

Parental use of EpiPen for children with food allergies

Jennifer S. Kim, MD,^a James M. Sinacore, PhD,^b and Jacqueline A. Pongracic, MD^a

Chicago and Maywood, Ill

Background: EpiPen is often underused in children with food allergy experiencing anaphylaxis.

Objective: We explored whether underuse of EpiPen might be attributed to parental discomfort with administration, as measured by a lack of parental empowerment and knowledge of proper administration.

Methods: A written survey was mailed to parents of children with food allergy. Those children with physician-diagnosed food allergy who had been prescribed EpiPen were included in the analysis. Parents were recruited from a local food-allergy support group and private allergy practice. Perceived comfort with administering EpiPen was measured by using a 10-cm visual analog scale. Knowledge of EpiPen use and anaphylaxis was tested by using a series of multiple-choice questions. Empowerment was measured with a 16-item instrument that included statements from the Family Empowerment Scale. Multiple regression analysis was used to determine how much of the variance in the comfort ratings could be explained by knowledge, empowerment, and other factors assessed in the survey.

Results: Of 360 mailed surveys, 165 (46%) completed surveys met the inclusion criteria and were analyzed. Anaphylaxis was reported in 42% of children (n = 70); 8% of parents (n = 14) had administered EpiPen to their child. Factors correlating with comfort included prior administration of EpiPen ($P = .009$), EpiPen training ($P = .005$), and empowerment ($P < .0005$). Neither a history of anaphylaxis nor knowledge correlated with an increased level of comfort with administration.

Conclusions: Empowerment directly correlated with increased comfort with EpiPen use, but knowledge did not. Physicians should continue to instruct all parents on EpiPen administration because this correlated significantly with comfort. Other psychological factors beyond empowerment might contribute to underuse of EpiPen. (*J Allergy Clin Immunol* 2005;116:164-8.)

Key words: Food allergy, anaphylaxis, self-injectable epinephrine, adrenaline, EpiPen, training, empowerment, comfort

Food allergy affects up to 6% of children,¹ and reactions can be fatal. Anaphylaxis is a serious and potentially life-threatening event. IgE-mediated food hypersensitivity is the most common cause of anaphylaxis in children outside of the hospital setting.² Mortality is uncommon but does occur.³ Appropriate treatment consists of early administration of injectable epinephrine, which might be life-saving by reversing, delaying, or halting the progression of anaphylaxis. Proper treatment depends on the following: (1) availability of the medication in a convenient delivery system, such as EpiPen (Dey, Napa, Calif); (2) knowledge regarding indications for its use; and (3) technically accurate use of the device. Previous studies have revealed deficiencies in parental knowledge surrounding indications for EpiPen use, as well as methodological aspects of its administration.⁴⁻⁶

Several studies have described infrequent use of EpiPen in children with recurrent episodes of anaphylaxis.⁴⁻⁶ In one retrospective telephone survey of children attending a specialist allergy service,⁴ EpiPen was used in only 29% of recurrent anaphylactic reactions. Parents were found to be deficient in their knowledge of the symptoms of anaphylaxis, as well as the use of the device itself. Another survey of EpiPen use in patients with a history of anaphylaxis⁵ revealed that 84% of parents proved to know the circumstances for which EpiPen was indicated, but only a minority (37%) demonstrated proper administration. Yet another report⁶ found that only 21% of study families correctly demonstrated the use of EpiPen.

In addition to deficiencies in knowledge, given the critical nature of anaphylaxis, there could be a psychological component (eg, fear or anxiety) that contributes to the underuse of EpiPen. Prior studies⁷⁻⁹ suggest that there are psychological characteristics that have an effect on overall quality of life. The available studies in the medical literature exploring the effect of childhood food allergy report that quality of life appears to be diminished in this population. Primeau et al⁷ evaluated the psychological burden as perceived by parents of children with peanut allergy and compared them with parents of children with rheumatologic disease. Parents of children with peanut allergy were found to have significantly more disruption in their daily activities. Sicherer et al⁸ explored parental

From ^athe Departments of Pediatrics, Northwestern University Feinberg School of Medicine, Chicago, and ^bthe Department of Preventive Medicine and Epidemiology, Loyola University Stritch, School of Medicine, Maywood.

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Reprint requests: Jennifer S. Kim, MD, 2300 Children's Plaza, #60, Chicago, IL 60614. E-mail: jskim@childrensmemorial.org.

