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Improving epinephrine autoinjector usability and carriage frequency among patients at risk of anaphylaxis: a quality improvement initiative

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ABSTRACT

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Correspondence to Dr Tiffany Jean; tjean1@hs.uci.edu Although epinephrine autoinjectors (EAIs) are crucial for the management of anaphylaxis, patient carriage frequency of EAI is as low as 57% and usage of EAIs is erroneous 35%–43% of the time. Our objective was to improve patient carrying frequency of EAI and understanding of EAI usage.

We implemented a quality improvement initiative using consistent closed-loop education, redesigned clinic workflow, electronic medical record reminder-based interventions, and educational materials to improve patient EAI carriage compliance and understanding of EAI indications and proper technique.

The percentage of our patients who carried the EAI at all times increased from 55% to 93% in 6 months. Participants knowledge of EAI indications also improved from 22% to 91%. Patient demonstration scores of the EAI device improved from 21% to 91% as well. Our quality improvement interventions demonstrated a significant improvement>80% in EAI carriage frequency, knowledge of indications, and proper device technique.

PROBLEM Problem

Our institution is an academic, tertiary care centre with approximately 6000 outpatient visits seen in the Division of Basic and Clinical Immunology annually. The standard practice for patients with indications for EAIs are to prescribe and refill the device as appropriate, and to educate the patient at that time. The healthcare providers document the specific type of EAI and whether the patients brought their EAIs to the visit. We have found that at routine follow-up visits, there is a large percentage of non-compliance of EAI carriage. In addition, there is lack of knowledge of EAI indications and steps of use when patients are asked to demonstrate technique with the epinephrine trainer devices.

Aim

To increase patient carriage frequency of EAI and knowledge of indications and proper technique to at least 80% after 2 cycles of education in a 6-month period.

WHAT IS ALREADY KNOWN ON THIS TOPIC

 \Rightarrow Patient carriage frequency of epinephrine autoinjectors (EAIs) is as low as 57% and usage of EAIs is erroneous 35%–43% of the time.

WHAT THIS STUDY ADDS

⇒ This study highlights that quality improvement initiatives can improve EAI carriage compliance and understanding of EAI usage.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Using multifaceted interventions with closed-loop education, electronic medical record reminders, and educational materials, this quality improvement initiative provides a clinic workflow process that healthcare providers can use to improve EAI carriage frequency and understanding of usage in patients at risk for anaphylaxis.

BACKGROUND

Anaphylaxis is a life-threatening systemic hypersensitivity reaction with high probability of occurrence in the community setting.^{1 2} Epinephrine autoinjectors (EAIs) are the first-line treatment for anaphylaxis.³ The proper use of EAIs is a life-saving skill not only for healthcare personnel but for patients themselves. It is crucial for patients to always carry their EAIs and be sufficiently skilled in correctly and safely administering them. Management of anaphylaxis is multifactorial and includes early recognition, proper device carriage and technique, as well as subsequent communication with emergency medical services.

Although patients are provided EAIs by general physicians, emergency department physicians, and specialists alike, they are not always taught how often they should carry them or how to use the devices in an effective manner. The current literature has demonstrated that there is a suboptimal practice of anaphylaxis management in regards to adult patient self-administered epinephrine via autoinjector devices.⁴ In particular, daily EAI device carriage represents a significant barrier fundamental to proper anaphylaxis management. The cost of the device, misperception of allergy severity, and not having experienced a prior allergic reaction have all been cited as reasons patients do not carry the device at all times.⁵ For those that routinely carry the device, studies have demonstrated that underuse is still common.⁶ When looking at food allergies, epinephrine was not administered for 30% of severe reactions where it was indicated.⁷ This is largely due to gaps in knowledge secondary to limited training as well as psychosocial barriers such as the perception of using a 'weapon-like' device.⁸ This trend also includes the ability of parents and other adults such as teachers to administer the device to children.^{9–11} Currently, there is a scarcity of literature examining how to effectively improve patient EAI carriage as well as understanding of the indications and proper device technique, leaving the needs of patients largely unmet. Ridolo et al examined the knowledge of device use in patients who had been prescribed EAIs for a minimum of 1 year and were taught by an allergist at initial prescription and during routine follow-up visits. Only 39% of subjects demonstrated correct use of the device which signifies that effective methods to improve patient compliance and knowledge of EAIs need to be developed as per the system.¹²

MEASUREMENT

This was a prospective quality improvement project which involved a multidisciplinary team including allergy providers, nursing staff and clinic administration. Our inclusion criteria consisted of paediatric and adult patients who were prescribed EAIs for allergic indications which included: anaphylaxis, angioedema, food or drug allergies, stinging insect allergies, and/or allergy immunotherapy. Our study cohort consisted of a total of 106 patients during the period between 15 April 2019 to 15 November 2020. Data were collected during the initial visit, as well as at 3-month, and 6-month follow-up appointments. We excluded 12 patients who did not follow-up at either the 3-month or 6-month time periods post initial intervention. Given that EAI device education and use is standard of care, participants were not consented for the study.

