

Need for Community Pharmacist–Provided Food-Allergy Education and Auto-injectable Epinephrine Training

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ABSTRACT

Objective: To determine whether community pharmacist–provided food-allergy education and auto-injectable epinephrine training is needed.

Design: Cross-sectional assessment.

Setting: United States.

Participants: 1,887 recently joined members of the Food Allergy & Anaphylaxis Network.

Intervention: Electronic survey.

Main Outcome Measures: 35 items covering past education and training associated with food allergy and use of auto-injectable epinephrine, demographics, attitudes toward pharmacist–provided education about food allergy, training in the use of auto-injectable epinephrine, confidence in managing food allergies on a daily basis and in emergency situations, and the necessity for pharmacists to provide education and training about food allergy and auto-injectable epinephrine use.

Results: Prescriber-provided food-allergy education and auto-injectable epinephrine training is incomplete (60.7%) or absent (16.3%) at the time auto-injectable epinephrine is first prescribed. These initial prescriptions are being dispensed from community pharmacies (94%), and written information is commonly provided with the medication (73.6%); however, oral counseling is largely absent (86.6%), and training in administration of auto-injectable epinephrine occurs infrequently (13.3%). Food-allergic patients and their caregivers are receptive to the idea of pharmacist-provided education and training. The majority (63.6% or more) feel confident about managing their food allergies. They are not requesting counseling when refill prescriptions are dispensed (81.4%); however, they would like to see routine review at refill time of the signs of allergic reaction (54.5%) and use of the epinephrine auto-injector (79.3%).

Conclusion: Community pharmacists have an opportunity to assist newly diagnosed food-allergic patients by working collaboratively with their pediatricians and allergists. Community pharmacists can provide ongoing assistance at refill time by retraining patients in the use of the epinephrine auto-injector and reviewing the signs of allergic reaction.

Keywords: Food allergy education, self-administered epinephrine, anaphylaxis, cognitive services, medication therapy management.

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Approximately 11 million Americans are affected by one or more food allergies that are triggered by the ingestion of or contact with certain foods, which cause a range of reactions including anaphylaxis. Approximately eight foods account for 90% of the reactions: peanuts, tree nuts, fish, shellfish, eggs, milk, soy, and wheat. Food allergy is the leading cause of anaphylaxis outside the hospital setting, accounting for an estimated 30,000 emergency department visits and 2,000 hospitalizations per year. Epinephrine is the medication of choice for controlling a food-allergy reaction and is available by prescription in an auto-injector.¹

Two recent U.S. studies have established an inability on the part of large numbers of patients/caregivers^{2,3} and pediatricians² to correctly demonstrate administration of auto-injectable epinephrine. In the asthmatic population, failure of the prescribing physician to demonstrate the use of auto-injectable epinephrine has been documented.³ Whether lack of training and education can be extrapolated to other users of auto-injectable epinephrine is unknown.

Absent from the literature are reports on the training and education provided to the larger population of users of auto-injectable epinephrine including food-allergic patients. Furthermore, whether

the education is provided by health care professionals (including pharmacists) and at what time it is provided in relation to diagnosis and acquisition of auto-injectable epinephrine is unexplored.

Two studies conducted in the United States document a need for improved patient/caregiver education in the administration of auto-injectable epinephrine.^{2,3} In a 2000 study, families and pediatricians of food-allergic children were asked to demonstrate the use of self-injectable epinephrine.² Many parents of food-allergic children and food-allergic teenagers could not correctly administer self-injectable epinephrine, and many did not have the product readily available. Furthermore, pediatricians were generally not familiar with these devices and often did not review their use with patients. An earlier study focused on asthmatic patients who had been prescribed auto-injectable epinephrine.³ A total of 80% of these patients received their prescriptions from physicians other than allergists, and 75% received no demonstration by the prescribing physician or other office staff member. A large portion, 63%, of the patients or their parents could not demonstrate the correct use of the device.