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Abbreviations used

FES: Family Empowerment Scale
IDDM: Insulin-dependent diabetes mellitus

perceptions of their child's physical and psychosocial functioning (by using the Children's Health Questionnaire or CHQ-PF50, a generic instrument designed to measure health-related quality of life). Parents of children with food allergy scored lower on several scales. They had a lower perception of overall health and illness, and they had more distress and worry concerning the child's condition. Parents of children with food allergy also reported interruption in usual family activities and increased family tension as a result of the child's health. Moreover, when compared with children with insulin-dependent diabetes mellitus (IDDM) in another study,⁹ children with peanut allergy reported being more fearful of an adverse event and having more anxiety about eating, especially away from home.

Furthermore, a parent's sense of empowerment as a psychological resource appears to contribute significantly to a higher level of adherence to treatment when examined among mothers of children with IDDM.¹⁰ Appropriate use of EpiPen constitutes proper treatment of food-induced anaphylaxis, although the outcome is more difficult to measure than glycosylated hemoglobin for patients with IDDM. The referenced Israeli study¹⁰ used, among other validated questionnaires, the Family Empowerment Scale (FES),¹¹ an instrument originally designed for families of children with emotional disabilities. FES standardization was based on subjects solicited from organizations for parents of children with emotional, behavioral, or mental disorders. However, the questions and subscales also appear to have face validity for families whose children have chronic health conditions.

Our study examined the extent to which experiential, historical, and psychological characteristics are related to the care of the child with food allergy, specifically in a projected crisis situation, such as anaphylaxis. Families living with food allergy are burdened by the task of strict avoidance, concern for potential cross-contamination, and fear of accidental exposure. We wondered whether the psychological effects of such a burden also interfered with the ability to carry out a predetermined emergency plan, specifically administration of epinephrine.

We also examined parental knowledge of EpiPen administration and its indications. We sought to understand whether basic knowledge, prior experience, and psychological characteristics (eg, a sense of empowerment) could identify parents who are and who are not likely to use epinephrine when necessary. We also attempted to characterize specific fears about administration. We hypothesized that parental empowerment in addition to knowledge of proper use are predictors for a higher comfort level with the administration of EpiPen to the child.

METHODS

Study participants

Parents of children with food allergy were recruited through mailings to members of a local suburban food-allergy support group and to patients of a private pediatric allergist's practice. Inclusion criteria required physician-diagnosed food allergy, and all patients must have been prescribed EpiPen for home use. Participants were limited to parents, and children were not surveyed. Survey data were limited to one child per parent; if surveys had been completed for multiple children from the same parent, only the oldest child's data were included. The study was approved by the Children's Memorial Hospital Institutional Review Board, and written informed consent was obtained.

Survey

The survey, mailed to 360 families, was self-administered, and parents were instructed to return the completed questionnaire in the provided self-addressed stamped envelope. The questionnaire collected demographic information and medical history, which included a prior self-reported history of anaphylaxis (defined as a "life-threatening allergic reaction"), past experience with EpiPen use, and knowledge of indications for use. Data from completed surveys were collected between June and August of 2003.

Knowledge about EpiPen use and anaphylaxis was based on answers to a set of multiple-choice and true-false queries, with a maximum possible score of 24 points. The questions addressed symptoms of anaphylaxis, actions taken after EpiPen is given, and technical steps necessary for proper administration.

Perceived comfort with future EpiPen administration was measured with a 10-cm visual analog scale that was anchored with "uncomfortable" at one end and "very comfortable" at the other. Parents were instructed to place an "x" on the straight, unmarked line to indicate how comfortable they believed they would be in the event they had to administer an EpiPen to their own child should a crisis occur. The comfort score was defined as the distance from the beginning of the line to the denoted "x" measured to the nearest 0.1 cm. The maximum possible comfort score was 10.0, which indicated that the parent was very comfortable with a future EpiPen administration.

Parents were asked to respond to a set of 36 statements to assess empowerment. Eight of these were taken directly from the FES,¹¹ a validated instrument. One of these statements is as follows: "When problems arise with my child, I handle them pretty well." Another 5 statements were modified from the FES to make them medically relevant. For example, the original FES statement "I am able to make good decisions about what services my child needs" was modified to read "I am able to make good decisions about what my child needs medically." It should be noted that work by Koren et al¹¹ has demonstrated good psychometric properties for the FES. They report the mean internal consistency (coefficient α) across all subscales as 0.87 and the mean test-retest reliability as 0.83. In addition, they demonstrate the construct validity of the FES by showing how the instrument was able to differentiate families involved in advocacy-related activities from those who were not.

