

EpiPen4Schools pilot survey: Occurrence of anaphylaxis, triggers, and epinephrine administration in a U.S. school setting

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ABSTRACT

Background: Although epinephrine is the treatment of choice for anaphylaxis, it remains underused.

Objective: This study was designed to describe anaphylactic events and epinephrine autoinjector (EAI) use in U.S. schools enrolled in the EpiPen4Schools program.

Methods: This exploratory, cross-sectional, Web-based survey of 6019 schools that participated in the EpiPen4Schools program assessed anaphylactic events and EAI use at responding schools during the 2013–2014 school year.

Results: A total of 919 anaphylactic events were reported in 607 schools. Of the 852 anaphylactic events with data on those who experienced an event, most 88.8% ($n = 757$) occurred in students, and 21.9% of events ($n = 187$) occurred in individuals with no known allergies. Of the 851 events with data on EAI use, 74.7% ($n = 636$) were treated with EAI and 8.5% ($n = 54$) received a second epinephrine injection. Of the 204 individuals not treated with an EAI, 77.0% ($n = 157$) received antihistamines, 12.7% ($n = 26$) received another treatment, and 8.3% ($n = 17$) received no treatment. Of the 850 events with data on hospital transport, 79.6% of individuals ($n = 677$) were transported to the hospital. Common triggers varied seasonally, with food listed most frequently overall (62.5%).

Conclusion: More than one in ten schools that participated in the EpiPen4Schools survey reported an anaphylactic event. Approximately 25% of individuals with anaphylactic events were not treated with EAI, and 20.4% of patients were not taken to the hospital after an anaphylactic event. Analysis of these data supports the value of stocking EAI and of providing continuing education regarding the recognition and proper treatment of anaphylaxis for school personnel.

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Anaphylaxis is a serious and acute allergic reaction that can be life threatening.¹ In the United States, the prevalence of anaphylaxis among the general population is estimated to be $\geq 1.6\%$.² Epinephrine has

been classified as an essential medication for the treatment of anaphylaxis by the World Health Organization, and guidelines recommend prompt intramuscular injection of epinephrine as first-line therapy for anaphylaxis.^{3,4} Epinephrine can be administered in the community setting by patients and caregivers *via* an epinephrine autoinjector (EAI) during an anaphylactic event.¹ EAI available in the United States are approved by the U.S. Food and Drug Administration for the first-line treatment of anaphylaxis.^{5–7} However, despite recommendations from guidelines and the availability of EAI, epinephrine remains underused.^{8–11} Delay of treatment with epinephrine or failure to treat with epinephrine is of high concern given that anaphylaxis can result in fatal consequences.^{12,13}

Anaphylaxis can be induced by various triggers, including foods, drugs, biologics, insect stings, latex, and exercise.^{1,14} Foods are common triggers of anaphylactic reactions, with food allergy rates estimated between 1% and 8% for children and between 3% and 4% for adults in North America.^{15,16} Epidemiologic evidence further indicates that the prevalence of food allergy is increasing among school-aged children.¹⁷ These findings emphasize the need for school personnel to be

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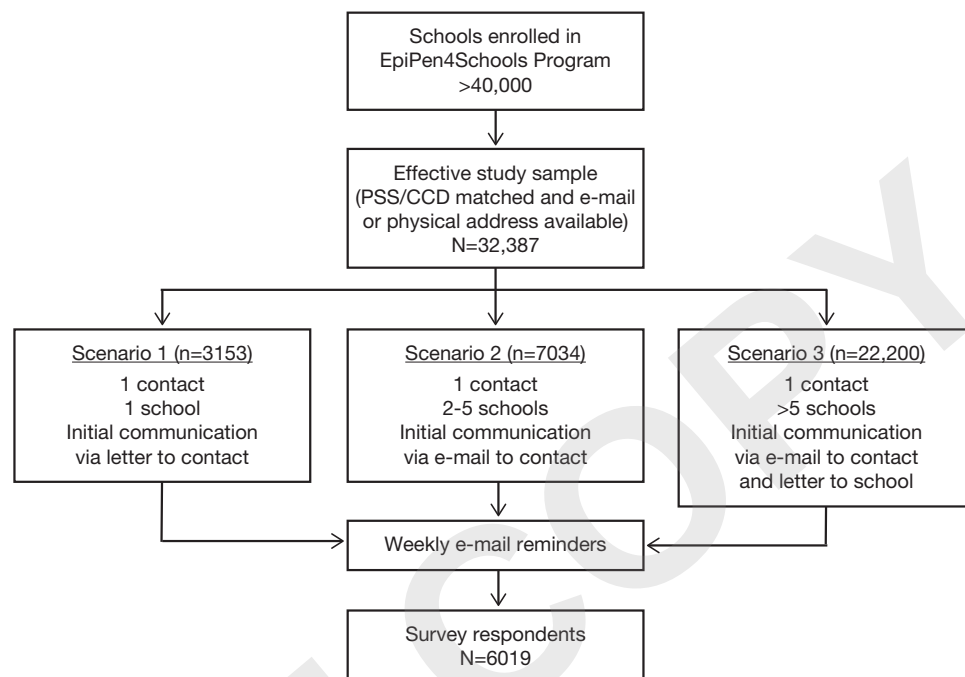


