki Declaration and its later amendments. The chairman of the ethics committee of the University of Witten/Herdecke (Prof Dr P.W. Gaidzik, December 2019) waived a formal ethical approval, because data collection and investigation for missing weights were solely performed by staff of the Cologne EMS or the admitting hospitals, which are subject to national data protection laws. As requested by the ethics committee, all data enabling the identification of a person were deleted once reviewed and verified.

RESULTS

The EMS of the City of Cologne, the fourth largest town in Germany with 1.1 million inhabitants, treated more than 91,000 emergency cases in patients of all ages during 20 months from March 2007 to October 2008 (Table 1). This number had risen to more than 256,000 until the 20-month period from March 2018 to October 2019 with those cases attended by an emergency physician increasing from 25,000 to almost 65,000. Of those physician-attended cases in 2007/08, 1.7% (437 patients) were children receiving any medication via a nonrectal or inhalational route. The study period 2018/19 saw an increase to 2.2% (1398 patients). Administered study medications in children increased from 0.25% (63 patients) to 0.76% (492 patients).

TABLE 1. Number of Cases During the 20-Month Observation Period at EMS of the City of Cologne and Demographic Data of the Cases Eligible for Further Analysis

	2007/08	2018/19	Difference, Significance
Total emergency cases	91,204	256,789	+182%
a) Cases with attending physician	25,076	64,847	+159%
b) Children with medication	437	1398	+220%
In relation to a	1.7%	2.2%	+24%
c) Children with study medication	63	492	$P < 0.001$*
In relation to a	0.25%	0.76%	+202%
Weight in medical record	2	150	$P < 0.001$*
In relation to c	3.2%	30.5%	+860%
Weight received from hospital	35	161	
In relation to c	55.6%	32.7%	−41%
d) Weight known in total	37	311	$P < 0.492$*
In relation to c	58.7%	63.2%	+7%
d) With 1 medication	15	182	
d) With ≥2 medications	22	129	
Total drug administrations, n	59	443	
Cases evaluated, see d	37	311	
Sex, f/m	16/21	117/194	*P = 0.592**
Age, mean ± SD, y	8.3 ± 4.5	9.5 ± 5.1	*P = 0.052*†
Age, min/max, y	0.7/17.9	0.0/17.8	
Weight, mean ± SD, kg	31.5 ± 17.6	36.8 ± 23.1	*P = 0.290*†
Weight, min/max, kg	8.0/80.0	1.6/160.0	

P values in italic are nonsignificant.

*Significance by 2-tailed Fisher exact test.

†Significance by 2-tailed 2-sample *t* test.

f, female; m, male; min, minimum; max, maximum.

Although only 2 children (3.2% of all eligible patients) had a weight documented on their prehospital medical record in 2007/08, this rate was almost 9 times higher in 2018/19. After adding the weights reported by hospitals, a comparable portion of all patients met inclusion weight criteria for further analysis (Table 1). The demographic data of both groups were comparable. Intranasal or buccal drug administration was not performed in 2008 but noticeable 2018/19, especially for fentanyl and midazolam (Table 2).

Between both periods of 2007/08 and 2018/19, the overall rate of drug dosing errors in the category of a DRD of greater than 300% decreased from 22.0% to 9.9% (RRR, 55%, CI, 21%–74%; $P = 0.005$). This effect was primarily seen for fentanyl (RRR, 94%, CI, 76%–98%; $P < 0.001$) but also for epinephrine. Almost 4 of 5 severe drug errors with epinephrine were prevented in 2018/19 (RRR, 78%; CI, 25%–93%; $P = 0.016$).

DISCUSSION

The introduction of the PaedER and multiple educational measures and activities over the past decade has more than half the rate of life-threatening medication errors with all monitored medications and prevented 4 of 5 life-threatening errors with epinephrine administration. Although a DRD of greater than 20% is commonly used as a description of a drug dose error,[13] such deviations rarely cause harm especially for analgesic and sedative drugs. Individual titration resulting in higher doses than what a responsible initial dose recommendation proposes is frequently required to achieve the intended effect. The observed rates of greater than 63% with a DRD of greater than 20% for midazolam and ketamine at both time points may not present a direct threat to patient safety. In contrast, a DRD of greater than 300% with the potentially respiratory depressant opioid fentanyl is likely to result in harm. The observed reduction by more than 90% of a DRD of greater than 300% errors with fentanyl can be considered clinically significant. This effect is beyond doubt for epinephrine where a DRD of greater than 300% is clearly beyond the recommendations for patients of any age, and all international guidelines explicitly caution against such doses.[14,15]

The most widely used EMS protocol in Germany is the one recommended by German Interdisciplinary Association for Intensive Care and Emergency Medicine and does not contain a field for the patients' weight until now.[16] By adding a field for the patients' weight into the EMS protocol sheet in Cologne, we increased the focus on identifying and considering the children's weight and, therefore, automatically increased the vigilance on the issue of drug dosing. As a result, emergency physicians documented the weight of children almost 9 times more often when administering drugs.

