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Pediatric Anaphylaxis: Minimizing Dosing Error with Epinephrine

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Abstract:

The incidence of life threatening emergencies in children comprises a small portion of all medical emergencies yet failure to appropriately manage them has profound consequences to these patients, their families and the health care providers charged with their care. Pediatric anaphylaxis occurs most often in the youngest children who are the most vulnerable to a medication dosing error. Anaphylaxis requires swift and accurate administration of epinephrine; however, as exposure to this true pediatric emergency is not a routine occurrence, healthcare systems are under-practiced and underprepared to handle it. Experts in pediatric care have called for system improvements to prevent pediatric medication errors. In accordance with pediatric medication safety initiatives, one novel approach has been the application of pediatric color-coding and indication-based labeling to medication syringes. Incorporation of this labeling system directly to pediatric devices effectively prevents critical dosing errors at the point of administration.

Pediatric Medication Error

Unsafe medication practices and medication errors are universal targets for reducing preventable harm in health care systems. Compared with adults, children are at three-fold increased risk of a medication error due to their small size and weight based prescriptions. Of medication errors in pediatrics, medication dosing errors are the primary source of error.[1] These vulnerable patients and their families may suffer life-long physical, emotional, and economic harm as a result. The second victims of these errors are the well-meaning healthcare professionals who must live with social, psychological and pecuniary ramifications[2] potentially resulting in the end of otherwise exemplary careers.[3] The cost of medication errors is great.[4, 5] The World Health Organization (WHO) estimates the global burden of medication error at $42 billion annually.[6] Lawsuits and liability claims can result in considerable financial losses for healthcare systems.

Pediatric emergencies: Uncommon and Unfamiliar

The 2015 National Hospital Ambulatory Care Survey (NHACS) reported only 19.8% of emergency department (ED) visits are for children under the age of 15. Of those, only 4.8% were triaged as “immediate” or “emergent.” This means less than 1% of cases seen in EDs are critically ill children. If practice makes perfect, using a body of knowledge and skills less than 1% of the time cannot foster confidence and is a breeding ground for error.

Children are known to be at higher risk for medical error, yet general clinicians and facilities are the least prepared to care for them. Approximately 90% of ED visits for children are seen outside children’s hospitals, yet only 10% of EDs across the country have a separate ED for pediatrics.[7] Only 1 in 10 pediatric ED visits are to those staffed with physicians sub specialty trained in pediatrics or pediatric emergency medicine. Together, this indicates that 90% of pediatric patients presenting to EDs are cared for in community or general medicine EDs by clinicians likely to be minimally trained to care for children and with variable experience after formal training.[8]

The pre-hospital paramedic and EMT also lack sufficient training and exposure to pediatric emergency care.[9-12] During formal education, pediatrics encompasses only a small portion of overall training; and indeed in a 2017 survey, 58% of paramedic respondents thought their initial training did not include enough training in pediatrics.[13] Of the pediatric visits reported in the 2015 NHACS report, only 4.7% of those age < 15 years arrived by ambulance; and accordingly, less than 1% of those would require administration of life saving medications given the same immediate or emergent triage criteria. In a large survey of ambulance calls in a 4 state region, children comprised only 4% of patients. With only 14% of those receiving

any ALS treatment, this equates to less than 0.6% of pediatrics getting ALS intervention with only a fraction being a dose of medication.[11] This is consistent with another study that reported pediatric patients requiring medications were only 0.16% of ambulance responses. Of the respondents, less than 1/3 of the paramedics had delivered a medication to a pediatric patient during the 2 year period observed.[14]

Pediatrics emergencies in the ED and in the pre-hospital setting are uncommon and general care providers are unlikely to be practiced or confident in dosing medications during pediatric emergencies.

Pediatric Anaphylaxis:

The highest rates of anaphylaxis are in children. Food-induced pediatric anaphylaxis related emergencies are on the rise in the United States with a 2018 study by Motosue et al reporting a 214% increase in ED visits.[15] That study, European registries, and a meta-analysis confirm the highest rates of pediatric anaphylaxis are in the youngest children.[16, 17] Fatal anaphylaxis is rare. France reported 43 cases of anaphylaxis related deaths during a 35 year period.[18] Childhood deaths associated with anaphylaxis were reported at 0.3% of all cases in the United States.[19]

How good are we at treating it?