Figure 1. Preparation of samples and notification procedures. CCD, Common Core of Data; PSS, Private School Universe Survey.

prepared to manage life-threatening reactions to food as well as other triggers of anaphylaxis that may be encountered in a school setting (e.g., insect stings). The purpose of this exploratory survey was to describe anaphylactic events and EAI use in U.S. schools that received EAIs through the EpiPen4Schools® (Mylan Specialty L.P., Canonsburg, PA) program during the 2013–2014 school year.^{18–20} The program, launched in 2012, offers two free EpiPen Auto-Injector 2-packs (Mylan Specialty), two EpiPen Jr Auto-Injector 2-packs (Mylan Specialty), or one of each 2-pack to qualifying public and private U.S. schools, inclusive of kindergarten, elementary, middle, and high schools.

METHODS

Study Design

An exploratory, Web-based, cross-sectional survey of schools that participated in the EpiPen4Schools program was conducted. The survey involved completion of a brief online questionnaire by the person best suited to respond regarding all occurrences of severe allergic reactions and treatment(s) administered at each school during the 2013–2014 school year.

Sample Preparation

The study sample consisted of U.S. schools that were registered with the EpiPen4Schools program; BioRidge Pharma (Florham Park, NJ) maintains the database of registered schools. These schools were matched to the Common Core of Data (CCD) (U.S. Department of Education, Washington, DC) or to the Private School Universe Survey (PSS) (U.S. Department of Education,

Washington, DC) databases to obtain key demographic information for analysis and to facilitate the process of contacting school administrations. A list of school principals' names and e-mail addresses for matched schools was purchased from Quality Education Data (MCH Strategic Data, Sweet Springs, MO). The effective sample for the survey consisted of 32,387 schools for which there was either a physical or e-mail address at the school or contact level (Fig. 1).

Sample Contact and Notification

There were three possible scenarios for contacting and notifying the respondents, which varied based on the number of schools for which the listed contact was responsible. Schools in the first scenario had a single school per contact ($n = 3153$) and received an initial letter *via* standard surface mail (Fig. 1). Schools in the second scenario ($n = 7034$) shared one contact with two to five other schools (Fig. 1) and received an initial letter *via* e-mail. Schools in the third scenario ($n = 22,220$) shared one contact with more than five schools (Fig. 1). Contacts in this last scenario received initial letters *via* standard surface mail. Notification letters, however, were sent *via* e-mail because they included a list of all the schools associated with a contact person. Initial letters inviting participants to take the survey were customized to the individual school, and they referenced a web address for accessing the survey by using a unique user identification. E-mail reminders to complete the survey were sent weekly beginning 1 week after the introduction letter was mailed to all schools that had not completed the survey.

