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Incomplete and incorrect epinephrine auto-injector training to food-allergic patients by pharmacists in the Netherlands

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ABSTRACT

Background: Successful treatment of anaphylaxis in the community relies on early and correct use of epinephrine auto-injectors (EAI). In the Netherlands pharmacists supply EAI to patients and have a crucial role in instructing patients in how and when to use EAI. However, there are currently no data in Europe on the quality of such instruction provided by pharmacists. Therefore, the aims of this study were to investigate the knowledge, attitudes, and beliefs regarding food allergy among pharmacists in the Netherlands, and to investigate the quality of EAI instructions and demonstrations to patients by pharmacists.

Methods: Pharmacists were asked to complete an online questionnaire. Quality of instructions and demonstration accuracy were assessed in mystery guest visits to randomly selected pharmacies. For the statistical analysis descriptive methods were used.

Results: In total 25 out of 115 questionnaires were completed. Only two (8%) respondents gave correct answers concerning the proper EAI demonstration. Twenty-one (84%) respondents thought that the provision of instructions was the responsibility of pharmacists. In total, ten pharmacies were included in simulated patient visits. Five of them (50%) demonstrated the EAI. None of them demonstrated the EAI use correctly.

Conclusion: Food-allergic patients at high risk for anaphylaxis who receive their EAI from a community pharmacy are often not instructed on how to use an EAI or receive incorrect instructions. Pharmacists show considerable gaps in knowledge about food allergy and its management. These data suggest that opportunities exist to improve the quality of care provided by pharmacies to high risk food-allergic patients.

KEY WORDS

anaphylaxis

demonstration

epinephrine auto-injector

food allergy

pharmacies

ABBREVIATIONS USED

EAI(s)	Epinephrine Auto-injector(s)
GP(s)	General practitioner(s)

INTRODUCTION

The need for improved epinephrine auto-injector (EAI) training has been a recurring theme in the literature on anaphylaxis(1-3). Anaphylaxis usually occurs in the community, and therefore, all food-allergic patients at risk for anaphylactic reactions as well as their parents (and other caregivers) should be provided with educational resources. Training should cover avoidance strategies, recognition of symptoms, and when and how to administer an EAI. Physicians prescribing an EAI should provide such EAI training, although it has been shown that failure to provide this is commonplace(4,5). Pharmacists are obliged to give instructions when they supply medications to patients and Dutch pharmacies charge each patient a certain amount for explaining how the medicine is to be used.

A previous study showed that general practitioners (GPs) in the Netherlands feel that giving instructions about how and when to use an EAI is the responsibility of pharmacists(6). Therefore pharmacists have a crucial role training patients in how and when to use an EAI. However, there are currently no data on the quality of instructions given by pharmacists regarding the use of the EAI. Studies in this area are limited to evaluation of EAI demonstration rates and open assessment of EAI demonstration steps(7-12). There is, to our knowledge, no study assessing real-world EAI instructions and demonstrations by pharmacists in Europe(13).

Our primary aim was to investigate the knowledge, attitudes, and beliefs regarding food allergy and anaphylaxis among pharmacists in the Netherlands as the

quality of instructions, on which there is currently no data, may depend on such knowledge.

Secondly, we aimed to investigate how accurately community pharmacists in the Netherlands demonstrate how and when to use an EAI to patients.

METHODS

Study population

The study population consisted of pharmacists and pharmacy assistants who were currently working in a pharmacy in the Northern part of the Netherlands.

Pharmacies were recruited through two associations: (1) the Frisian Pharmacists Association (Frieze Apotheken Vereniging (FAV)) and (2) Groningen Pharmacists Association (Groningen Apotheken Vereniging (GAV)). These associations represent all pharmacies of the Dutch provinces Friesland, Groningen and Northern part of Drenthe. The pharmacists were asked to complete an online questionnaire and to participate in a mystery guest visit. This study was conducted between March-October 2015. Participation was voluntary.