The remaining 23 statements, modeled from the FES, were designed by the first author (JK) to assess one's sense of empowerment in handling a child who has the potential to have a life-threatening allergic reaction. Two examples of these statements are as follows: "I can calmly handle a crisis situation involving my child" and "I am decisive and act quickly." Responses to all 36 empowerment statements were recorded on a 7-point scale anchored with "not characteristic of me" on one end and "very characteristic of me" on the other.

Food allergy, dermatologic diseases, and anaphylaxis

TABLE I. Statements that were added to the FES

I can calmly handle a crisis situation involving my child.
I am confident in my abilities to protect my child from danger.
I trust my physician.
I am decisive and act quickly.

Responses to these statements were recorded on a 7-point scale anchored with "not characteristic of me" on one end and "very characteristic of me" on the other.

The 36 items were used to compute Cronbach's coefficient α , a measure of internal consistency, to develop an empowerment score. Items were dropped one by one until the coefficient was maximized. As a result, 16 statements remained that yielded an α value of .91. By using these 16 items, the maximal empowerment score was 112. Four of these statements were ones specifically designed for this study and are shown in Table I.

Statistics

Simple frequencies and percentages were computed to report most of the findings from the food-allergy survey. In addition, a multiple regression analysis was conducted to examine the relationship between perceived parental comfort with a future EpiPen administration and 6 predictor variables: (1) whether the parent was experienced with EpiPen administration, (2) whether the parent had made a prior EpiPen judgment error (ie, whether a physician told the parent that EpiPen should have been used in a prior situation but it was not), (3) history of anaphylaxis, (4) whether the parent was trained in the use of EpiPen, (5) parental knowledge of anaphylaxis symptoms and EpiPen use, and (6) parental empowerment. These predictors were chosen because they are experiential, historical, and psychological variables that were believed to be associated with parental comfort with a future EpiPen administration.

To estimate the required sample size for the regression analysis, we assumed that the 6 predictor variables collectively would explain about 25% of the variance in comfort ratings. Moreover, we estimated that each predictor variable would account for about 4% of the variance in those ratings. With an α level of .05, computations indicated that 154 subjects were required to have 80% power for detecting the expected associations.

RESULTS

Surveys were returned by 170 families. Three surveys were returned without signed consent forms, and 2 subjects had food allergy but had not been prescribed EpiPen. These surveys were not included in the data analysis. Hence 165 completed surveys with signed consent were included in the study, for a response rate of 46% (165/360).

The vast majority of respondents were married white mothers who held college or graduate degrees (Table II). The only minority represented were Asians, who made up 5% of our sample. There were no Hispanics or African-Americans among the respondents. The mean parental age was 37.4 years (SD, 4.64; range, 29.6-55.8 years).

The children were ages 1 to 19 years, the majority of whom were male and younger than 5 years of age (Table II). Only 2 of the children were in high school. Anaphylaxis was reported in 42% of children ($n = 70$), most of whom had a single experience. Of those, 29 (41%

TABLE II. Demographic characteristics of respondents and children

	N	%
Respondent		
Mother	161	98
White	155	94
Married	160	97
College or graduate degree	153	93
Full-time homemaker	88	53
Prior EpiPen administration	14	8
Child		
Male	106	64
Age <5 y	96	58
History of anaphylaxis	70	42
Allergic to > 1 food	131	79

TABLE III. Frequency of specific food allergies reported by parents

Allergen	N	%
Peanut	140	85
Tree nut	87	53
Egg	78	47
Cow's milk	69	42
Soy	24	15
Shellfish	24	15
Fish	21	13
Wheat	20	12
Other*	52	32

*Sesame was most commonly reported ($n = 10$).

of 70) children had 2 or more total episodes of anaphylaxis (one parent reported 7). Fourteen (8%) parents reported they had administered EpiPen to their child. Fourteen parents also reported that their physicians told them they should have used EpiPen in a prior situation when they did not. The most commonly cited reasons for not using EpiPen were "I recognized the symptoms but gave Benadryl first" (71%, $n = 10$) and "I did not think the reaction was serious" (50%, $n = 7$).