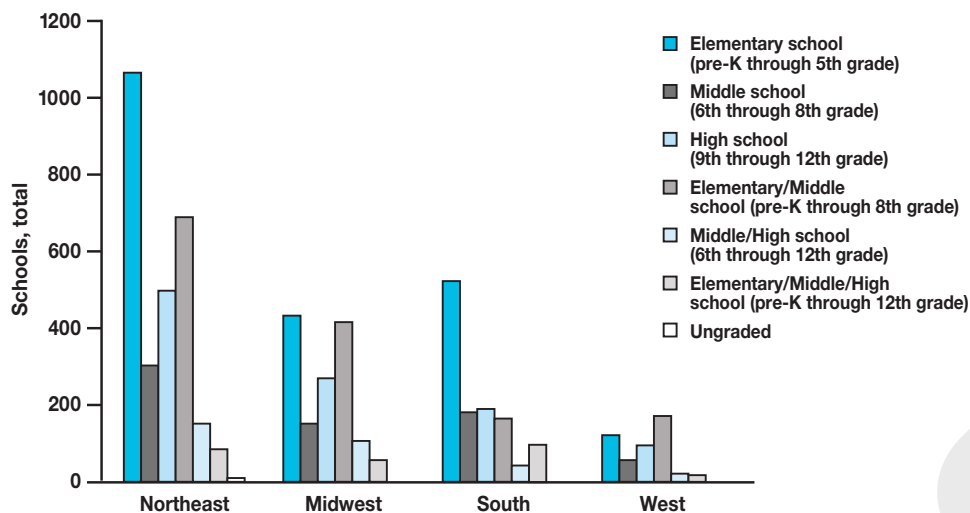


Figure 2. Distribution of reporting schools by type of school and census region. *preK*, prekindergarten.

Survey Development and Administration

The survey consisted of 15 questions, 8 of which were repeated for each anaphylactic event reported per school. The web-based survey was self administered, with a time frame for completion between May 21, 2014, and July 9, 2014. Respondents were provided access to a toll-free telephone number and an e-mail address for technical assistance.

Data Analysis

A descriptive analysis of the characteristics of reported anaphylactic events was conducted. Characteristics included the individual who experienced the anaphylactic event (*e.g.*, student, staff, visitor), the presence of known allergies, the trigger that caused the anaphylactic event, the medication used to treat the anaphylactic event (*e.g.*, epinephrine, antihistamines), the source of the EAI used for treatment (*i.e.*, school stock, individual), and transportation to a hospital after the anaphylactic event. The relative frequency of each characteristic was calculated by dividing the total number for each response category of the variable of interest across all schools by the combined number of responses (including “unknown”) across all schools. Missing responses were excluded from the analysis. Descriptive analyses of additional characteristics were conducted to further describe participating schools. These included the census region and grade levels of responding schools, type and source of EAIs stocked, anaphylactic events by census region, triggers by census region, and triggers by season.

RESULTS

Survey Completion

A total of 6019 surveys were submitted during the designated time frame. Nonresponses to questions in the survey did not preclude submission; thus, most

questions included a count of “missing data.” Of the 6019 surveys, the position of the survey respondent was reported in 5935 responses. Most surveys were completed by school nurses ($n = 4560$ [76.8%]), and the remainder were completed by school principals ($n = 639$ [10.8%]) and other staff members, such as administrators, counselors and student services staff, and teachers ($n = 736$ [12.4%]).

Characteristics of Responding Schools

Surveys were submitted from all four major U.S. Census Bureau regions. These included 2822 surveys from the Northeast (46.9%), 1450 surveys from the Midwest (24.1%), 1234 surveys from the South (20.5%), and 513 surveys from the West (8.5%) (Fig. 2). The information obtained from the CCD and Private School Universe Survey databases indicated that 2146 schools (35.8%) were grade schools (prekindergarten through 5th grade), 1443 (24.0%) were grade/middle schools (prekindergarten through 8th grade), 703 (11.7%) were middle schools (6th through 8th grade), and 1064 (17.7%) were high schools (9th through 12th grade). The remaining 645 schools (10.7%) were composed of other grade-level combinations. Grade level was unavailable for 18 schools in the database.

EAI Stocks

During the 2013–2014 school year, 5713 schools reported the number of EAIs stocked. Of these schools, 2241 (39.2%) stocked one EAI, 3239 (56.7%) stocked two or more EAIs, and 233 (4.1%) did not stock any EAIs. It is not clear why the schools that participated in the program may not have had the EAIs in stock, but one respondent noted that their school had recently enrolled in the program and had not yet received its supply. A total of 5477 schools reported the number of

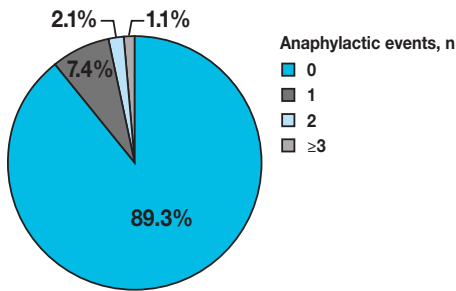


Figure 3. Distribution of schools by number of anaphylactic events reported.