Treatment of pediatric anaphylaxis is often delayed or undertreated despite meeting clinical criteria. When clinicians do treat, errant doses of epinephrine have been discovered. As pediatric anaphylaxis is a small portion of reported emergencies, robust data on treatment is not available. However, a study of pediatric anaphylaxis managed in a pediatric emergency department revealed 15% of epinephrine doses erred by more than 10%.[20] In simulated pediatric anaphylaxis, 54% of EMS crews incorrectly administered epinephrine. 20% gave a $\geq$5 fold overdose and 14% gave it the wrong route.[21]

Dosing error is pervasive across health care settings

In hospital and emergency department medication errors are well documented with the most errors in dosing and or the wrong route. [20, 22-26] From ambulatory care to inpatient facilities, including pediatric hospitals and neonatal intensive care units, dosing error has been found

in 11% up to 82% of administrations with 10-fold dosing errors shown to occur 8% of the time.[27-33] Decades of research has implicated calculation errors as direct contributors to many of these errors.[34-37] In the emergency department, dosing errors have been reported in up to 39% of doses with 16% of those errors having the potential for harm.[38-40] In the pre-hospital setting, clinical, classroom and simulation data published on the incidence of error reveals paramedics commit dosing errors 49–63% of the time with miscalculation as a primary cause.[12, 14, 21, 37, 41-51] Calculation is an error prone process, but even a 10-fold dosing error can occur because a simple calculation error places the decimal point in the wrong place.[52]

Emergencies are high hazard environments where cognitive load is elevated and time for decision making and performance is condensed.

Medication Errors: Underreported and Undetected

The true breadth of medication error is likely underreported as most reporting systems are voluntary and reporting of an error can only take place if it is detected. In one study, 21%-56% of healthcare providers reported making no error in the previous year.[42] In a study of paramedics, only 9.1% reported making a medication error.[43] The confidence shown by healthcare providers is discordant with the rates of errors found in the literature. Rowe reported in 2 cohorts, 60% and 95% of inappropriate doses were missed by pediatric resident physicians.[53] Errors in pediatric doses may not be detected at the time of care as small differences used in dosing children are not visually obvious.[54, 55] Many dosing errors may go undetected and or unreported because they simply didn't result in any harm. However, if healthcare providers report making no errors despite the well documented rates of error, this lack of awareness indicates a significant number of medication errors go undetected and pose an implicit danger to patients.

Healthcare providers can be unfamiliar visualizing variable weight-based doses for children and therefore fail to recognize error.

Calls for Help

Over a decade ago, the Institute of Medicine's Committee on the Future of Emergency Care in the United States Health System called upon Department of Health and Human Services and the National Highway Traffic Safety Administration to fund medication dosing, formulation, labeling and administration techniques to maximize safety of all children in the emergency care setting.[56] Clinicians and healthcare providers place a high priority on developing simplified methods that eliminate dose calculation to reduce dosing error in children.[13, 57, 58] Healthcare facilities have been called upon to place indication-based labels on manufactured epinephrine products in crash carts and pharmaceutical companies to commercially manufacture medications standardized for use in infants and children.[12, 70]

Healthcare providers want systems of delivering medications that eliminate calculations, utilize indication based labeling and use standardized medications for use in neonates, infants and children.

What have we done?

Strategies employed to reduce harm from pediatric medication errors include electronic prescription entry with decision support, medication reconciliation, barcode medication tracking, clinical pharmacists present in patient care areas, mandatory double checking policies, improved training of medical staff, package changes to standardize labeling, and color coding (i.e. Broselow-Luten Universal Pediatric Color Coding system, HandTevy[59], etc). Patient safety initiatives have been implemented, yet the problem of medication errors persists.[55, 60]

National data show the youngest children have the highest incidence of anaphylaxis, yet there are few options in the community for providing an optimal epinephrine dose for first-line treatment despite recommendations for infants to receive their exact weight based dose.[61-63] When using color-coded systems, predetermined weight-dose charts, or calculating doses, systems still recommend a second provider verify correct dose.

The independent double check (IDC) has been touted as best practice in pediatrics to detect a high risk medication error prior to the point of administration.[64] Its intention is for two clinicians to separately check each step of the medication use procedure. Each must do this in isolation--a distraction free environment—and without bias from another provider. Only then do the two come together to compare. When done correctly, IDC is time consuming and requires qualified, available and competent personnel.

