



<http://dx.doi.org/10.1016/j.jemermed.2012.11.069>

Administration of Emergency Medicine

MEDICATION ERRORS IN THE MANAGEMENT OF ANAPHYLAXIS IN A PEDIATRIC EMERGENCY DEPARTMENT

Rislaine Benkelfat, MD, BSC,* Serge Gouin, MDCM, FRCPC,* Guylaine Larose, MD, FRCPC, LLM,*
 and Benoit Bailey, MD, MSC, FRCPC*†

*Division of Emergency Medicine, Department of Pediatrics, Centre Hospitalier Universitaire Sainte-Justine, Université de Montréal, Montreal, Quebec, Canada and †Division of Clinical Pharmacology and Toxicology, Department of Pediatrics, Centre Hospitalier Universitaire Sainte-Justine, Université de Montréal, Montreal, Quebec, Canada

Reprint Address: Serge Gouin, MDCM, FRCPC, Centre Hospitalier Universitaire Sainte-Justine, Université de Montréal, 3175 Côte Sainte-Catherine, Montreal, QC H3T 1C5, Canada

Abstract—Background: Despite the publication of recent guidelines for anaphylaxis management, many studies show that physicians are still not at ease with the management of anaphylaxis. **Objectives:** To evaluate the rate and severity of medication errors before and after implementation of a standard order form for anaphylaxis management. **Methods:** A before-and-after study was conducted. All children <18 years of age presenting to a tertiary care pediatric hospital Emergency Department with anaphylaxis between September 2007 and November 2010 were included. Patients were divided into two groups according to intervention (Pre and Post). Intervention consisted of the implementation of a standard order form (SOF) for anaphylaxis management. The post-intervention group was further sub-divided into SOF+ (when the SOF was used) and SOF− (when the SOF was not used). **Results:** A total of 96 medical charts were reviewed. There were 31 patients in Pre and 65 in Post (29 in SOF+ and 36 in SOF−). A total of 243 drugs were ordered. Thirty-five percent (85/243) of these orders contained at least one medication error. Fifty-five percent (47/85) were dosage errors. The rate of medication errors was the same between Pre and Post (60% vs. 59%, $p = 0.95$). However, the rate of dosage errors was significantly reduced when the SOF was used (21% in SOF+ vs. 50% in Pre, $p = 0.02$ and 21% in SOF+ vs. 50% in SOF−, $p = 0.02$). **Conclusions:** Medication errors in the management of anaphylaxis were frequent. Use of an SOF significantly reduced the rate of dosage errors. © 2013 Elsevier Inc.

Keywords—anaphylaxis; medication errors; standard order form; pediatric Emergency Medicine

INTRODUCTION

Anaphylaxis is a common pediatric Emergency Medicine diagnosis, with reported rates up to 1 in 1000 (1). However, its management is still subject to variability (2). New guidelines have recently been published, which all agree on the central role of epinephrine (3–5). Despite the publication of these guidelines, many studies show that physicians are still not at ease with the management of anaphylaxis (6,7).

A medication error may be defined as an error in drug ordering, transcribing, dispensing, administering, or monitoring (8). Medication errors are frequent in children (9). Kozer et al. reported a 14% rate of medication errors studying 12 consecutive days in a pediatric Emergency Department (ED) in the summer of the year 2000 (9). Larose et al. found that 15% of orders in the resuscitation room contained a medication error (10). Obviously, these numbers are unsatisfactory. Elaborating new strategies to reduce medication errors should be a priority to improve the quality of clinical care we provide to patients. As such, many different modalities have been attempted (11).

In our ED, a standard order form (SOF) was introduced in 2008 for the prescription of drugs in the management of anaphylaxis. It was derived from the previously proposed guidelines and consists of a separate preprinted order form that physicians can use in addition to the usual ED order sheets (4). To our knowledge, no previous study has evaluated the impact of an SOF for anaphylaxis management in the ED. We hypothesized that the introduction of such an SOF would decrease the number and severity of medication errors in the management of anaphylaxis.

The primary objective of our study was to evaluate the rate, type, and severity of medication errors before and after implementation of an SOF for anaphylaxis management in a pediatric ED. The secondary objective was to identify predictive risk factors for medication errors.