Study procedures

Pharmacists were invited to participate in this study by a personal invitation by e-mail containing a hyperlink to the online questionnaire and were asked for their informed consent for a mystery guest visit at their pharmacy. After entering the website, the participants were asked whether they were currently practicing or not. If this question was completed affirmatively, the survey started automatically. Pharmacies were informed that the results of the mystery guest visit would be used to improve quality of care. No information about the study and purpose of the visit

was revealed. A random sample of pharmacies who gave their informed consent to a mystery guest visit was selected. For the mystery guest visit a fixed scenario was used and data collection tool capturing demographic variables (type/location of pharmacy, hour of visit, total number of personnel, number of waiting patients, gender and estimated age), and self-injectable epinephrine variables (materials used for demonstration, use of references, steps used in demonstration, errors or omissions in demonstration and other advice provided). Prior to the study, the usability of the scenario was assessed. The data collection tool was evaluated for usability in a round-table discussion.

Online questionnaire

The questionnaire used for this research was previously used in a study of general practitioners(14), and was adapted for pharmacists in this study. A pre-test was performed with two pharmacists. They were asked to complete the online questionnaire and comment on the content and format of the questionnaire. After this pre-test, the online questionnaire was modified slightly based on their comments. Changes were made to the wording of some of the questions, but not to the content. All data was entered into a database. During the study, an independent auditor cross-checked data entered in the database. Data in disagreement were corrected in the database prior to analysis.

The questionnaire contained 56 questions to investigate food allergy knowledge, EAI experience, and attitudes and beliefs among the pharmacists. The questionnaire was divided into four categories: (1) participant characteristics (n=8); (2) knowledge items (n=34); (3) EAI experience items (n=11), and (4) attitudes and beliefs items (n=3).

Characteristics of participating pharmacies

Data on the characteristics of participating pharmacies were collected. Of the eight participant characteristics items there were four items regarding personal characteristics, three items regarding work related issues, and one item regarding a food-allergy related issue.

Pharmacists' knowledge

Of the 34 knowledge items, one item had multiple responses and the other items were multiple-choice questions. In addition, participants were able to answer every knowledge item with '*I don't know*'. Overall knowledge scores of participants were calculated by counting all correctly answered knowledge items. Percentages of participants who answered the individual knowledge items correctly and incorrectly were calculated.

Pharmacists' EAI experience

Of the eleven experience items, three items consisted of a multiple-choice question, two items consisted of multiple-choice scaling (yes/no/don't know/not applicable), and two items consisted of multiple-choice scaling (never/now and then/sometimes/almost always/always). In addition, participants were able to answer every EAI experience item with '*I don't know*' or '*not applicable*'. Overall EAI experience scores of participants were calculated by counting all correctly answered EAI experience items. Percentages of participants who answered the individual EAI experience items correctly and incorrectly were calculated.

Pharmacists' attitudes and beliefs

Of the three attitudes and beliefs items, one item consisted of seven statements with multiple-choice scaling (agree/disagree/don't know), one item consisted of a multiple-choice question, and one item consisted of an open-ended question for suggestions or improvements of quality of care for food-allergic patients. Overall knowledge scores of participants were calculated by counting all correctly answered attitudes and beliefs items. Percentages of participants who answered the individual attitudes and beliefs items correctly and incorrectly were calculated.

Mystery guest visits

The scenario for the mystery guest visit was initiated by the mystery guest asking for the pharmacist to fill a prescription for an EpiPen® or Jext®. Pharmacies were randomly assigned to fill a prescription for an EpiPen® or Jext®. The mystery guest practised the role of the simulated patient, and learnt a script so that all responses to the pharmacists' questions were similar. Questions that might be asked by the pharmacist were anticipated and responses practised during a training session. If a pharmacist asked any question beyond those anticipated and for which responses had not been prepared, the mystery guest answered either "I can't remember" or "I don't know".

The mystery guest was a medical student with an allergy to peanut, tree nuts and sesame seeds, and a trained EAI user. She was accompanied by a researcher who was also a medical student, and who observed the demonstration and made an audio recording of the meeting. If the mystery guest recognised the pharmacist or pharmacy assistants on duty, the visit was abandoned and the pharmacy excluded.