Are Independent Double Checks Effective in Emergencies?

IDC policies are not without their limitations. An IDC of a pediatric dose may not be practical in an emergency as this process can take up to 20 minutes.[65] As levels of training and competency vary widely in providers who are innately fallible, the IDC process relies on two imperfect people with the assumption neither will make the same cognitive and/or procedural mistake. Add time compression during a pediatric emergency in healthcare systems that are routinely understaffed and operate in an overburdened environment, the IDC becomes far less effective as the requirement will not be completed as intended—or not at all.

Non-adherence to Independent Double Checks

Multi-tasking, staffing shortages and interruptions from healthcare team members are contributing dynamics in healthcare systems and can distract from the process of calculating, preparing and delivering medication.[66] As many as 90% of nurses report distractions during medication preparation; and while the American Academy of Pediatrics recommends IDC of high risk medications, these checks occur only 30% to 2/3 of the time.[67, 68]

Current strategies are not universally present at the bedside during emergencies and some are impractical outside the hospital environment. Paramedics have been shown to have a high rate of medication dosing error. They are often self reliant as the highest medical authority or working within a team environment—without another independent, qualified colleague to adequately perform the IDC. In an emergency, a double check is likely to be cursory and habitual rather than a valid independent check.[69] With a child in the midst of life threatening anaphylaxis, the provider at the patient's side lacks a method of self-verification that is simple and effective.

Pediatric specific medication administration systems need a simple, quick double check for confirming pediatric dosing at the point of administration.

Color Coding for Dose Confirmation

Color-coding systems were introduced to assist clinicians by reducing cognitive load during management of pediatric emergencies.[59, 70-73] These color coding systems are used to confirm or determine equipment size and proper medication dosing in pediatrics; and, have found their way into current standards of care used in the fire service, emergency medical services and emergency rooms.

Elimination of Severe Dosing Errors

Applying a color coding system directly to syringes has been studied in clinical simulations of pediatric resuscitation. Use of this approach resulted in an overall reduction in dosing errors (Figures 1 and 2) and elimination of critical dosing errors (Figure 3). Using the conventional system in the ED based simulation of pediatric intubation and cardiac arrest, 9 out of 10 nurse-physician teams made at least 1 critical dosing error; and of all doses given, 17% were defined as critical dosing errors. A similar study was conducted with paramedics managing pediatric cardiac arrest in the back of an ambulance. 8 of the 10 paramedics administered at least 1 dose critically deviating from expected; and overall, 39% of all doses given were defined as critical dosing errors. In both studies, the magnitude of the errors was reported and included repeated 10-fold overdoses (Figure 3).

Figure 1: ED Dosing Error: Standard (Left) Color-Coded Syringes (Right)