Several studies and commentaries from outside the United States also document a similar need for greater patient/caregiver education and training.⁴⁻⁸ A Canadian study focused on 122 health care professionals attending an annual pediatric update.⁴ Pediatricians, emergency physicians, family practitioners, medical residents, pharmacists, and nurses were sampled. Overall, only 25% demonstrated correct use of auto-injectable epinephrine, but 80% of pharmacists were able to do so. The report concluded that a new approach to educating professionals and patients and maintaining skills is required. In a study from Scotland only 11% of parents of children with auto-injectable epinephrine who reported receiving initial training were offered a subsequent training review.⁵ In a study from Australia, results from a telephone questionnaire documented that parental knowledge was deficient regarding the use of auto-injectable epinephrine and knowledge of symptoms of anaphylaxis.⁶ An allergist in England noted that six of his eight peanut-allergic referral patients had not previously been trained, concluding that issuing a prescription with no demonstration is inadequate care.⁷ The anxiety associated with coping with anaphylaxis in a child was documented in a Canadian study in which 17 families were interviewed about their experiences in adjusting to living with anaphylaxis.⁸ The authors suggested that filling gaps in crucial information and providing support could help relieve anxiety.

AT A GLANCE

Synopsis: Prescribers and community pharmacists often do not provide education or training in the use of auto-injectable epinephrine to food-allergic patients or their caregivers, according to this national survey of 1,887 recently joined members of the Food Allergy & Anaphylaxis Network (FAAN). Patients and their caregivers often leave both physicians' offices and pharmacies with the devices and some written information, but many feel they could have used more complete explanations about when to use epinephrine and how to administer the drug with the auto-injector. Respondents generally supported a greater role for the community pharmacist in providing both education about food allergies and their treatment and training about use of the auto-injector device.

Analysis: *The 11 million Americans with food allergies suffer from a range of reactions, including life-threatening anaphylaxis, brought about by ingesting or having contact with certain foods. Food allergy is the leading cause of anaphylaxis in nonhospital settings, and epinephrine is the first-line treatment for food-allergy reactions. Community pharmacists can meet the need for educating newly diagnosed food-allergic patients and their caregivers and retraining long-standing food-allergic patients and caregivers in the use of auto-injectable epinephrine. The FAAN members surveyed would welcome education and training, as well as retraining, if these services were offered by community pharmacists.*

Objectives

Food-allergic individuals and their caregivers in the United States were surveyed to determine whether community pharmacist-provided food-allergy education and auto-injectable epinephrine training is needed. The following questions were addressed:

■ What education and training is provided to food-allergic individuals or their caregivers at the time auto-injectable

epinephrine is first prescribed, at the time the prescription is dispensed, and at the time the prescription refills are dispensed?

■ How confident are food-allergic individuals or their caregivers about managing food allergies on a daily basis and in emergency situations?

■ What is the attitude of food-allergic individuals or their caregivers toward pharmacist-provided food-allergy education and auto-injectable epinephrine training?

■ When picking up refills for auto-injectable epinephrine, about what topics do food-allergic individuals or their caregivers feel pharmacists should routinely provide counseling?

Methods

Before this research project began, the study protocol was approved by Mercer University's Institutional Review Board for Research Involving Human Subjects and the Research Advisory Board of the Food Allergy & Anaphylaxis Network (FAAN). The universe for this study consisted of food-allergic users of auto-injectable epinephrine, or their caregivers, who had joined FAAN within the prior 3 years. The latter criterion was established because recall related to initial diagnosis of food allergy was important, and most individuals who join FAAN do so at the time of their initial diagnosis. Data were collected using a cross-sectional design. In December 2003, a link to an online questionnaire was sent by electronic mail to the 5,172 FAAN members who met the above criteria. No personally identifiable information was requested. The data were encrypted using secure sockets layer technology and was transferred directly into a database for analysis. A second electronic mailing of the survey link was sent to the same sample 2 weeks following the initial mailing. Anonymity was assured.