The observed increase of study medications administered was over proportional to all medications. This was, at least in part, attributable to the newer routes of administration (intranasal and buccal), which had not been used in 2007/08 but represents almost one third of all midazolam and fentanyl administrations in 2018/19. The possibility of easily feasible and safe drug administrations via the nasal route may have lowered the threshold to treat a child. Subsequently, fentanyl was used in 15% of all analyzed drug administrations in 2007/08 and increased to 24% one decade later. This and the relevant increased dosing accuracy indicate that more emergency physicians feel safe and comfortable to treat a child with fentanyl in the prehospital setting. As a limitation of this trial, we were unable to acknowledge the use of the PaedER in individual cases because there was no formal directive from the employer on its mandatory use. Based on the results presented here, authorities

TABLE 2. Drug Doses as Deviations From the Recommended Dose

	2007/08	2018/19	*P**
All drugs, n	59	443	
Dose, mean (range)	364% (20–2500)	109% (7–1000)	
DRD >20%, n/%	42/71.2%	302/68.2%	0.766
DRD >300%, n/%	13/22.0%	44/9.9%	**0.014**
	RRR = 55%, CI = 21%–74%, $P = 0.005$		
Midazolam, fentanyl, ketamine, n	55	434	
Dose, mean (range)	151% (20–682)	108% (7–667)	
DRD >20%, n/%	38/69.1%	297/68.4%	1.000
DRD >300%, n/%	9/16.4%	42/9.7%	0.156
Epinephrine, n	4	9	
Dose, mean (range)	882% (28–2500)	182% (13–1000)	
DRD >20%, n/%	4/100%	5/55.6%	0.228
DRD >300%, n/%	4/100%	2/22.2%	**0.021**
	RRR = 78%, CI = 25%–93%, $P = 0.016$		
Midazolam, n	27	206	
Buccal administrations	0	28/13.6%	
Nasal administrations	0	29/14.1%	
Dose, mean (range)	107% (20–333)	106% (16–615)	
DRD >20%, n/%	17/63%	157/76.2%	0.159
DRD >300%, n/%	4/15%	28/13.6%	0.772
Fentanyl, n	9	108	
Nasal administrations	0	32/29.6%	
Dose, mean (range)	340% (78–682)	121% (34–667)	
DRD >20%, n/%	9/100%	62/57.4%	**0.011**
DRD >300%, n/%	4/44.4%	3/2.8%	**<0.001**
	RRR = 94%, CI = 76–98%, $P < 0.001$		
Ketamine, n	19	120	
Nasal administrations	0	13/10.8%	
Dose, mean (range)	125% (45–476)	99% (7–400)	
DRD >20%, n/%	12/63.2%	78/65.0%	1.000
DRD >300%, n/%	1/5.3%	11/9.2%	1.000

Relative risk reduction is provided, when 2-tailed Fisher exact test was significant. All drug doses are presented as percentage of the recommended dose (intravenous or intraosseous administration): epinephrine for resuscitation/anaphylaxis 10 μg/kg; midazolam 0.05 mg/kg as sedative, 0.1 mg/kg for anesthesia, nasal application 0.1 mg/kg an buccal 0.3 mg/kg; fentanyl 1 μg/kg as analgesic and 2 μg/kg for anesthesia, nasal application 1.5 μg/kg; ketamine 0.5 mg/kg as analgesic and 1 mg/kg for anesthesia; esketamine 0.25 mg/kg as analgesic and 0.5 mg/kg for anesthesia, nasal application 1 mg/kg.

P values in boldface are significant.

*Two-tailed Fisher exact test.

might issue a formal instruction on the consistent use of PaedER in all pediatric emergencies.

Most of the available trials evaluating drug safety measures in pediatric emergencies used simulated scenarios. In general, those include a relevant bias because they are not able to reproduce the unpredictable circumstances and locations of real-life scenarios. In addition, participants improve their performance just because of their awareness of being observed (Hawthorne effect).[17] Moreover, study designs relying solely on self-reporting, like the Anaesthesia PRactice In Children Observational Trial[18] monitoring complications in pediatric anesthesia, introduce a selection bias. Although this trial was not primarily focusing on medication errors, the reported incidence of 1 drug error per 635 pediatric anesthesia patients is far lower from findings by external observation with 1 error in every second adult patient.[19]

Taking the previously mentioned limitations of most trials into account, the major strength of our trial is fully covering real-life cases of two 20-month periods without the EMS teams being aware of study participation. In addition, error detection did not use self-reporting but external scrutiny. Therefore, our data offer an unbiased view into real-life drug dosing accuracy during preclinical pediatric emergencies. Although stronger effects would be desirable, the reduction of life-threatening medication errors for fentanyl and epinephrine represent a relevant improvement of safety in emergency care of children in daily practice. In addition to the decrease in observed error rates, the vast increase in children with a documented weight in their preclinical medical records emphasizes a shift in vigilance for drug safety issues over the observed decade. This is encouraging news and motivating to extend and further develop this and other initiatives for pediatric drug safety.

Many simple measures—like the use of a weight-related dosing table[20]—are known to reduce drug dosing errors.[2] Nevertheless, no single intervention or range of interventions can provide complete drug safety and fully eliminate medication errors.[10] Even the strictest code of conduct is limited by human factors, whereas even simple tasks, such as reading a drug or dose, may result in erroneous action. In addition, a constant optimal vigilance of every

health care provider in all cases is unattainable with the resilience of every individual human. In addition, the enthusiasm for safety and the acceptance of one's own fallibility are individual and should be addressed in all concepts for patient safety. A pragmatic and prioritized approach was described in our educational activities, publications, and recommendations and focused on high-risk drugs, such as epinephrine, and the main human factors, such as acceptance of fallibility and vigilance for drug safety.

CONCLUSIONS

This study demonstrated that a relevant impact on pediatric drug safety in preclinical emergencies can be achieved with the introduction and maintenance of safety measures. Although there is still a need to further reduce rates of threatening drug dosing errors, the observed halving of a DRD of greater than 300% over all studied medications and elimination of such errors in 4 of 5 cases for the administration of epinephrine is encouraging. This study will therefore motivate to develop and extent pediatric drug safety initiatives. All initiatives must prioritize high-risk drugs and recognize principle human factors, such as the acceptance of fallibility and vigilance for drug safety. The use of aiding devices supporting the drug dosing safety in pediatric emergencies should be considered to become mandatory for all EMS providers.

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