EpiPen Auto-Injector 0.3 mg 2-packs that were stocked from the EpiPen4Schools program during the 2013–2014 school year. Of these schools, 3391 (61.9%) stocked one EpiPen Auto-Injector 0.3 mg 2-pack, 1662 (30.3%) stocked at least two EpiPen Auto-Injector 0.3 mg 2-packs, and 424 schools (7.7%) did not stock any EpiPen Auto-Injector 0.3 mg 2-packs. Overall, the EpiPen4Schools program supplied 31.0% of the total EpiPen Auto-Injector 0.3 mg 2-packs stocked across these 5477 schools. Schools also reported the amount of EpiPen Jr Auto-Injector 0.15 mg 2-packs stocked from the EpiPen4Schools program during the 2013–2014 school year. Of the 4614 schools that responded, 3202 (69.4%) stocked one EpiPen Jr Auto-Injector 0.15 mg 2-pack, 993 (21.5%) stocked at least two EpiPen Jr Auto-Injector 0.15 mg 2-packs, and 419 schools (9.1%) did not stock any EpiPen Jr Auto-Injector 0.15 mg 2-packs. Overall, 41.0% of the total EpiPen Jr Auto-Injector 0.15 mg 2-packs stocked across 4614 schools were supplied by the EpiPen4Schools program. A majority of schools ($n = 3370$ [59.0%]) reported that other brands of EAI were allowed to be stocked at their school. However, only 1146 of these schools (34.0%) stocked one or more EAI brands other than EpiPen Auto-Injector.

Characteristics of Anaphylactic Events

Eleven percent of schools (607 of 5683 schools that responded to the survey) reported a total of 919 anaphylactic events. There were 543 schools (9.6%) that reported one to two events, and 64 schools (1.1%) that reported at least three events (Fig. 3). The remainder of schools ($n = 5076$ [89.3%]) reported no anaphylactic events (Fig. 3). Of the schools that reported at least three anaphylactic events, a majority were located in suburban areas ($n = 35$ [54.7%]). Fifty percent of the schools that reported at least three anaphylactic events were high schools.

Approximately half of all the events reported by survey participants from the EpiPen4Schools program ($n = 455$) were reported by schools in the Northeast; however, the largest number of survey respondents were from the Northeast (46.9% [2822/6019]). As a

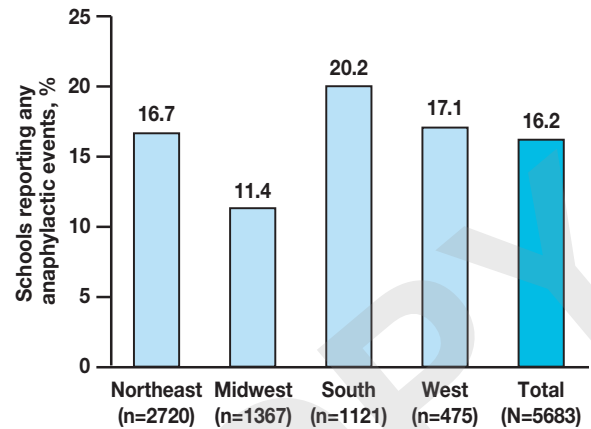


Figure 4. Distribution of rates of anaphylactic events reported by census region as a percentage of the number of responding schools within a region. Percentages were calculated based on the number of schools in each region that completed a survey and reported any anaphylactic events.

percentage of responding schools within a region, the South reported the highest rate of anaphylactic events, with 227 events in 1121 schools (20.2%) (Fig. 4). This was followed by the West with 81 events in 475 schools (17.1%), and the Northeast with 455 events in 2720 schools (16.7%) (Fig. 4). Midwest schools experienced the lowest rate of events with 156 events in 1367 schools (11.4%) (Fig. 4). Across all regions, the rate of events reported was 16.2% among the 5683 responding schools.

A total of 852 anaphylactic events included data on who experienced the event. Of these, 757 events (88.8%) were experienced by students, 84 (9.9%) by school staff, and five (0.6%) by visitors (three adults and two minors). Six events (0.7%) were reported as unknown. The majority of individuals ($n = 588$ [69.0%]) who had an anaphylactic event had a known allergy, whereas 187 (21.9%) had no known allergy. For 75 (8.8%), the survey respondent did not know if the individual who experienced the anaphylactic event had any preexisting allergies.