The questionnaire consisted of 35 items written in English. Demographics and past education and training associated with food allergy and use of auto-injectable epinephrine were explored in 26 questions that used forced-choice and open-ended responses. Six items were attitudinal with a 5-point Likert response scale, ranging from 1, strongly disagree, to 5 strongly agree. These questions presented both positive and negative statements related to pharmacist-provided education about food allergy and training in the use of auto-injectable epinephrine. Content domain was addressed by a review of literature to ensure the attitudinal items included those mentioned in the literature as possibly important in affecting attitudes toward education and training about food allergy and use of auto-injectable epinephrine.²⁻⁸ For three items, respondents rated their confidence in managing food allergies on a daily basis and in emergency situations on a 4-point ordinal scale, which ranged from 1, extremely unconfident, to 4, extremely confident. For four items, respondents rated the necessity for pharmacists to routinely counsel about various aspects of food allergy and auto-injectable epinephrine use on a nominal scale, necessary versus not necessary. The questionnaire was reviewed by three practicing pharmacists and three pharmacist educators and pilot tested

by five food-allergic individuals. Items subsequently underwent minor editing for clarity.

The data were analyzed using Statistix Version 8 (Analytical Software, Tallahassee, Fla.). Statistical tests included simple descriptive statistics, Pearson correlations, and *t* tests. Significance was set at $P < .05$. In an effort to improve accuracy, those respondents who had been diagnosed as food allergic for greater than 3 years were eliminated from the analyses that required recall of information related to an initial prescription for auto-injectable epinephrine.

Results

A total of 1,887 responses were received, a 36.5% response rate. Responses came from all regions of the United States, including the mid-Atlantic (26.6%), the midwest (23.9%), the west (17.6%), New England (15.7%), the southeast (15.2%), and regions outside the contiguous 48 states of the United States (1.0%).

Of the respondents, 93 (4.9%) were food-allergic individuals, and 1,791 (95.1%) were parents or caregivers who answered the questionnaire on behalf of a food-allergic individual. The respondents were primarily women (90.4%). The majority indicated that their occupation was non-health care related (51.4%). A minority worked in a health care-related occupation (15.9%). Full-time homemakers, retirees, or the unemployed comprised 32.7% of respondents.

The mean ($\pm$ SD) age of the food-allergic individuals was 5.74 ± 8.17 years. The food-allergic individuals had been diagnosed with the food allergy for 3.26 ± 4.53 years. The most common food allergy reported was peanut (80.3%), followed by tree nuts (51.0%), eggs (46.7%), milk (38.8%), soy (16.2%), shellfish (12.8%), wheat (11.9%), and fish (8.1%). A wide variety of other food allergies were reported by 20.8% of respondents. The majority (88.7%) of respondents had never administered auto-injectable epinephrine in response to an anaphylactic reaction.

Education and Training Provided by Prescriber

Respondents were asked to recall the first time the food-allergic individual received a written prescription for auto-injectable epinephrine. Information was collected about the specialty of the prescribing physician, the information and training provided by the prescriber from six possible categories, and the medium for providing it (Table 1). Allergists were the most common prescribers, followed by pediatricians.

Approximately two thirds of the respondents had received general information about what a food allergy is. Slightly more than one half of the respondents had received information about the signs of an allergic reaction, training in the use of auto-injectable epinephrine, and information about specific foods to avoid. Less than half of the respondents had received drug information about

Table 1. Education and Training Provided at Time Auto-injectable Epinephrine Was Initially Prescribed

<i>Primary specialty of prescribing physician (n = 1,437), No. (%)</i>	
Allergist	818 (56.9)
Pediatrician	508 (35.4)
Emergency physician	80 (5.6)
Family practitioner	20 (1.4)
Other ^a	11 (0.8)
<i>Information and training provided by prescriber (n = 1,413), No. (%)</i>	
General information about what food allergy is	940 (66.5)
Information about signs of allergic reaction	832 (58.9)
Training in the use of auto-injectable epinephrine	830 (58.7)
Information about specific foods to avoid	821 (58.1)
Drug information about epinephrine	611 (43.2)
Information about the day-to-day management of food allergy	556 (39.3)
Comprehensive (all of the above categories)	333 (23.0)
No information or training provided	231 (16.3)
<i>Prescriber medium for providing information and training (n = 1,330), No. (%)</i>	
Oral instruction by prescriber	987 (74.2)
Written information	621 (46.7)
Oral instruction by prescriber's staff	454 (34.1)
Video	90 (6.8)

^aOther specialties include internal medicine, gastroenterology, pulmonology, dermatology, otolaryngology, and rheumatology.

epinephrine and information about the day-to-day management of food allergy. For 23.0% of respondents, the information and training provided was comprehensive, covering all six categories. For 16.3% of respondents, no information or training had been provided. For the remaining 60.7% of respondents, the information and training was incomplete, covering some but not all six categories. When information or training was provided, a variety of methods were used by prescribers, the most common being oral instruction by the physician, followed by written information.