Electronic medical record (EMR) was reviewed for patient demographics including age, gender and ethnicity. Our main goals were to assess whether patients knew the clinical indication(s) of epinephrine use, had consistent daily device carriage and knew the correct steps of usage. In addition, we assessed the time when the device was first prescribed, the provider or staff who did the most recent EAI teaching, patient comfort and confidence level with administration, quality of life measures with carrying and knowledge of device use, the number of severe past allergic reactions, the number of past EAI uses, and whether subjects had any prior medical education or experience in healthcare.

The foundation underlying our clinical indications of EAI use was set by the anaphylaxis guidelines from the National Institute of Allergy and Infectious Diseases and Food Allergy Research & Education in 2006, which have also been re-emphasised in Anaphylaxis Practice Parameters 2020. The following criteria for anaphylaxis were used, with anaphylaxis highly likely when any one of the three criteria are met: (1) acute onset of an illness (over minutes to several hours) involving skin and/or mucosal tissue in the setting of respiratory compromise, reduced blood pressure, or other signs of end-organ dysfunction, (2) two or more system involvement after exposure to a likely allergen such as involvement of the skin-mucosal tissue, respiratory compromise, reduced blood pressure or associated symptoms of end-organ dysfunction, or persistent gastrointestinal symptoms, or (3) reduced blood pressure after exposure to a known allergen for that patient.^{3 13} This criteria was prospectively validated in the emergency department setting with a positive likelihood of 3.26 and negative likelihood of 0.07.¹⁴ In addition, this anaphylaxis criteria is supported by the American Academy of Allergy, Asthma, and Immunology, American College of Allergy, Asthma, and Immunology, and World Allergy Organisation.¹⁵ Anaphylaxis recognition was assessed in our patient cohort in a multiple-choice format by a preintervention survey as well as postintervention surveys administered at 3-month and 6-month periods.

Assessment of EAI carriage frequency was conducted through our patient survey and provider confirmation that subjects were in possession of the device on the day of clinic visits. The survey question directly asked whether patients carry the EAI at all times, and for those under 18 years, whether they carry or have the device available at school. EAI device carrying compliance was measured at the initial, 3-month, and 6-month timepoints. EAI carriage at educational facilities was also examined in our appropriate paediatric population given the significant amount of time children spend at school. Lack of anaphylaxis recognition, device access and administration knowledge have all been cited as barriers to anaphylaxis treatment which our study aimed to improve. Delayed epinephrine administration is associated with increased mortality and represents an area of improvement that would greatly benefit patients at risk.¹⁶