The mystery guest would wait and see whether the pharmacist explained how and when to use the EAI. Accurate demonstration of EAI was defined as one that successfully completed all ten steps (Table 1)(15,16). Errors and omissions in demonstration were (voice) recorded, along with materials used for demonstration and any additional advice provided by the pharmacist.

Immediately after the visit the researcher completed a data collection tool and subsequently entered data into a database [SPSS version 20.0, SPSS Inc. Chicago, IL, USA].

Statistical analyses

Statistical analyses were primarily descriptive. Overall knowledge scores and percentages were calculated by counting all correct knowledge -, EAI experience - and attitudes and beliefs items. All analyses were performed using SPSS version 20.0, SPSS Inc. Chicago, IL, USA.

Ethical approval

This study was approved by the local medical ethics review commission who deemed that no further approval was required from the Medical Ethical Committees of the University Medical Centre Groningen. Participants were asked to participate voluntarily in the present study and were only able to enter the online questionnaire after reading the information and instructions page. Completing the online questionnaire after reading this information was taken as an informed consent. Participants were asked in writing to participate in a mystery guest visit and had to reply to give their informed consent.

RESULTS

Study population

In total, 115 pharmacies in the Northern part of the Netherlands were asked to complete an online questionnaire and to participate in a mystery guest visit: 55 through the *Frisian Pharmacists Association* and 60 through *Groningen Pharmacists Association*.

Online questionnaire

Characteristics of participating pharmacies

In total 25 pharmacists completed the online questionnaire (response rate 22%) and were eligible for analysis. The majority of the participants who completed the online questionnaire were female (n=19) and pharmacists (n=20), and also the majority of them had a private practice. Participant characteristics are shown in Table II.

Pharmacists' knowledge

The overall knowledge score of participants was nineteen out of 34, which means that 55% of the knowledge items were answered correctly (Table III). The individual item with the highest score was '*Adrenaline is a natural hormone that is produced by the body*', which was answered correctly by all participants (100%) (Table III). The item with the lowest score was '*What is the highest dose of epinephrine for adults after a severe allergic reaction*', which was answered correctly by one participant (4%) (Table III).

Pharmacists' EAI experience

The majority of participants (52%) filled prescriptions for children over 15 years of age. Twenty-four participants (96%) answered that of all prescriptions that they filled less than five percent was for the treatment of food allergy.

Eleven participants (44%) gave instructions most of the time on how to use an EAI to patients, six participants (24%) sometimes gave instructions and eight occasionally gave instructions. The majority of them did not use an EAI trainer to explain how to use an EAI (88%) and patients did often not get the opportunity to practice themselves with an EAI trainer at the pharmacy (92%).

Seventeen participants (71%) did not instruct patients to consult national reference materials including patients' information websites. Seven participants (29%) always gave flyers to the patient when filling a prescription of an EAI.

Pharmacists' attitudes and beliefs

The majority of the participants (42%) believed that identifying the cause of food allergy is most important to help food allergic patients.

Most participants did not agree with the following statements: *'My education adequately prepared me to care for food allergic patients'*, *'Pharmacists and pharmacy assistants are knowledgeable about food allergy and its management'* and *'General practitioners are more responsible than pharmacists for giving instructions about the EAI to food allergic patients'* (Table IV).

Most participants agreed with the following statements: *'Confident in my ability to care for patients with food allergy and an EAI'* and *'Food allergic patients know how to use their EAI'* (Table IV).

Mystery guest visits

In total, fifteen pharmacies gave their informed consent for a mystery guest visit. Ten of them were selected for a mystery guest visit. All ten of them were included for analysis. Eight pharmacies were asked to fill a prescription of EAI® and two were asked to fill a prescription of Jext®. See Table V for pharmacy and participant characteristics.

Demonstration accuracy and errors

Half of the pharmacists (50%) demonstrated how to use an EAI. Of the pharmacists who agreed to demonstrate how to use an EAI, none of them demonstrated the device (Epipen®) correctly according to the ten step scoring system (Figure 1). One pharmacist demonstrated all steps incorrectly.