Initial Prescription Dispensed for Auto-injectable Epinephrine

As shown in Table 2, epinephrine auto-injectors were nearly always obtained from community pharmacies (94.0%). Approximately three fourths of the respondents had received both a manufacturer-produced patient insert and a drug information leaflet with their dispensed medication, while approximately one fourth had received only the patient insert. Nearly all respondents indicated that they had read the patient insert either by itself or in addition to the drug information leaflet.

Table 2. Dispensing of Initial Prescription for Auto-injectable Epinephrine

<i>Where the prescription was dispensed (n = 1,433), No. (%)</i>	
Community pharmacy	1,347 (94.0)
Hospital outpatient pharmacy	65 (4.5)
Health maintenance organization/clinic pharmacy	14 (1.0)
Physician's office	5 (0.4)
Mail service pharmacy	2 (0.1)
<i>Written information dispensed with prescription (n = 1,258), No. (%)</i>	
Both patient insert and drug information leaflet	926 (73.6)
Only patient insert	299 (23.8)
Only drug information leaflet	25 (2.0)
No written drug information	8 (0.6)
<i>Dispensed information read by patient/caregiver (n = 1,279), No. (%)</i>	
Both patient insert and drug information leaflet	834 (65.2)
Only patient insert	370 (28.9)
Only drug information leaflet	41 (3.2)
None	34 (2.7)

Education and Training Provided by Pharmacist

Respondents who received their first auto-injectable epinephrine from a pharmacy were asked to recall the content of any oral counseling that was provided by the pharmacist (Table 3). The majority of respondents (86.6%) did not recall receiving oral counseling. When counseling did occur, it consisted of drug information about epinephrine (13.4%) and training in the use of auto-injectable epinephrine (13.3%). The majority of respondents (81.4%) who had obtained refills for their auto-injectable epinephrine indicated they never asked for counseling at refill time for this product, and the majority (94.7%) were not counseled the last time refill prescriptions were dispensed.

Respondent Confidence

Using a 4-point ordinal scale, most respondents felt confident, but not extremely confident, in their ability to recognize the signs of allergic reaction, their ability to administer correctly the epinephrine auto-injector, and the day-to-day management of food allergy (Table 4). However, a considerable number (22.8%) were not confident in their ability to administer correctly the epinephrine auto-injector.

Attitudes Toward Pharmacist-Provided Education and Training

Responses to the six attitudinal items were analyzed to assess reliability. The results of *t* tests indicated that each item discriminated between the upper and lower 25% of responses. Corrected item-total correlations met the criteria of being greater than 0.35 and significant at $P < .05^9$; therefore, no items were eliminated

Table 3. Education and Training Provided at Point of Pharmacy Dispensing of Auto-injectable Epinephrine

Content of oral counseling provided when prescription was initially dispensed (n = 1,284^a), No. (%)

No oral counseling occurred	1,112 (86.6)
Drug information about epinephrine	172 (13.4)
Training in use of auto-injectable epinephrine	171 (13.3)
Information about signs of allergic reaction	30 (2.3)
Information about specific foods to avoid	14 (1.1)
General information about what food allergy is	13 (1.0)
Information about day-to-day management of food allergy	11 (0.9)

Frequency with which the patient/caregiver has requested counseling when obtaining refills of epinephrine (n = 1,498^b), No. (%)

Never	1,219 (81.4)
Once	133 (8.9)
Occasionally (more than once, but not always)	116 (7.7)
Always	30 (2.0)

Content of oral counseling provided the last time epinephrine refill was dispensed (n = 1,441^b), No. (%)

No oral counseling occurred	1,365 (94.7)
Drug information about epinephrine	76 (5.3)
Training in the use of auto-injectable epinephrine	62 (4.3)
Information about signs of an allergic reaction	22 (1.5)
Information about the day-to-day management of food allergy	13 (0.9)
Information about specific foods to avoid	4 (0.3)

^aEliminated responses from those diagnosed as food allergic longer than 3 years, those who could not recall, and those not using pharmacies to obtain epinephrine auto-injectors.