Patient understanding of device usage was assessed via graded demonstrations at each visit (figure 1). The administration instructions set by the manufacturer included: (1) removal of device cap, (2) injection into lateral thigh, (3) confirmation of audible click, (4) device engagement for>3s, and (5) calling 911. In addition, we evaluated patient knowledge of (6) ability to use device over clothes, and (7) avoidance of placing thumb or any finger over the needle tip.¹⁷ A total score was then calculated and participants scores were followed longitudinally during the course of our study to demonstrate the benefit of the proposed interventions.

```
1. Removes blue cap before injection
   A. Yes
   B. No
2. Presses EpiPEN on lateral thigh
   A. Yes
   B. No
3. Presses EpiPEN until clicking sound
   A. Yes
   B. No
4. Holds EpiPEN in place for at least 3 seconds
   A. Yes
   B. No
5. Call 911 or get emergency medical help
   A. Yes
   B. No
6. Knows EpiPEN can be used on top of clothes
   A. Yes
   B. No
7. Knows to never put thumb or any finger over the orange tip (needle area)
   A. Yes
   B. No
Total Score:
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Figure 1 Epinephrine Autoinjector Demonstration Scoring Criteria.

At baseline, 55% of participants confirmed they carried the EAI at all times. Initial knowledge of EAI anaphylaxis indications started at 22%. Only 21% of participants were able to demonstrate all the correct steps of EAI.

Statistical analysis

Patient baseline demographics were obtained to demonstrate applicability of our sample size to the general population. Participants age, gender, ethnicity, Epipen prescription indication, instructor type, and mean time of prescription were measured. Next, participants knowledge of Epipen steps, quality of life, indications knowledge, demonstration scores and device carrying rates were measured longitudinally at baseline, 3 months, and 6 months. Carrying rates were further analysed to examine gender and age differences, and inclusion of rates of device carriage at school in applicable children. The Wilcoxin-Pratt Test was used as an association measure for demonstration scores at the different time intervals, with values of p<0.05 considered statistically significant. R V.3.6.3 was used to perform all calculations.

DESIGN

Design and strategy

The Plan-Do-Study-Act format was used in this study. Paediatric and adult patients who had been prescribed EAIs were recruited for our study between 15 April 2019 to 15 November 2020. A preintervention survey was provided to assess baseline patient knowledge and deficit areas. This included EAI carriage frequency, indications of use, self-reported level of knowledge and quality of life measures. Patients were subsequently provided a trainer device and were graded on their demonstration of use. Several interventions were instituted in this study after meeting with clinical faculty who had identified gaps in EAI knowledge among their patients (Plan). Clinic workflow changes included ancillary staff such as medical assistants and nurses identifying patients with EAIs when completing the medicine reconciliation while rooming the patients. In addition, there was utilisation of EMR notifications to create reminders to all the providers which included attending physicians, fellows and residents, to incorporate patient-focused closed-loop teaching sessions during clinical visits as well as provide EAI reference materials for patients to refer to in their discharge paperwork (Do). Using the EMR, we created reminders in the physicians' daily schedules and in the patient's individual chart to alert the providers which patients had EAIs. Closedloop education was also used which focused on demonstrating EAI steps of use and indications; after physicians completed the same teaching at the initial, 3 and 6 month visits, they asked their patients if they could repeat the EAI indications and redemonstrate steps of usage with the trainer device (Study). Teaching sessions were done at the conclusion of the visit and were approximately 10 min in duration. The content focused on reinforcing the steps of EAI usage and indications of use and matched the summary document given to the patients. Patients were then given a summary document of the EAI indications, steps of usage, proper storage, and when to call 911 or emergency medical services in their clinic discharge summary paperwork so they could refer to the documents on their own time. We noticed all these workflow changes added more time to the overall clinic visit. In order to save time, we asked our nurses to place the survey forms in the patient chart prior to the visit so patients could complete them during registration (Act). A postintervention survey was administered at follow-up appointments at 3-and 6 months to examine their epinephrine carriage frequency and retention of knowledge. Patients were then again graded on their demonstration of technique and subsequently received closed-loop education on proper EAI techniques in an effort to improve their understanding (figure 2).

RESULTS