Anaphylactic Triggers

Data on the type of triggers were recorded for 847 anaphylactic events. Of these, 529 triggers (62.5%) were listed as food, 172 triggers (20.3%) were listed as unknown, 81 triggers (9.6%) were listed as insect bite and stings, 56 triggers (6.6%) were listed as environmental or as medication or health related, and 9 triggers (1.1%) were listed as latex (Fig. 5). Compared with all other regions, the participating schools in the Northeast had the largest proportion of anaphylactic events triggered by food, and schools located in the Western region had the largest proportion of anaphylactic events caused by insect bites and stings or unknown triggers.

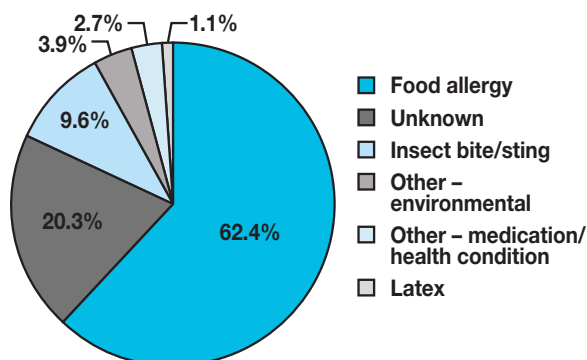


Figure 5. Types of anaphylactic triggers.

Triggers also varied seasonally. Overall, fewer events occurred in winter (December, January, February) ($n = 143$) compared with fall (September, October, November) ($n = 243$) and spring (March, April, May) ($n = 268$). A higher frequency of events of unknown origin was reported during the spring season compared with other times of the year. Food was the predominant trigger for anaphylaxis across all seasons. As expected, anaphylactic events triggered by insect stings or bites were relatively less frequent during winter compared with spring and fall.

Treatment of Anaphylactic Events

Of the 851 anaphylactic events with data on EAI use, 74.7% of individuals ($n = 636$) were treated with an EAI, 24.0% ($n = 204$) were not treated with an EAI, and 1.3% ($n = 11$) had unknown data regarding administration of epinephrine with an EAI. Of the 636 individuals who experienced an anaphylactic event and were treated with an EAI, 310 (48.7%) were treated with an EpiPen Auto-Injector from the school's stock, 289 (45.4%) were treated with a personal EpiPen Auto-Injector, 27 (4.2%) were treated with an EAI other than an EpiPen Auto-Injector, and 9 (1.4%) were treated with an EAI of unknown type or source. The question regarding the type of EAI used at the school was left blank for one of the reported events (0.2%). In addition, 54 individuals (8.5%) who were treated with an EAI received a second EAI injection, 545 individuals (85.7%) did not get a second injection, and, for 36 individuals (5.7%), the respondent did not know if a second injection had been administered.

Of the 204 anaphylactic events reported as not being treated with an EAI, 157 individuals (77.0%) received antihistamine, 26 (12.7%) received some other treatment, and 17 (8.3%) received no treatment. Data on alternative treatment were reported as unknown for four events (2.0%). Some of the other treatments reported were epinephrine injection from a vial, nebulizer, and inhaler, and unknown treatments administered by emergency medical services or other medical personnel.

Of the 850 anaphylactic events with data on hospital transportation, 677 individuals (79.6%) were transported to a hospital. Approximately three-fourths ($n = 513$) were transported by ambulance, and 164 individuals (24.2%) were transported by some other means (e.g., parent, guardian). In 16 of the events (2.4%), the respondent did not know if the individual had been taken to the hospital.

DISCUSSION

This exploratory survey examined information on the characteristics of anaphylactic events in U.S. schools that participated in the EpiPen4Schools program. Although exploratory in nature, analysis of the data indicates that anaphylaxis is not uncommon in U.S. schools. More than 10% of the 5683 schools that answered questions regarding anaphylactic events reported at least one anaphylactic event during the 2013–2014 school year. It is not known whether schools that were chosen to participate in the EpiPen4Schools Program have a higher than normal incidence of such events. Of the anaphylactic events that were reported, 21.9% occurred in individuals with no known allergies, and, in 8.8% of cases, it was unknown whether an allergy existed before the attack. These numbers are comparable with those reported in Massachusetts, where 25% of anaphylactic events were reported in individuals with no known allergies in both 2003 and 2010.^{21,22} Analysis of these findings indicates a need for an anaphylaxis plan that would protect all students, staff, and visitors, and not just those already considered at risk of anaphylaxis.