^bEliminated responses from those who had not obtained refills, those who could not recall, and those not using pharmacies for refills.

from the attitude scale. The split-half reliability (correlation of responses to one half of the items with responses to the other half) was 0.98. Table 5 contains the mean response for each attitudinal item. Scores on the six attitudinal items were combined using the method of summated rating to produce an overall attitude toward pharmacist-provided education and training.¹⁰

The mean ($\pm$ SD) overall attitude toward pharmacist-provided

food-allergy education and auto-injectable epinephrine training was 3.47 ± 0.63 on the 5-point Likert scale, representing an attitude that was between neutral and favorable. Stronger attitudes were demonstrated with respect to four statements (Table 5). Respondents disagreed with the statements: *A pharmacist who tried to talk with me about food allergies would be wasting my time*; and *The only thing that pharmacists should do for the food allergic is fill their prescriptions*. Respondents agreed with the statements: *When I pick up the epinephrine auto-injector, the pharmacist should counsel me, without asking me or waiting for me to ask*; and *I would welcome the chance to update my knowledge and skills about food allergies by talking with a pharmacist*.

Necessary Elements of Routine Refill Counseling

Respondents were asked what topics should be part of routine counseling when a refill for an epinephrine auto-injector was dispensed (Table 6). A slight majority (54.5%) indicated a review of the signs of allergic reaction was necessary. A larger majority (79.3%) indicated a review of how to use the epinephrine auto-injector was necessary. The majority did not feel pharmacists needed to routinely counsel them about foods and allergens to avoid, nor did they feel information had to be provided each time about the day-to-day management of food allergy.

Discussion

An opportunity for community pharmacists to assist newly diagnosed food-allergic patients or their caregivers was documented in this study. Food-allergic patients or their caregivers report that prescriber-provided food-allergy education and auto-injectable epinephrine training is incomplete, and in some cases absent, at the time auto-injectable epinephrine is first prescribed. An initial prescription for auto-injectable epinephrine often follows a patient's first allergic incident, so patient/caregiver knowledge about food allergy and its relief at this point can be quite limited. These initial prescriptions are being dispensed by community pharmacies, where oral education about food allergy and training in the administration of auto-injectable epinephrine are largely absent. The experience of an initial allergic reaction can be daunt-

Table 4. Confidence of Food-Allergic Patients or Their Caregivers in Aspects of Managing Food Allergy

Statements	Level of Confidence			
	Extremely Unconfident No. (%)	Unconfident No. (%)	Confident No. (%)	Extremely Confident No. (%)
<i>How confident do you feel in your:</i>				
Ability to recognize the signs of allergic reaction (n = 1,886)	14 (0.7)	149 (7.9)	1,284 (68.1)	439 (23.3)
Ability to administer correctly the epinephrine auto-injector (n = 1,885)	38 (2.0)	392 (20.8)	1,198 (63.6)	257 (13.6)
Day-to-day management of food allergy (n = 1,885)	17 (0.9)	183 (9.7)	1,371 (72.7)	314 (16.7)

Table 5. Attitudes of Food-Allergic Patients or Their Caregivers Toward Pharmacist-Provided Food-Allergy Education and Auto-injectable Epinephrine Training

Statements	Mean $\pm$ SD (No.) ^a
Pharmacists are qualified to counsel about food allergies (i.e., provide education and training).	2.54 $\pm$ 0.85 (1,884)
When I pick up the epinephrine auto-injector, the pharmacist should counsel me, without asking me or waiting for me to ask.	3.64 $\pm$ 1.04 (1,883)
A pharmacist who tried to talk with me about food allergies would be wasting my time.	2.32 $\pm$ 0.90 (1,990)
The only one who should counsel me about food allergies is a medical doctor.	2.46 $\pm$.05 (1,882)
I would welcome the chance to update my knowledge and skills about food allergies by talking with a pharmacist.	3.64 $\pm$ 0.93 (1,881)
The only thing that pharmacists should do for the food allergic is dispense their prescriptions.	2.23 $\pm$ 0.88 (1,873)
Grand mean of above items, reflecting respondents' overall attitude. ^b	3.47 $\pm$ 0.63 (1,886)

^aMeasured on a 5-point Likert scale: 1, strongly disagree; 2, disagree; 3, neither agree nor disagree; 4, agree; 5, strongly agree.