MATERIALS AND METHODS

A *before and after* study was conducted, with a retrospective review of medical records. The study took place in the ED of a tertiary care urban pediatric hospital with an annual census of 60,000 patient visits. All children <18 years of age who presented to the ED of a tertiary pediatric hospital with anaphylaxis between September 1, 2007 and November 1, 2010 were included in our study. Patients were excluded if the coding diagnosis was wrong according to the information found in the patient's chart or if the latter was missing.

Patients were divided into two groups, based on the timing of their ED visit. The *before* (Pre) group consisted of patients seen between September 2007 and December 2008 (before the implementation of the SOF). Patients seen between January 2009 and November 2010 formed the *after* (Post) group. The Post group was further subdivided into SOF+ (when the SOF was used) and SOF− (when the SOF was not used).

Anaphylaxis was considered to be highly likely on the basis of the diagnostic criteria established by the second

Symposium of the National Institute of Allergy and Infectious Disease (Table 1) (3).

The SOF for the management of anaphylaxis encompassed all the different types of recommended medications for the management of anaphylaxis (epinephrine, H₁-antagonists, β_2 -agonists, intravenous fluids, corticosteroids, H₂-antagonists) (3–5). Dosage references were issued from the pharmacological index of the *Dictionnaire de Thérapeutique Pédiatrique Weber* (12).

For the purpose of this study, we defined the correct use of epinephrine in the management of anaphylaxis in the ED as follows: epinephrine 1/1000 (1 mg/mL), 0.01 mg per kg or 0.01 mL per kg (maximum: 0.5 mg = 0.5 mL) intramuscularly, with repeat doses every 5 to 15 min as needed.

Incorrect medication dosage, frequency, and route of administration were considered medication errors. A difference of 10% above or below the recommended dosing range of the medication was considered erroneous, as previously done in other studies (10,13,14). A second analysis was made using a less stringent deviation of 25% from the recommended dose. Administration of a drug other than that prescribed was considered an error. Failure to administer a prescribed drug or delay in administration (15 min for epinephrine and 30 min for any other drug) was also considered an error.

The absence of date and unclear signature were not considered errors, even though they constitute rule violation in our institution.

A drug given without a written order was not considered an error, as verbal orders are a common practice in our institution, though our hospital policy states they should all be confirmed afterwards by writing.

The definition of an event being a medication error was not dependent on whether or not the error caused harm to the patient.

The severity of errors was classified according to the degree of clinical impact on patients: no consequence, need for surveillance, alteration of vital signs or need

Table 1. Anaphylaxis Diagnostic Criteria

Anaphylaxis is Highly Likely When Any One of the Following 3 Criteria are Fulfilled:
Acute onset of an illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (e.g., generalized hives, pruritus or flushing, swollen lips-tongue-uvula)
AND AT LEAST ONE OF THE FOLLOWING
Respiratory compromise (e.g., dyspnea, wheeze-bronchospasm, stridor, reduced PEF, hypoxemia)
Reduced BP or associated symptoms of end-organ dysfunction (e.g., hypotonia [collapse], syncope, incontinence)
Two or more of the following that occur rapidly after exposure to a <i>likely</i> allergen for that patient (minutes to several hours):
Involvement of the skin-mucosal tissue (e.g., generalized hives, itch-flush, swollen lips-tongue-uvula)
Respiratory compromise (e.g., dyspnea, wheeze-bronchospasm, stridor, reduced PEF, hypoxemia)
Reduced BP or associated symptoms (e.g., hypotonia [collapse], syncope, incontinence)
Persistent gastrointestinal symptoms (e.g., crampy abdominal pain, vomiting)
Reduced BP after exposure to <i>known</i> allergen for that patient (minutes to several hours)
Infants and children: low systolic BP (age specific) or >30% decrease in systolic BP

PEF = peak expiratory flow; BP = blood pressure.

Adapted from Sampson et al. (3).

for further investigation, need for treatment or prolonged stay, permanent injury, or death (10).

Patients were identified via an internal electronic ED database, using “anaphylaxis” and “anaphylactic shock” as diagnostic codes. However, only charts with anaphylaxis as defined in Table 1 were included in our study and reviewed by one of the authors (R.B.). Data were collected from the patients’ charts, medication order sheets, and nurses’ notes. A second author (S.G.) independently reviewed a random sample of 10% of medical records to ensure inter-observer agreement.