Among respondents who answered questions about how anaphylactic events were treated, 74.7% stated that an EAI was used to treat the event. Although these numbers are encouraging, 204 anaphylactic events (24.0%) were not treated with epinephrine; of these events, most (77.0%) were treated with antihistamines. These findings are consistent with reports from other studies that show frequent use of H₁- and H₂-antihistamines for the treatment of anaphylaxis.^{10,23} Despite the key role of histamine in anaphylaxis, antihistamines are inadequate for first-line treatment of anaphylaxis because they fail to completely control all symptoms, including some life-threatening symptoms.²⁴ In addition, one study on severe allergic reactions in schools revealed that school staff members were unaware of life-threatening allergies in 24.0% of cases and, therefore, did not have physician orders for epinephrine or an anaphylactic emergency action plan in place for the affected students.²² Therefore, it is important to continue to educate school nurses, other school staff members, and patients about the symptoms of anaphylaxis, development of individual emergency action plans that incorporate epinephrine as

first-line therapy for anaphylaxis, and adherence to recommended treatment guidelines.

The proportion of patients transported to the hospital after an anaphylactic event was lower among our study population compared with data reported by the Massachusetts Department of Health (80% versus 98%, respectively).²¹ For the majority of patients, symptoms resolve within a few hours of treatment, but, for the ~20% of patients who experience biphasic anaphylactic reactions, which are defined as a second phase of anaphylactic activity after a period of inactivity, symptoms have been reported to reoccur as few as two or as many as 38 hours after the first reaction.^{25,26} Analysis of these data indicates the importance of educating school staff about the need to seek medical attention after an anaphylactic event.

Study Limitations

In general, surveys are subject to a number of measurement errors, including systematic and random variance that resulted from the respondents themselves (e.g., failing to carefully read a question or misreporting an event) as well as variance related to interpretation of the questions' meaning. In addition, surveys have the potential for response bias, whereby respondents who complete the survey may differ from those who do not complete the survey in some significant way and, therefore, may not be representative of the target population. Response bias may arise from oversampling schools from a particular region or from low overall response rates. Future studies may address such bias by comparing respondents and nonrespondents so that differences can be adjusted to ensure equal sampling distribution. Also, a survey study does not allow for determination of the number of reported cases of anaphylaxis in which the respondent had a confirmed diagnosis.

This exploratory survey had a response rate of 19%. Factors that contributed to this response rate included collection of the data during the final weeks of the school year. The timing of the survey at the end of the school year also limited the possibility of pursuing responses through repeated contacts *via* mail and telephone. In addition, some schools could not participate without formal district approval, and there was no time to complete such an approval process within the time limits of the study. Another factor that affected the response rate was the lack of direct and verifiable contact information for respondents. Thus, efforts to reach key respondents were hindered by a lack of direct contact information which, in turn, significantly reduced the response rate. A study with a larger pool of EpiPen4Schools program participants and an extended study period is currently being conducted and should address some of the study limitations discussed

here. Revisions to the questionnaire could address any confusion or potential issues that often affect self-report measures. The completeness of the data collected was dependent on the quality of record keeping that pertained to cases of anaphylaxis, the availability of such information in the school's records, and the recollection of the respondent. Many schools had incomplete records, or their records did not include all of the information requested in the survey.

CONCLUSIONS

More than one in ten schools that participated in the EpiPen4Schools survey reported an anaphylactic event. Of these, 21.9% were experienced by individuals with no known allergies, which indicates a need for an anaphylaxis plan that extends to all students, staff, and visitors, regardless of known risk of anaphylaxis. In addition, 24.0% of individuals who experienced an anaphylactic event were not treated with epinephrine, the first-line therapy for anaphylaxis. Most of these individuals were treated with antihistamines instead, which do not resolve all of the life-threatening symptoms that present with anaphylaxis. Furthermore, 20.4% of patients were not taken to the hospital after an anaphylactic event, potentially putting patients who may experience a biphasic reaction at risk. Thus, analysis of these data indicates the value of stocking EALs and providing continuing education for school personnel about the recognition and management of anaphylaxis.

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Erratum

In the article *IgE reactivity to carbohydrate moieties of glycoproteins in wheat allergy*, *Allergy Asthma Proc* 36, 192–199, 2015; doi: 10.2500/aap.2015.36.3815, there was an error in the grant information. Also, the contributed equally information should have been included in the first page footnotes. The correct grant information and contributed equally information are:

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The printer regrets the error.

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