^bOverall mean was first computed for each respondent by reversing the score for negatively worded items, determining the individual's mean, and then taking the grand mean of all respondents' means.

ing and is often associated with extreme anxiety and a range of other emotions⁸ that could get in the way of patients or caregivers availing themselves of the opportunity to be educated and trained by the pharmacist. Furthermore, pharmacists may not be initiating counseling depending on the intensity of the state's counseling regulation, busyness of the pharmacy, and age of the pharmacist (younger pharmacists are more likely to provide oral risk information).¹¹ In the past, availability of placebo units for training purposes may have presented a barrier to patient education; however, epinephrine auto-injectors are now available in packaging that contains a demonstration unit.¹²

Food-allergic patients or their caregivers are reading the written information that is being dispensed with their prescriptions at the pharmacy. The majority of food-allergic patients or their caregivers report they have eventually come to feel confident in their ability to recognize the signs of allergic reaction, their ability to administer correctly the auto-injectable epinephrine, and managing their food allergy on a daily basis. Out of necessity these patients or their caregivers must quickly become adept regarding these aspects of their food allergies. Community pharmacists are in a position to fill the gaps in the patient's/caregiver's knowledge and assist in building confidence. When presented with the idea of pharmacist-provided education and training, food-allergic patients or their caregivers are in retrospect receptive.

Community pharmacists should consider working collaboratively with pediatricians and allergists who do not provide education and training at the time an initial prescription order is written for auto-injectable epinephrine. Similar patient care activities have been implemented in community settings for a variety of clinical areas including immunizations, dyslipidemia, diabetes, asthma, and obesity.¹³ Furthermore, information is available on how to establish compensation for such services in the community setting.¹³

An opportunity for community pharmacists to assist food-allergic patients or their caregivers on an ongoing basis was also documented in this study. At refill time, these individuals would

benefit from retraining in the use of the epinephrine auto-injector and a review of the signs of allergic reaction. While they are not in the habit of requesting refill counseling, routine review of these areas is considered a necessity by the food allergic or their caregivers.

Limitations

The results of the current study are limited by the survey research methodology, which resulted in a response rate of 36.5%. Nonresponder data could not be collected because of the anonymous nature of the study. The retrospective nature of the study made it subject to recall bias.

Table 6. Opinion of Food-Allergic Patients or Their Caregivers About Necessary Elements of Routine Refill Counseling for Epinephrine Auto-injectors

Statements	Necessary No. (%)	Unnecessary No. (%)
<i>When picking up refills for the epinephrine auto-injector, how necessary do you feel it is for pharmacists to provide:</i>		
Review of signs of allergic reaction (n = 1,814)	989 (54.5)	825 (45.5)
Review of how to use auto-injector (n = 1,843)	1,462 (79.3)	381 (20.7)
Review of foods and allergens to avoid (n = 1,766)	484 (27.4)	1,282 (72.6)
Information about day-to-day management of food allergy (n = 1,766)	588 (33.3)	1,178 (66.7)

Conclusion

Community pharmacists have an opportunity to assist newly diagnosed food-allergic individuals by working collaboratively with their pediatricians and allergists. Community pharmacists can provide ongoing assistance at refill time by retraining patients in the use of the epinephrine auto-injector and reviewing the signs of allergic reaction. Given the minimal amount of time and effort required of community pharmacists to provide this service, the potential benefit for the patient can be lifesaving.

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"Castle Rock" • At 37,000 feet east of Moab, Utah (an inversion left the valleys shrouded and caused buttes to appear as islands in a cloud sea) • January 2004 • Peter Van Zile, PharmD

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