Demographic and clinical variables such as medical history, known allergies, usual medication, clinical presentation including type of exposure and organ system involvement, pre-ED and ED therapies received were recorded using a standard data collection sheet (Excel format; Microsoft Corporation, Redmond, WA). Use of the SOF was recorded in the *after* period.

A minimum sample size of 62 patients (31 patients per group) was needed to detect a 25% difference in medication error frequency between the Pre and Post groups ($\alpha = 0.05$; $\beta = 0.9$). Data were entered in an Excel format database (Excel 2007, Microsoft Corporation) and analyzed using an SPSS software package (SPSS v17, Rainbow Technologies, Chicago, IL). Only patients for whom at least one drug was prescribed were included in the analysis. A p value ≤ 0.05 was considered significant. Results were expressed as proportions and means with standard

deviations. Comparisons between Pre and Post as well as between Pre and SOF+, and SOF+ and SOF–, were made using chi-squared (χ^2) tests. Odds ratios and difference of means with 95% confidence intervals (95% CI) were calculated. Linear and logistic regressions were used to try to identify risk factors associated with errors. Preselected potential risk factors included age, sex, weight, time of day at arrival, severity of the anaphylactic reaction (evaluated by general appearance, triage category, location in the ED upon arrival), and level of expertise of the physician in charge (Pediatric Emergency Medicine [PEM] physician, PEM fellow, general pediatrician, family physician). The kappa (κ) score was calculated to evaluate inter-observer concordance.

This study was approved by the local scientific and ethics board.

RESULTS

One hundred twenty-two patients were initially identified. Of these, 26 were excluded: 8 were older than 18 years of age, 15 had a wrong diagnosis, and 3 had unavailable ED charts. Thus, a total of 96 patients were included in the study. There were 31 patients in Pre and 65 in Post (29 in SOF+ and 36 in SOF–). There were 30 patients in Pre and 59 in Post (29 in SOF+ and 30 in SOF–) for whom at least one drug was ordered. Baseline characteristics were similar between groups (Table 2). The mean

Table 2. Baseline Characteristics

	Pre	Post	SOF+	SOF–
n	31	65	29	36
Age (years) (mean $\pm$ SD)	6.3 $\pm$ 4.5	6.7 $\pm$ 6.0	8.3 $\pm$ 6.0	5.4 $\pm$ 5.7
Sex (male) (%)	48	58	48	67
Weight (kg) (mean $\pm$ SD)	23.4 $\pm$ 15.2	25.2 $\pm$ 21.2	29.0 $\pm$ 19.7	22.0 $\pm$ 22.2
Allergic PMH (%)	77	72	69	75
Pre-ED intervention (%)	71	65	45	61
EMS (%)	65	37	31	42
Time upon arrival (%)				
Day	32	34	31	36
Evening	61	58	62	56
Night	7	8	7	8
Location upon arrival (%)				
Ambulatory	36	35	14	53
Observation room	6	5	3	5
Resuscitation room	58	60	83	42
Triage category (%)				
1	13	25	35	17
2	77	55	52	58
3	7	15	10	19
4	3	5	3	6
5	0	0	0	0
Level of expertise of MD in charge (%)				
Pediatric emergency medicine physician	74	77	76	78
Pediatric emergency medicine fellow	19	9	14	6
Pediatrician	7	8	7	8
Family physician	0	6	3	8

Pre = pre-intervention; Post = post-intervention; SOF = standard order form; PMH = past medical history; ED = Emergency Department; EMS = emergency medical services.

Table 3. Drugs Involved in Errors

	Prescriptions (n = 243) n (%)	Medication Errors (n = 85) n (%)	≥10% Dosage Errors (n = 47) n (%)
Epinephrine	46 (19)	12 (14)	7 (15)
H ₁ -antagonists	78 (32)	29 (34)	16 (34)
Corticosteroids	76 (31)	28 (33)	16 (34)
β ₂ -agonists	29 (12)	6 (7)	5 (11)
H ₂ -antagonists	14 (6)	10 (12)	3 (6)

age was 6.3 ± 5.5 years in Pre and 6.7 ± 6.0 in Post. There were 58% of males in Pre and 48% in Post. Seventy-seven percent had a past medical history of atopy in Pre, compared to 73% in Post.