The most frequent errors in demonstration were '*massage injection site after use*' (100%) and '*call the emergency number to ask for an ambulance and say 'anaphylaxis'*' (100%). Other common errors were failure to state to press the tip of EAI firmly into mid-anterolateral thigh until a 'click' is heard confirming the injection has started, and incorrect positioning of the thumb over the needle of the EAI.

Demonstration materials and anaphylaxis advice

Of the five pharmacists who demonstrated how to use an EAI three of them (60%) consulted reference materials including books, websites and the device itself prior to attempting to demonstrate. One pharmacist (10%) gave information about how and where to store an EAI, another pharmacist (10%) gave information about the side effects of adrenaline. Two pharmacists (20%) mentioned to regularly check the expiry date of the EAI. None of the pharmacists explained the signs of

anaphylaxis, asked if the mystery guest was aware of the precipitating allergen or checked if the mystery guest had an anaphylaxis action plan.

DISCUSSION

This is the first study to investigate the knowledge, attitudes, and beliefs regarding food allergy among pharmacists in the Northern Netherlands and the quality of EAI use instructions. However, our study showed that there are knowledge gaps about food allergy and its management among these pharmacists in the Netherlands, and that they often give incorrect and incomplete demonstration of EAI use.

Anaphylaxis usually occurs in the community, and thus all food-allergic patients and their family, but also other allergic patients at risk for anaphylaxis, should be provided with educational resources and training about when and how to administer an EAI. A previous study by Saleh-Langenberg et al.(6) showed that general practitioners in the Netherlands feel that giving instructions about how to use an EAI is the responsibility of the pharmacist. Therefore, it is necessary that pharmacists in the Netherlands know about food allergy and its management. Even though most pharmacists reported that they are confident that their knowledge is sufficient to care for food allergic patients, a suboptimal knowledge about food allergy of pharmacists in the Netherlands was found in this study. This is an important addition to the previously reported international lack of allergy knowledge (6,14,17,18).

In addition, pharmacists need to know how to correctly demonstrate the use of an EAI. However, our study shows that of the pharmacists who agreed to demonstrate how to use an EAI, none of them demonstrated the device correctly according to the ten step scoring system. Errors made by pharmacists in this study

are in keeping with other studies(7,9,10,12,13,19,20). For example, van Dijk et al.(21) also showed that when dispensing first or repeat prescription medications at the pharmacy counter, pharmacy staff do provide medication-related information, but this information is incomplete according to the professional guidelines of the pharmacist organization.

Other frequent errors in demonstration were failure to activate the device, to hold it firmly for ten seconds after the injection and incorrect positioning of the thumb. These errors are of concern. The instructions given by the pharmacist may lead to a patient not receiving epinephrine or unintentional injection of epinephrine from these devices. Although the true rate of occurrence of unintentional injection of epinephrine from auto-injectors is unknown, it is said to be increasing(22). These data suggest that opportunities exist to improve the EAI demonstration by pharmacists to food-allergic patients.

Pharmaceutical care in European countries are quite diverse because of legal, political and healthcare systems and because practices have developed in different ways and at different paces in different countries(23-27). To our knowledge there are no studies investigating the knowledge, attitudes, and beliefs regarding food allergy among pharmacist elsewhere in Europe. One may speculate that opportunities to improve EAI demonstrations by pharmacists to food-allergic patients may be also of international concern.

Strengths and limitations

Strength of this study is the use of mystery guest visits. This technique is well described in the literature as a measuring tool (28). By posing as a regular customer, the mystery guest can map experiences and provide practical insights for quality

improvement. Another strength is that we voice recorded the demonstration between the pharmacist and the mystery guest, therefore recall bias was limited to the minimum.