The most common food allergen reported was peanut (85%), followed by tree nuts (53%; Table III). Thirty-two percent of parents reported a food allergy in their child other than or beyond the 8 most common, which included peanut, tree nuts, egg, milk, soy, shellfish, fish, and wheat. The most commonly reported food in the "other" category was sesame seed ($n = 10$), followed by mustard ($n = 3$). Other foods were reported singly.

One hundred thirty-seven (83%) parents reported that they had been trained on how to use EpiPen (109 had been educated with an EpiPen trainer). Physicians and nurses were responsible for 47% and 36%, respectively, of parents' initial education. Only 48% of parents reported having reviewed EpiPen administration within the prior 12 months, most commonly with a nurse (44%) or a physician (35%). Seventy-eight percent of parents reported carrying EpiPen with them always or almost

TABLE IV. Frequency of parents who correctly answered items about EpiPen administration

Item	N	%
Cannot reuse after initial injection	165	100
No refrigeration needed	165	100
Cannot store in glove compartment of car	157	95
Remove grey cap before administration	157	95
Clothing need not be removed prior	153	93
Inject in outside part of thigh	151	92
Replace if liquid appears brown	146	88
Press until clicking sound is heard	131	79
Hold for 10 seconds after injection	115	70

always, whereas 7% admitted to hardly ever having EpiPen with them.

Knowledge of the symptoms of anaphylaxis is presented in Table E1 (available in the Journal's Online Repository at www.mosby.com/jaci). Parents were asked to consider each item as if it was the only symptom or sign present at the time of their decision to administer EpiPen. More than 75% of parents were able to identify most laryngeal or respiratory symptoms, although less than half cited hoarseness or repetitive cough as symptoms of anaphylaxis. One quarter of parents indicated that urticaria was a symptom of anaphylaxis.

When surveyed regarding the technical aspects of EpiPen administration, the vast majority of parents answered these questions correctly (Table IV). Knowledge of what to do after EpiPen administration also was assessed. Most parents correctly answered "call 911" (77%), "go to the emergency department" (65%), or both. Multiple answers were allowed. Only 1% (n = 2) claimed they would self-monitor the child's response to the injection before taking further action.

Knowledge scores ranged from 8 to 24 (mean, 16.5; SD, 3.5). Empowerment scores ranged from 76 to 112 (mean, 95.7; SD, 10.2), and perceived comfort ratings spanned the full width of the 10-cm visual analogue scale (range, 0-10 cm; mean, 6.6 cm; SD, 2.9). There were 75 parents who, in addition to their comfort rating, believed that they would feel outright uncomfortable in administering EpiPen to their child. Of those, 38 (51% of 75) noted that the reason for discomfort would stem from their not being able to recognize the symptoms of anaphylaxis. Thirty (40%) feared hurting their child, and 27 (36%) thought they would forget how to use EpiPen in a high-pressure situation.

The multiple regression analysis revealed that an adjusted 28% of the variance in parents' comfort ratings was explained collectively by the set of predictor variables (F [6,156] = 11.22, $P < .0005$). The negative regression coefficients in Table V show that those who had not administered EpiPen in the past and those who had not been trained on its use had lower comfort ratings. On the basis of the partial correlation coefficients, the strongest association was found with empowerment. In fact, empowerment (partial $r = 0.39$) accounted for about half of the total explained variance in comfort ratings (0.39²/

TABLE V. Results of the multiple regression analysis explaining the variance in patients' comfort with a future EpiPen administration

Predictor	β	Partial r	t	P value
Prior EpiPen administration	-0.196	-0.21	-2.64	.009
Prior EpiPen judgment error	0.125	0.14	1.79	.076
History of anaphylaxis	-0.009	-0.00	-0.12	.907
Trained to use EpiPen	-0.199	-0.22	-2.83	.005
Knowledge	0.113	0.13	1.62	.107
Empowerment	0.365	0.39	5.33	<.0005

The analysis of variance for regression was significant: F (6, 156) = 11.22, $P < .0005$, and adjusted $R^2 = 0.28$.

0.28 = 0.54). As one would expect, parents with higher empowerment scores had higher comfort ratings.