A total of 243 drugs were ordered, with H₁-antagonists and corticosteroids being the most common ones (Table 3). Thirty-five percent (85/243) of these orders contained at least one medication error. Fifty-five percent (47/85) were dosage errors. H₁-antagonists and corticosteroids were also the drugs most commonly involved in medication errors (Table 3). Epinephrine represented 19% of orders and 14% of medication errors.

The percentage of medical charts containing at least one medication error was the same between Pre and Post (60% vs. 59% respectively, $p = 0.95$) and with the use of the SOF (55% in SOF+ vs. 60% in Pre, $p = 0.71$ and 55% in SOF+ vs. 63% in SOF−, $p = 0.52$) (Table 4). However, the percentage of charts containing at least one dosage error (≥10% deviation from the recommended dose) was significantly reduced when the SOF was used (21% in SOF+ vs. 50% in Pre, $p = 0.02$ and 21% in SOF+ vs. 50% in SOF−, $p = 0.02$) (Table 4). These results held true when using a 25% deviation criterion for medication error (10% in SOF+ vs. 37% in Pre, $p = 0.02$ and 10% in SOF+ vs. 33% in SOF−, $p = 0.03$) (Table 4).

Accordingly, the mean number of medication errors per patient was the same between Pre and Post (1.10 ± 1.3 vs. 0.88 ± 0.9 respectively, $p = 0.42$) (Table 5).

Nonetheless, the mean number of dosage errors per patient was significantly reduced when the SOF was used (0.21 ± 0.4 in SOF+ vs. 0.67 ± 0.8 in Pre, $p = 0.01$ and 0.21 ± 0.4 in SOF+ vs. 0.70 ± 0.8 in SOF−, $p = 0.01$) (Table 5). When using a 25% deviation as the defining criterion, this decrease was still significant between SOF+ and Pre (0.10 ± 0.30 vs. 0.40 ± 0.6 respectively, $p = 0.02$) and almost reached statistical significance between SOF+ and SOF− (0.10 ± 0.3 vs. 0.33 ± 0.5 , respectively, $p = 0.06$) (Table 5).

Ninety-nine percent (84/85) of medication errors were ranked as having no clinical consequence for the patient. Only one error resulted in a prolonged stay for the patient.

Age, sex, weight, time of day upon arrival at the ED, severity of the anaphylactic reaction, and level of expertise of the physician in charge were not found to predict medication errors in our study.

When 10 (10%) charts were reviewed by a second reviewer, the unweighted κ score was 0.90 (95% CI 0.85–0.95).

DISCUSSION

To our knowledge, this is the first study to show a decrease in dosage errors in anaphylaxis management with the use of an SOF, as shown by a statistically significant decrease in rate and number of errors in SOF+ as compared to Pre and SOF−.

The *before and after* design of the study represents an original descriptive approach to evaluate the effects of an intervention, and as such, has successfully been used by others (9,10,14). Kozier et al. found a 45% decrease in medication errors with the use of a preprinted structured order form (9). Likewise, Larose et al. documented a 9% reduction in medication errors when a dedicated order sheet for emergent medication was used in the resuscitation/trauma room of our institution (10).

Use of the SOF tended to decrease overall medication errors. These comprise prescribing errors and administration

Table 4. Percentage of Charts Containing at Least One Medication Error

	Pre n (%)	Post n (%)	SOF+ n (%)	SOF− n (%)	p Value	OR (95% CI)
Pre/post						
Error	18 (60)	35 (59)	X	X	0.95	0.97 (0.40–2.38)
≥10% Dosage error	15 (50)	21 (36)	X	X	0.19	0.55 (0.23–1.35)
≥25% Dosage error	11 (37)	14 (22)	X	X	0.14	0.49 (0.19–1.28)
Pre/SOF+						
Error	18 (60)	X	16 (55)	X	0.71	0.82 (0.29–2.31)
≥10% Dosage error	15 (50)	X	6 (20)	X	0.02	0.26 (0.08–0.82)
≥25% Dosage error	11 (37)	X	4 (10)	X	0.02	0.20 (0.05–0.81)
SOF+/SOF−						
Error	X	X	16 (55)	19 (63)	0.52	1.40 (0.50–3.98)
≥10% Dosage error	X	X	6 (20)	15 (50)	0.02	3.83 (1.22–12.10)
≥25% Dosage error	X	X	4 (10)	10 (33)	0.03	4.33 (1.05–17.85)

Pre = pre-intervention; Post = post-intervention; SOF = standard order form; OR = odds ratio; CI = confidence interval.