A limitation in this study is the number of pharmacists who filled out the online questionnaire and pharmacists who participated in the mystery guest visits which may limit the generalizability of our findings. However, it remains worrisome that all the pharmacists we studied demonstrated considerable knowledge gaps about food allergy. The mean overall knowledge score of participants was nineteen out of 34, which means that 55% of the knowledge items were answered correctly. If we consider that answering 50% of the knowledge items correctly (cut-off point 50% = chance for guessing) representing sufficient knowledge, only 11 out of 25 pharmacists ((44%)(95% CI: 24-64)) would be considered to have sufficient knowledge. Cut-off points higher than 60% correspond to none of the pharmacists being considered to have sufficient knowledge. Further research is required to quantify the extent of this problem and its generalizability.

Another limitation of this study may be the low response rate on the online questionnaire. Pharmacists who filled out the online questionnaire may be those who feel to be well informed about food allergy and its management this may thus lead to an overestimation of the overall pharmacists' knowledge about food allergy and its management to some degree.

In summary, pharmacists show considerable gaps in knowledge about food allergy and its management. Food-allergic patients at high risk for anaphylaxis who receive their EAI from a pharmacy in the Northern Netherlands are often not or incorrectly instructed on how to use an EAI. Given the importance of timely and correct administration of epinephrine in case of a (severe) food allergic reaction,

improvement of demonstration accuracy is promptly needed. These data suggest that opportunities exist to improve the quality of care provided by pharmacists to food-allergic patients.

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Table I Ten demonstrations steps for EAI

Step	Demonstration
1	Grasps the EAI firmly
2	Has thumb closest to the safety cap
3	Removes safety cap with other hand
4	Holds EAI about 10cm away from injection area or places gently the injector tip against mid-anterolateral thigh
5	Place and press the tip of EAI firmly into mid-anterolateral thigh
6	A 'click' is heard confirming the injection has started
7	Holds the EAI firmly in place for 10 seconds
8	Removes EAI
9	Massages the injection area for 10 seconds
10	Gives instructions to call emergency number to ask for an ambulance and say "anaphylaxis"

Table II Participant characteristics of online questionnaire (n=25)

Characteristic		n(%)
Gender	Male	5 (20.0)
	Female	19 (76.0)
	Total	24 (96.0)
	Missing data	1 (4.0)
Total		25 (100)
Age (years)	25-30	4 (16.0)
	31-35	3 (12.0)
	36-40	4 (16.0)
	41-45	5 (20.0)
	46-50	4 (16.0)
	51-55	1 (4.0)
	56-60	3 (12.0)
	61-65	1 (4.0)
Total		25 (100)
Function	Pharmacist	20 (80.0)
	Pharmacy assistant	5 (20.0)
	Total	25 (100)
Type of pharmacy	Indepenent	14 (56.0)
	Healtcare center based	11 (44.0)
	hospital based pharmacy	0 (0.0)
	Total	25 (100)
Food allergic acquaintance	Yes, him/herself	5 (20.0)
	Yes, spouse/partner/child	1 (4.0)
	Yes, brother/sister, caretaker	0 (0.0)
	Yes, relative/friend	5 (20.0)
	No	14 (56.0)
	Total	25 (100)

Table III Knowledge

Knowledge questions	Answers						Missing data	
	Correct		Incorrect		Don't know			
	N	%	N	%	N	%	N	%
1. How often EAI is prescribed for apple allergy	13	52	12	48	/	/	0	0
2. Food component that causes food allergic reactions	24	96	1	4	0	0	0	0
3. Age group most likely to have food allergy	16	64	5	20	3	12	1	4
4. Timely administration of epinephrine prevents fatal anaphylaxis	18	72	4	16	3	12	0	0
5. Number of EAI's that are prescribed to children <12 years of age	4	16	21	84	/	/	0	0
6. Shelf-life of an EAI after production	6	24	19	76	/	/	0	0
7. Use of EAI after expiry date	16	64	8	32	/	/	1	4
8. Dose of epinephrine, child weight 27 kg	19	76	4	16	2	8	0	0
9. The highest dose of epinephrine for adults after severe allergic reaction	1	4	17	68	6	24	1	4
10. Onset of symptoms after accidental ingestion (time)	3	12	21	84	/	/	1	4
11. Type of injection (intra muscular)	17	68	8	32	/	/	0	0
12. Injection site	17	68	8	32	0	0	0	0
13. Using EAI when allergic reaction is not sure	12	48	12	48	/	/	1	4
14. Duration of holding the EAI firmly in place	16	64	8	32	/	/	1	4
15. Duration of massaging the injection area	12	48	12	48	/	/	1	4
16. Instructions to patients after using EAI	11	44	13	52	/	/	1	4
17. When to use second dose of epinephrine	17	68	6	24	/	/	2	8
18. Law for mandatory labeling of 14 allergenic ingredients on every food label	3	12	16	64	5	20	1	4