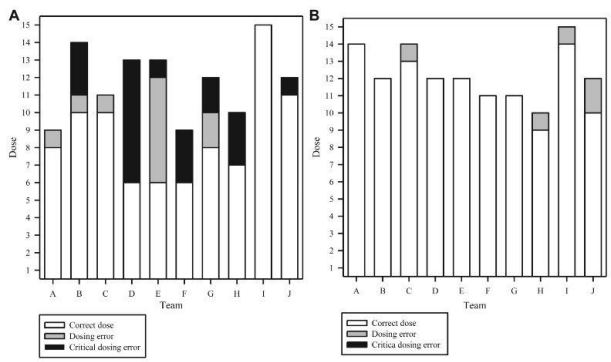
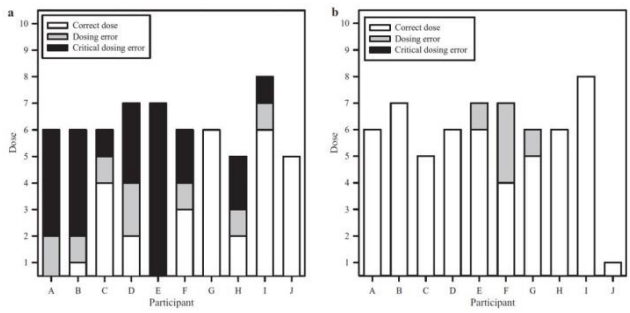
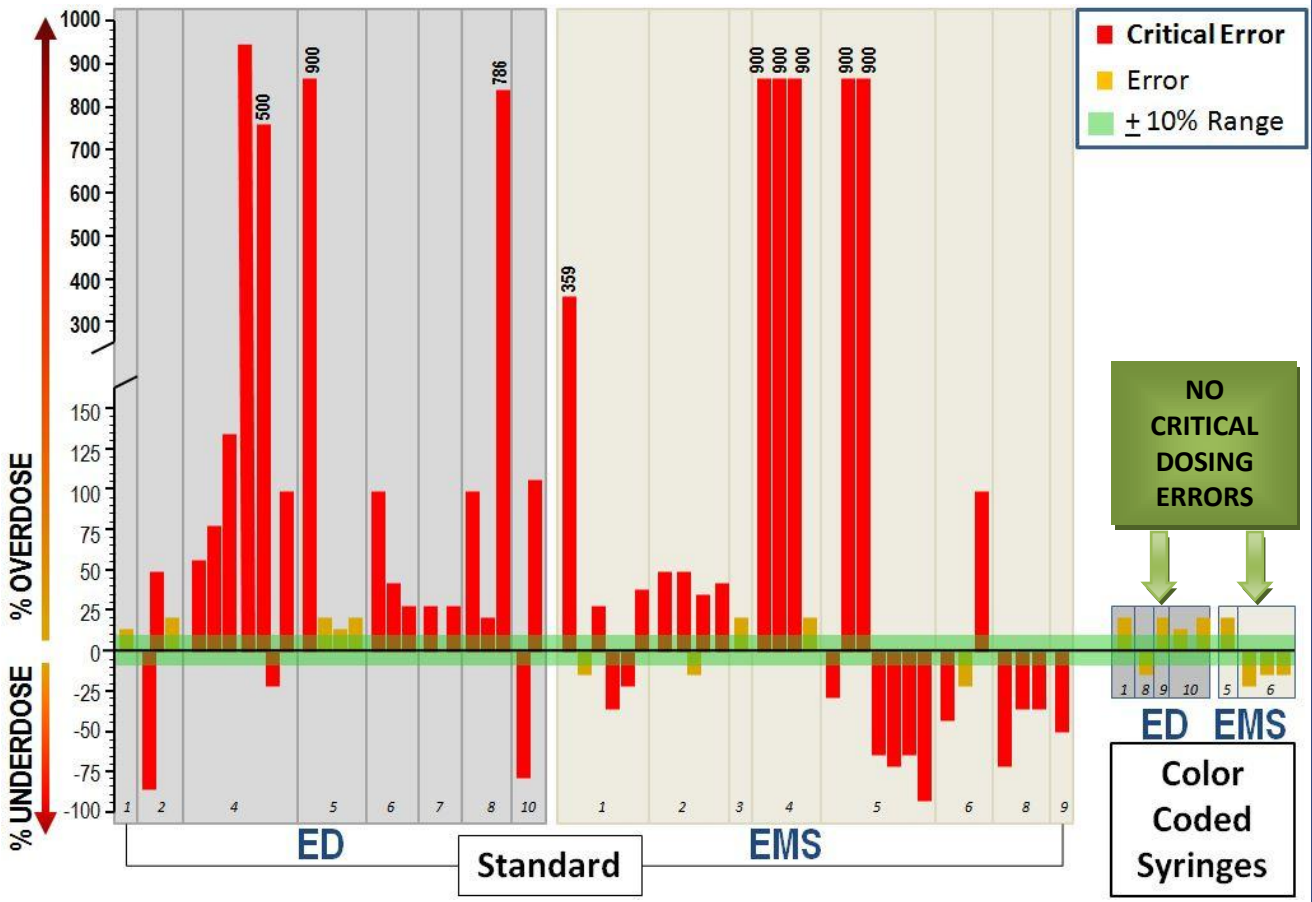


Figure 2: EMS Dosing Error: Standard (Left) Color-Coded Syringes (Right)



When the same participants in both studies utilized syringes with a color-coding system applied directly to the syringe, **critical dosing errors were eliminated**.[74, 75]

Figure 3: Magnitude of Dosing Errors: Standard/Conventional Methods (Left) versus Color-Coded Syringes (Right)