Table 5. Mean Number of Medication Errors per Patient

	Pre Mean $\pm$ SD	Post Mean $\pm$ SD	SOF+ Mean $\pm$ SD	SOF– Mean $\pm$ SD	p Value	Difference of Means (95% CI)
Pre/Post						
Error	1.10 $\pm$ 1.3	0.88 $\pm$ 0.9	X	X	0.42	0.27 (–0.32 to 0.76)
≥10% Dosage error	0.67 $\pm$ 0.8	0.46 $\pm$ 0.7	X	X	0.23	0.21 (–0.13 to 0.55)
≥25% Dosage error	0.40 $\pm$ 0.6	0.22 $\pm$ 0.4	X	X	0.13	0.18 (–0.05 to 0.41)
Pre/SOF+						
Error	1.10 $\pm$ 1.3	X	0.79 $\pm$ 0.9	X	0.28	0.31 (–0.26 to 0.87)
≥10% Dosage error	0.67 $\pm$ 0.8	X	0.21 $\pm$ 0.4	X	0.01	0.46 (0.10 to 0.82)
≥25% Dosage error	0.40 $\pm$ 0.6	X	0.10 $\pm$ 0.3	X	0.02	0.30 (0.06 to 0.54)
SOF+/SOF–						
Error	X	X	0.79 $\pm$ 0.9	0.97 $\pm$ 0.9	0.54	–0.17 (0.74 to 0.39)
≥10% Dosage error	X	X	0.21 $\pm$ 0.4	0.70 $\pm$ 0.8	0.01	–0.49 (–0.85 to 0.13)
≥25% Dosage error	X	X	0.10 $\pm$ 0.3	0.33 $\pm$ 0.5	0.06	–0.23 (–0.47 to 0.01)

Pre = pre-intervention; Post = post-intervention; SOF = standard order form; CI = confidence interval.

errors; lack of statistical significance here may underlie a preferential impact of the SOF on prescribing errors compared to administration errors. Larose et al. also showed a significant decrease in administration errors with use of a dedicated order sheet (10).

Medication errors were frequent. The high frequency of medication errors in children, especially in an acute care setting such as the ED, has multiple possible explanations, such as weight-based orders requiring calculations, paucity of crash clinical presentations, stressful working environment with multiple patients to care for simultaneously associated with frequent interruption, resident physicians placing orders, and lack of a pharmacist to double-check doses (15). However, our medication error rates were higher than previously reported rates, which lie between 10% and 15% (9,10,16). Indeed, Kozer et al. found that 10.1% of ED charts contained at least one prescribing error (9). Larose et al. found a 15% rate of medication errors in the resuscitation room (10). More recently, Vilà-de-Muga et al. recorded a 15% rate of medication errors in a pediatric ED during 1 week (16).

Our somewhat concerning high rate of medication errors can partially be explained by the use of varying definitions of medication errors as well as different means of reporting errors between these studies. Indeed, stringent defining criteria for errors were used in our study, including a relatively small deviation from the recommended dose as well as strict time windows for drug administration. We chose such stringent criteria as a 10% deviation from recommended doses due to epinephrine's high potency compared to its relatively small therapeutic index. By contrast, Kozer et al. and Vilà-de-Muga et al. used a 20% deviation (9,16). Because the epinephrine dosage is a small number (0.01 mg per kg), a variation of 10% would occur easily, especially for small children. Our timeframe for administering medications was 15 min for epinephrine and 30 min for other medications, whereas Kozer et al. allowed for an hour delay between

medication prescription and administration (9). Furthermore, we reported prescribing errors as well as administration errors, whereas some studies only reported on prescribing errors. For example, in the study by Vilà-de-Muga et al., all medication errors were prescribing errors (16). This may have to do with the inherent difficulties in identifying administration errors in retrospective chart reviews.