Knowledge of anaphylaxis symptoms and EpiPen use, as well as history of anaphylaxis, was not significantly associated with comfort ratings. Prior EpiPen judgment error was near significance ($P = .076$), but the partial correlation coefficient (partial $r = 0.14$) was too low to consider the variable important.

DISCUSSION

Self-injectable epinephrine, currently available in the form of EpiPen and EpiPen Jr in the United States, is a critical element of the treatment plan for IgE-mediated food allergies. There are an estimated 150 deaths per year in the United States attributed to anaphylaxis caused by food allergy.³ The median time to respiratory or cardiac arrest was found by one study¹² to be 30 minutes for food anaphylaxis. Bock et al³ reported on 32 fatalities, but it could be confirmed that epinephrine was available for use at the time of the reaction in only 10% (3/32) of the cases. Other retrospective studies confirm underuse of epinephrine, as well as inappropriate dosing or administration.¹³ Knowledge regarding administration among our cohort was surprisingly not a significant factor contributing to a parent's comfort in administering EpiPen. We acknowledge, however, that a self-administered survey might not be as sensitive a measure as a face-to-face interview or demonstration.

Although knowledge did not prove to be a significant contributor to parental comfort, our study shows that training parents how to use EpiPen is an important component to improving parental comfort in treating their child. We highly recommend using an EpiPen trainer as a visual and tactile tool to demonstrate administration. One survey of physicians¹⁴ revealed that 81% of participants did not have a placebo trainer to educate their patients. Physicians and their staff in the outpatient office setting should give priority to such instruction, and a demonstration with each return visit would reinforce correct technique and promote discussion regarding use.

Although parental knowledge of the symptoms of anaphylaxis and use of EpiPen was not a significant variable in our survey, we still believe that arming parents

with such information is vital for the proper care of the child with food allergy. The influence of a pediatric allergy clinic has been shown to significantly improve parental knowledge of EpiPen use.¹⁵

In this study parental comfort with EpiPen use correlated the strongest with parental empowerment. Psychological factors are likely to be important in a scenario such as impending anaphylaxis, but these are not fully understood and, consequently, difficult to assess. Interestingly, although prior parental EpiPen administration significantly correlated with parental comfort, a prior history of anaphylaxis in the child did not. These parents recognized that their child had experienced a life-threatening allergic reaction, yet they were uncomfortable with the idea of administering EpiPen. This suggests that fear might be a psychological component that paralyzes instead of enables a parent to act accordingly in the event of anaphylaxis in their child. Prior studies^{7,8} have confirmed the psychological effect that food allergy has on quality of life. These intellectual and emotional burdens that affect aspects of daily living might also impair a parent's response to an acute life-threatening event.

Admittedly, our cohort was not a representative group because the vast majority were characterized as well-educated, married white mothers who were mostly members of a suburban food-allergy support group. However, our study sample was similar to the one used to norm the FES; a majority of parents in the sample were white women with a mean age of 40 years. We were surprised that knowledge did not affect comfort, even in a well-educated group of parents, despite adjunctive collaboration with a support group. Perhaps there are psychological factors specific to socioeconomic status or support group participation.

In addition to the homogeneity of our sample, there was a paucity of the number of adolescents represented in this study. Only 2 children were in high school. Of note, adolescence is a risk factor for fatal anaphylaxis.³ Our study focused on parental attitudes, but the young adult and teenage group would be of particular interest to direct future investigations.

This is the first study that sought to identify psychological factors that might influence EpiPen administration by parents to their children with food allergy. Previous cross-sectional surveys and evaluative studies have frequently reported that parents use epinephrine auto-injectors incorrectly,^{4-7,12} despite education at the time of EpiPen prescription.⁴ Our findings in this self-administered survey suggest that parental sense of empowerment might also significantly affect the use of epinephrine.

In conclusion, food allergy and the potential for anaphylaxis is a significant problem that has no easy

solution. Families must balance daily living with the constant threat of a potentially life-threatening exposure. Being prepared to face such an event requires acceptance that anaphylaxis might occur and taking ownership of knowing how to administer treatment, which includes EpiPen. This study explored how parents projected themselves to feel and respond to this situation. We have shown that there are factors that can improve on parental comfort, such as training the parents in proper use of the EpiPen device. We would encourage all health care providers to ensure that such instruction is given at every opportunity. Other means to help parents empower themselves will need to be explored in future studies.

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