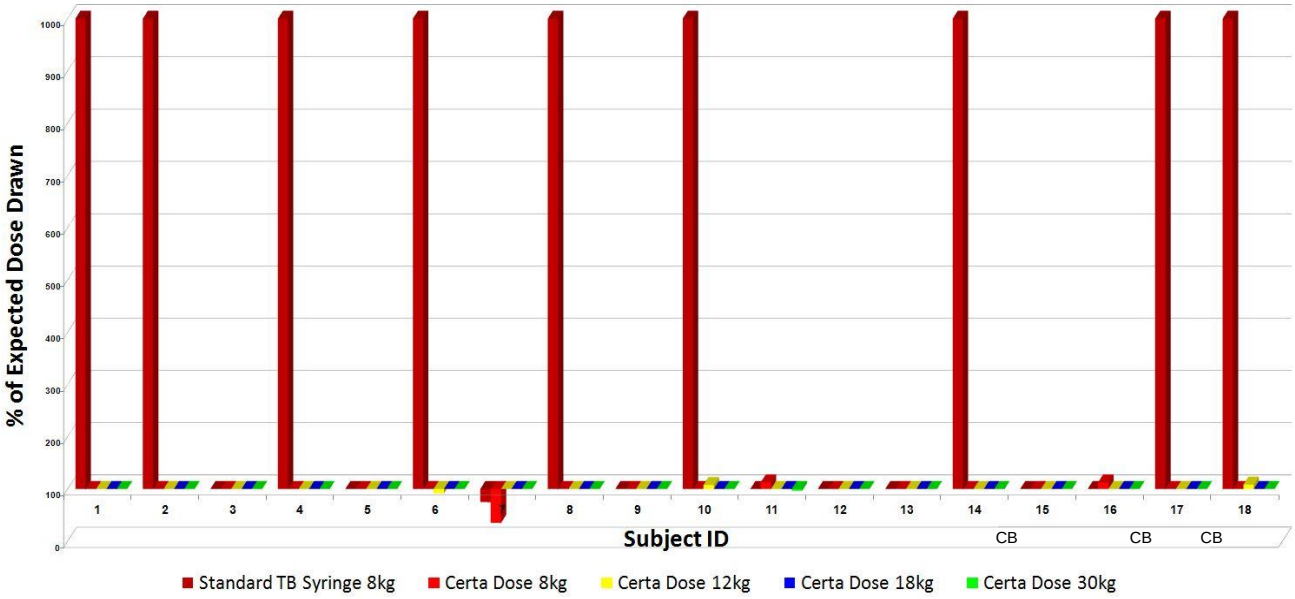


High reliability organizations prioritize safety by seeking out and implementing safety promoting characteristics within their systems.[76]

A human factors validation study evaluated the Certa Dose Pediatric Epinephrine syringe in a mixed user group of 18 representative users experienced in giving emergency injections to pediatric patients. The group consisted of physicians, nurses, paramedics and an EMT. 3 participants were colorblind. Data was collected on their ability to draw correct doses of epinephrine into the CD PD Epi Syringe for 4 different doses for weights across color zones. Using the standard 1 mL TB syringe, 50% of the draws were 10 fold overdoses which is consistent with published data.

When using the CD PD Epi Syringe there were no clinically significant dosing errors.

Figure 4: Comparison of Standard of Care to the Certa Dose Epinephrine Epinephrine Syringe



SUMMARY:

Pediatric patients are at higher risk of medication errors and entities must continuously pursue system improvements to achieve global pediatric patient safety initiatives.

Pediatric emergencies are uncommon and the general medical community is underprepared to consistently and confidently administer medications to children. Despite implementation of computerized reconciliation and policies for independent double-checks of medications, prescriptions and doses, system improvements are still needed in high hazard environments such as emergency rooms, neonatal units and pre-hospital emergency medical services. Current risk reduction strategies are not universally present at the bedside and some are impractical outside the hospital environment.

Color-coding systems on syringes have been proven to eliminate critical dose deviations in the preparation and administration of medications in pediatrics. The Certa Dose Pediatric Epinephrine (CD PD Epi) Syringe is designed to be used in pediatric anaphylaxis and supports users in safely, accurately and effectively dosing and administering epinephrine doses for neonates, infants, toddlers, children and adolescents.

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