The high medication error frequency found in this study may also come from the particular clinical situation of anaphylaxis. Indeed, despite the publication of new guidelines for anaphylaxis management, many studies show that physicians are still not at ease with the management of anaphylaxis (6,7). In a survey of physicians at Dunedin Hospital in New Zealand, 92% of participants would have given epinephrine as a first-line treatment to a patient with anaphylaxis, but only 20% knew the correct dose and route of administration (6). In another survey of physicians in a United Kingdom (UK) medical trust, 69% of hospital physicians would choose the wrong route of administration for epinephrine, 62% would either not know the dosage to use or would choose an incorrect dose of epinephrine, and only 15% would administer epinephrine as recommended by the UK resuscitation guidelines from 2008 (7). Furthermore, doses, frequency, and route of delivery of epinephrine vary greatly with the many indications. Different concentrations of epinephrine exist, and epinephrine vials can be labeled in mass concentration (1 mg per mL) or ratio (1 mL of a 1/1000 or 1/10,000 solution). As such, epinephrine is error prone and 10-fold error can easily occur. A study showed that physicians managing an acute pediatric anaphylaxis in a simulated scenario, when provided vials with mass concentration labels, gave a higher weight-based dose of epinephrine than the target dosage and took longer to do so (17). Thus, patients presenting with anaphylaxis are potentially even more at risk of medication errors. This is also illustrated by the fact that we found a higher rate of medication errors in patients with anaphylaxis in the

same setting than a previous study that included all patients in the resuscitation room. Thus, ED staff should pay particular attention to improving the process in caring for patients with anaphylaxis.

Fortunately, the vast majority of medication errors in our study had no significant clinical impact. Only one resulted in a prolonged stay for the patient: a nurse in Pre had administered six times the recommended/prescribed dose of epinephrine. Errors involving epinephrine are extremely concerning, as they have the potential to cause significant adverse effects including death. Coronary dissection, myocardial infarction, cardiomyopathy, transient left ventricular dysfunction, and ventricular dysrhythmias can all result from an epinephrine overdose (18). Moreover, a report on anaphylactic reactions to food in children and adolescents suggests that recovery is more likely if epinephrine is given within 30 min (19). In severe anaphylaxis, the interval between allergen exposure and arrest can be as rapid as 5 min (20). Administration delays can thus also have dramatic consequences in anaphylaxis. Limiting medication errors in this context takes on an even bigger importance.

In our study, no predictive risk factor for medication errors was identified, contrary to previously published studies. Severity of patient illness, time of day upon arrival to the ED, and level of expertise of the physician in charge have all previously been described as predictive risk factors (9,16). In the study by Kozer et al. and that of Vilà-de-Muga et al., prescribing errors by trainees were reported as such, whereas in our study, they were scored as errors by the physician in charge (except for the PEM fellows) (9,16). This may partially explain why the level of expertise of the physician in charge did not come out as a risk factor. Small numbers in our study may also have contributed to the lack of identification of risk factors.

Limitations

This was a retrospective study, with the inherent biases and limitations of a chart review. Moreover, the sample size was small, though sufficient to find a statistical difference in error risk between groups. Finally, use of the SOF was limited in Post, potentially due to its relative initial lack of accessibility, especially in the resuscitation room.

CONCLUSION

Medication errors in the management of anaphylaxis were frequent. An SOF for anaphylaxis management, when used, significantly reduced the rate and number of dosage errors. No predictive risk factor for medication error was identified in this specific clinical context. Though

most errors in our study had no clinical consequence, the potential for serious adverse effects in the case of anaphylaxis management is high. Use of an SOF represents a relatively inexpensive and easy way to help prevent them. Its generalizability to other clinical situations should therefore be encouraged.

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ARTICLE SUMMARY**1. Why is this topic important?**

Anaphylaxis is a common pediatric Emergency Medicine diagnosis, with reported rates up to 1 in 1000. However, its management is still subject to variability.

2. What does this study attempt to show?

We aimed to evaluate the rate, type, and severity of medication errors before and after implementation of a standard order form for anaphylaxis management in a pediatric Emergency Department.

3. What are the key findings?

Medication errors in the management of anaphylaxis were frequent. The percentage of charts containing at least one dosage error ($\geq 10\%$ deviation from the recommended dose) was significantly reduced when the standard order form was used (21% vs. 50%). These results held true when using a 25% deviation criterion for medication error (10% vs. 37%).

4. How is patient care impacted?

A standard order form for anaphylaxis management, when used, significantly reduced the rate and number of dosage errors. Though most errors in our study had no clinical consequence, the potential for serious adverse effects in the case of anaphylaxis management is high.