A total of 106 patients were included in the study, 46 male and 60 female. Of the 106, 38 (36%) were under the age of 18 years, for which surveys were filled out by a parent. The mean age (years) was 30.5±21.3. Mean time of initial EAI prescription was 27.8 months prior to enrolment, with median time being 12 months. Ethnicity of participants were white 37 (35%), Asian 25 (25%), Hispanic 23 (22%), African American 6 (5%), and other 15 (14%). Indication for prescription included food allergy in 55 patients (52%), allergy immunotherapy injections in 23 patients (22%), angioedema in 15 patients (14%), drug allergy in 7 patients (6%), hymenoptera venom allergy in 4 patients (4%), and for anaphylaxis of unknown aetiology in 12 patients (11%). Some of these participants had more than 1 indication for EAI. Participants reported their past teacher as being an allergist 55 (52%), primary

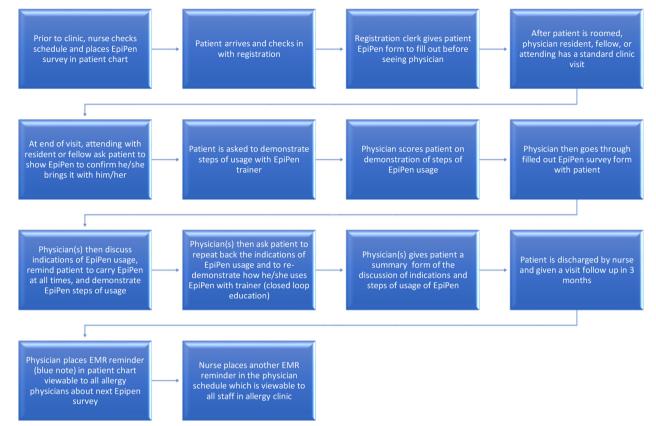


Figure 2 Process flow chart of pathway of patient in allergy clinic. Steps of clinic workflow process for allergy patients with epinephrine autoinjectors.

care physician 25 (24%), pharmacist 8 (8%), nurse 4 (4%), emergency medicine physician 2 (2%), and urgent care physician 2 (1%), and 11 individuals (10%) reported no one had taught them how to use EAI.

In examining EAI carriage among our total population, we demonstrated a longitudinal increase in frequency of carrying with each proposed intervention. Fifty (55)% of all participants carried the device at baseline, which increased to 84 (79%) at 3 months and 99 (93%) at 6

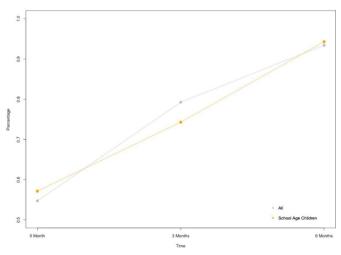


Figure 3 Epinephrine autoinjector carriage frequency. Carriage frequency (as a percentage) of all subjects (grey) and school aged children (yellow) at 0, 3 and 6 months.

months. In regards to our paediatric school-aged population (ages 4-18 years), carrying frequency at school followed a similar trend. Twenty (57%) carried the device at school at baseline, 26(74%) at 3 months, and 33(94%)by 6 months (figure 3). Gender differences in this paediatric subgroup that existed at baseline, namely females having higher carrying rates compared with male counterparts (71% vs 44%, respectively), normalised by the 6-month mark with both groups demonstrating equal carrying rates of 94%. Participants knowledge of EAI use improved longitudinally as well with 23 (22%) knowing the proper indications at baseline, improving to 66 (62%) by 3 months and 96 (91%) by 6 months (figure 4). Demonstration scores also followed a similar trend. Twenty (21%) performed all 7 EAI device steps properly at baseline which improved to 66 (62%) by 3 months and 96 (91%) by 6 months (figure 5). At the end of 6 months, the most missed steps were device engagement for>3s (4%) and remembering to call 911 (3%) after device use. The Wilcoxon-Pratt Test was used as an association measure for demonstration scores at the different time intervals to assess the benefit of our teaching intervention and at each point there was a statistically significant increase in scores (pre-test vs 3 months: 7.94, p<0.001, pre-test vs 6 months: 8.53, p<0.001, 3 months vs 6 months: 6.01, p<0.001).

Whereas 20% of our population reported having used their EAI during a severe allergic reaction at baseline,

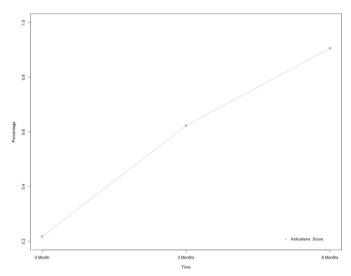


Figure 4 Understanding when to use an epinephrine autoinjector. Indication knowledge scores (as a percentage) of all subjects at 0, 3 and 6 months.

an increasing number reported use during subsequent episodes after our intervention (84.6% at 3 months and 71.4% at 6 months). At baseline, patients prescribed the epipen for stinging insect allergy or allergy immunotherapy injections had the highest rates of carrying, (75%)and 65%, respectively), with drug allergy and angioedema having the lowest rates (29% and 40%, respectively). By the 6-month time period, we noticed>80% carrying frequency among all groups. When examining baseline carrying rates and length of time of first EAI prescription, we used 6-month increments as a reference range to compare. Subjects with an initial prescription from 0.5 to 1 year were 0.92 times as likely to carry their device (95%) CI 0.32 to 2.65), those an initial prescription within the past 1-2year were 0.77 times as likely (95% CI 0.26 to (2.27), and lastly those with a prescription longer than (2.27)years were 1.35 times more likely (95% CI 0.44 to 4.18). Participants self-reported knowledge of all the steps

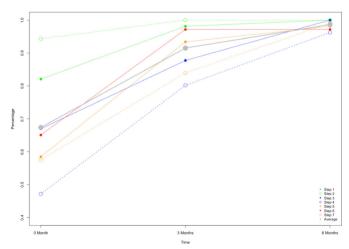


Figure 5 Demonstration scores of epinephrine autoinjector use. Demonstration score trend (as a percentage, separated by individual steps outlined in figure 1) at 0, 3 and 6 months. Average score is delineated by the grey line.

reached 100% by 6 months, compared with 76.6% at baseline. Quality of life measures demonstrated improvement from 0 to 6 months. Participants noted subjective improvement in their quality of life from carrying the device (84% at baseline, improving to 94% and 96% at 3-month and 6-month periods). They also reported consistently high levels in quality of life from knowing how to use the device, measuring 99% across all three time points.

LESSONS AND LIMITATIONS