19. Asthma is an important risk factor for severe anaphylaxis	16	64	7	28	2	8	0	0
20. Teenagers are at higher risk for fatal anaphylaxis than younger children	5	20	13	52	7	28	0	0
21. Food allergens are passed from maternal diet into breast milk	18	72	4	16	3	12	0	0
22. The number of children with food allergies in the Netherlands is increasing	22	88	1	4	2	8	0	0
23. There are no absolute contra-indications for prescribing an EAI	14	56	7	28	4	16	0	0
24. Instructions on how to use an EAI are shown on the device itself	20	80	2	8	2	8	1	4
25. A holiday destination influences how many EAIs are prescribed to a patient	14	56	7	28	4	16	0	0
26. Adrenaline is a natural hormone that is produced by the body	25	100	0	0	0	0	0	0
27. Law for administering EAI by public employees (e.g. at schools)	15	60	4	16	6	24	0	0
28. Immediate use of EAI after onset allergic symptoms	5	20	14	56	5	20	1	4
29. Daily antihistamine can prevent food allergic reaction	16	64	4	16	5	20	0	0
30. There is a cure for food allergy	20	80	1	4	4	16	0	0
31. An EAI cannot be injected through clothing	21	84	2	8	1	4	1	4
32. Adrenaline tablets can be prescribed to patients having an allergic reaction	25	100	0	0	0	0	0	0
33. Mild allergic reactions before severe life-threatening allergic reaction in 1 out of 10 patients	7	28	13	52	5	20	0	0
34. Three most common childhood food allergens	3	12	22	88	0	0	0	0

Table IV Attitudes and beliefs

Attitudes and beliefs statements	Answers					
	Agree		Disagree		Don't know	
	N	%	N	%	N	%
1. In public places an epinephrine auto-injector should be kept just like an automatic external defibrillator	6	23	11	44	8	8
2. Pharmacists and pharmacy assistants are knowledgeable about food allergy and its management	7	28	8	32	10	40
3. My education adequately prepared me to care for food allergic patients	2	8	20	80	3	12
4. Confident in my ability to care for patients with food allergy and an EAI	14	56	3	12	8	32
5. Food allergic patients know how to use their EAI	19	76	2	8	4	16
6. General practitioners are more responsible for giving instructions about the EAI to food allergic patients	3	12	21	84	1	4
7. Most people take food allergy seriously	16	64	7	38	2	8

Table V Pharmacy and participant characteristics of mystery guest visits (n=10)

Characteristic	n (%)
Pharmacy	
<i>Type/location</i>	
independent	6 (60)
healthcare center based pharmacy	3 (30)
hospital based pharmacy	1 (10)
Mystery guest visit	
<i>Time of visit</i>	
08:00am - 11:00am	6 (60)
11:00am - 02:00pm	4 (40)
02:00pm – 06:00pm	0 (0)
<i>Number of personnel</i>	
1-2	1 (10)
3-4	2 (20)
5-6	4 (40)
7 or more	3 (30)
<i>Number of waiting patients</i>	
1-2	6 (60)
3-4	2 (20)
5-6	2 (20)
Pharmacist	
<i>Gender</i>	
Male	0 (0)
Female	10 (100)
<i>Estimated age (years)</i>	
20-30	3 (30)
31-40	2 (20)
41-50	1 (10)
51-60	3 (30)
60+	1 (10)

Figure 1 Demonstration accuracy and errors (n=5)