Our goal was to improve patient EAI knowledge of indications, accurate usage and carrying frequency through a collaborative initiative. We showed a longitudinal increase in frequency of EAI carriage with each postintervention in our total cohort and school aged cohort. The number of patients who understood the indications of using EAI and who were able to use the EAI device correctly also improved. Our project highlights the importance of a multidisciplinary intervention involving providers, support staff and EMR to achieve our aim.

Anaphylaxis requires immediate access to epinephrine, which is the most important life-saving medication. Most studies have shown the gaps in patient knowledge of understanding anaphylaxis and preparedness with using EAI. Few studies have looked into ways to narrow the gap in knowledge.^{16 18 19} The success of our quality improvement initiative was due to a combination of patientfocused closed loop teaching, clinic workflow addition, EMR provider alerts, and reminder discharge summaries for patients. We were able to surpass our initial goal of>80% improvement in our patients.

Given the size of the multidisciplinary team, which involved attending physicians, training fellows, residents, medical students, nurses and clerks, it was difficult to arrange meetings to discuss with everyone involved. To overcome this barrier, we held several meetings in small groups so everyone would be updated. In addition since our project lasted several months, we often had to give reminders to the entire team and to train new staff when there were nursing or clerk changes. On reflection, it would have been more effective to assign a lead nurse and a lead clerk to facilitate communication.

Using EMR reminders to alert the physicians and nursing staff about which patients to give the epinephrine questionnaire forms was initially difficult to implement in the clinic workflow. For new patients, the physicians first give the preteaching questionnaire forms. After the closed-loop education is completed, the patients are given a discharge summary with the indications and steps of EAI usage. The nurses then add a reminder to their next visit on the physician EMR schedule. The physicians also place a reminder on the EMR blue notes which are automatically shared with all providers once the specific patient encounter has been opened. Prior to the next follow-up, the clerks place post-teaching questionnaire forms in the patient chart. This helps with time efficiency

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as patients can fill out the form while waiting for the physician appointment. A possibility may be that if some reminders were not placed in patients' EMR, it may have affected our number of patients for follow-up. However, we only had 12 participants who did not follow-up, which was a small number in our cohort.

Our quality improvement study has some limitations. Our patient cohort was in an academic hospital-based allergy clinic, and generalisability of our findings to nonhospital-based allergy clinics is not known. However, our interventions were straightforward and can practically be implemented into the clinic workflow. We did not have a control group who did not receive EAI teaching which prevented comparisons between our study cohort and controls. Balancing measures were not implemented during the limited time of our study. Furthermore, sustainability data were not collected.

Limitations of our study also included having a small percentage of patients who had severe allergic reactions after our teaching interventions. Therefore, our data were not sufficient to statistically analyse the number of patients who used their EAI appropriately during a severe reaction. However, we did see a trend of increasing patient self-use of their EAI device during severe reactions. This suggests that our multidisciplinary quality improvement initiative may have improved patient outcomes during anaphylaxis as well. Therefore, we would encourage further studies to determine the extent and effectiveness of higher patient EAI carriage rates and knowledge of indications with reduction of anaphylaxis morbidity and mortality.

CONCLUSION

We demonstrate the importance of a multifaceted approach in the setting of a university based allergy clinic to improve patient compliance through increasing EAI carriage rates and knowledge of the indications of use. Our initiative has shown a clear stepwise improvement in both paediatric and adult device carriage rates and increased recognition of when to use the device. Additionally, patient demonstration scores improved across all steps with each teaching intervention. These findings support the significance of patient-focused closedloop teaching sessions by providers at regular intervals in patient education and retention. We have learnt that implementing changes to clinic workflow and utilisation of EMR to alert and remind providers also contributed to the success of our quality improvement project. Our reference guides for EAIs also solidified each teaching session for the patients. These measures have been incorporated into our standard clinical workflow to best ensure our patient population at risk of anaphylaxis better understand how and when to use their EAI.

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Patient consent for publication Not applicable.

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