

**Research Article** 

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## Optimizing a Hospital Anaphylaxis Protocol: Our Experience

Leyla Pur Ozyigit<sup>1,2\*</sup>, Tugce Aytulu<sup>1</sup>, Asli Ozyildirim<sup>1</sup>, Ulku Burgess<sup>1</sup> and Ismail Bozkurt<sup>1</sup>

<sup>1</sup>American Hospital, Istanbul, Turkey

<sup>2</sup>Koc University School of Medicine, Department of Allergy and Immunology, Turkey

## Abstract

Anaphylaxis is a severe, life-threatening, systemic hypersensitivity reaction that usually occurs rapidly after contact with an allergy-inducing substance. Due to the underdiagnosing, underreporting and malpractice associated with this condition, anaphylaxis awareness projects are now becoming a priority in some communities. The diagnosis of anaphylaxis is clinical, and intramuscular adrenaline is well known as the first-line treatment of choice for its management. The majority of anaphylaxis deaths occur in a hospital. Therefore, it is important to render hospitals safe places for severe allergic reactions. A hospital anaphylaxis protocol is also mandatory for a better outcome as recommended by guidelines. Consequently, our protocol was planned with the contribution of different specialties, including allergy, emergency medicine, nursing, nutrition and pharmacy. General knowledge was tested among different departments by self-administered questionnaires, and specific education programs were utilized to improve the success of the protocol. The least correctly answered questions were about the rapidity of the occurrence of anaphylaxis, the route of adrenaline auto injector (AAI) administration. However, after education, the level of knowledge increased dramatically among caregivers. We propose that conducting regular education programs for healthcare workers and that implementing appropriate hospital anaphylaxis protocols prepared with multidisciplinary collaborations should be mandatory for the prevention, recognition and treatment of severe allergic reactions.

**Keywords:** Anaphylaxis; Protocol; Drug allergy; Patient safety; Health knowledge

## Introduction

Anaphylaxis is a severe, life-threatening, systemic hypersensitivity reaction that usually occurs rapidly after contact with an allergy-inducing substance [1].

The lifetime prevalence of anaphylaxis is estimated to be 0.05% to 2%, but this number is increasing [2,3]. Underdiagnosing, underreporting and miscoding of anaphylaxis are considerable barriers to correctly estimating its actual prevalence. In a report from hospital emergency departments in the United States, for example, it was reported that 57% of likely episodes of food anaphylaxis did not receive a diagnosis of anaphylaxis [4].

The diagnosis is clinical and requires the involvement of two or more organ systems, including the skin, gastrointestinal tract, airways and circulation, or the acute lowering of blood pressure after exposure to a known allergen for that patient. The clinical criteria are summarized in Table 1.

Anaphylaxis can result in fatalities in 0.65-2.0% of severe cases if not treated rapidly and correctly [5]. Intramuscular adrenaline is well known as the first-line treatment of choice for anaphylaxis, as recommended by all anaphylaxis guidelines [1,6]. Any delay in using adrenaline for the treatment of anaphylaxis has been associated with poorer outcomes [7-9]. However, the usage of adrenaline is infrequent; for example, in pediatric anaphylaxis cases, it has been reported that only 18% of cases utilized adrenaline [10]. The best way to provide first-aid treatment with adrenaline for anaphylaxis in the community is through the use of an auto injector. Two fixed adrenaline doses, 0.15 mg for children weighing less than 15 kg and 0.3 mg for adults, are available in auto injector formulations in most countries.

The proper management of anaphylaxis should also continue after the patient is discharged. Allergen avoidance is the optimal protective strategy against anaphylaxis. Therefore, patients may benefit from a detailed evaluation of the possible sources of anaphylaxis (food, drug, venom, latex, etc.). The prescription of adrenaline auto injector (AAI) devices and instructions for the treatment of new episodes and their prevention are also mandatory for optimal prophylaxis. However, according to one study, the majority (82%) of patients experiencing anaphylaxis did not receive any subsequent care with an allergist/ immunologist in the first year after an emergency department visit and/or hospitalization [11].

Anaphylaxis awareness projects are now becoming a priority in some communities. The areas for improvement in the management of individuals with anaphylaxis have already been defined in previous studies and guidelines. The main goal of these efforts is to teach people to recognize anaphylaxis, use adrenaline as the first-line treatment, prescribe them an AAI, and also to recommend follow-up after discharge, preferably with an allergy/immunology specialist. A hospital anaphylaxis protocol is also necessary for improved outcomes.

Our aim was to establish an anaphylaxis protocol in our hospital. This study summarizes the method that we developed to produce an optimal protocol.

### Methods

The hospital was founded in 1920 and was the first non-profit private hospital of Turkey. It has 262 beds and is equipped to treat medical, surgical and maternity patients.

The anaphylaxis protocol was planned to be the sixth hospital

\*Corresponding author: Leyla Pur Ozyigit, Koc University School of Medicine, Department of Allergy and Immunology, Turkey, Tel: +90 212 338 1176; Fax: +90 212 338 1168; E-mail: sozyigit@ku.edu.tr

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Anaphylaxis is highly lik	ely when any one of the	following 3 crite	eria are fulfilled:				
Acute onset of illness (minutes to several hours) with involvement of the skin, mucosal tissue, or both (e.g., generalized hives, pruritus or flushing, and swollen lips tongue-uvula) And at least one of the following:		Two or more of the following that occur rapidly after exposure to a likely allergen for that patient (minutes to several hours)				Reduced BP after exposure to a known allergen for that patient (minutes to several hours)	
Respiratory compromise (e.g., dyspnea, wheeze- bronchospasm, stridor, reduced PEF, and hypoxemia)	Reduced BP or associated symptoms of end-organ dysfunction (e.g., hypotonia [collapse], syncope, and incontinence)	Involvement of the skin- mucosal tissue (e.g., generalized hives, itch- flush, and swollen lips- tonque-uvula	Respiratory compromise (e.g., dyspnea, wheeze- bronchospasm, stridor, reduced PEF, and hypoxemia)	Reduced BP or associated symptoms (e.g., hypotonia [collapse], syncope, and incontinence)	Persistent gastrointestinal symptoms (e.g., crampy abdominal pain and vomiting)	Infants and children: low systolic BP (age specific) or greater than 30% decrease in systolic BP'	Adults: systolic BP G 90 mm Hg or a 930% decrease from the person's baseline

Low systolic blood pressure for children is defined as less than 70 mm Hg from 1 month to 1 year, less than (70 mm Hg + [2 age]) from 1 to 10 years, and less than 90 mm Hg from 11 to 17 years. PEF indicates peak expiratory flow; BP, blood pressure

Table 1: Clinical Criteria for Diagnosing Anaphylaxis [1].

protocol, with the previous five concerning hip fractures, intoxication, acute strokes, pressure ulcer prevention and treatment, and venous thromboembolism, respectively.

#### Nurses' contribution to the protocol

The gatekeeper in American hospitals is the admitting nurse, who is responsible for identifying any drug, food and environmental allergy/ intolerances or sensitivity during the initial assessment. Patients who have previously been admitted to the hospital and have had allergy/ intolerance data documented during previous hospitalizations will automatically be scheduled for new visits. The admitting nurse then evaluates archived allergy information and updates this information upon each readmission or patient encounter, after verifying the correctness of the information with the patient or next-of-kin. Any patient with known allergies should wear a single red allergy bracelet to act as an "alert" to the practitioner, identifying at the point of care that the patient has an allergy.

Dispensing, ordering or administering medication that the patient is allergic to is considered to be a "medication error".

Our Quality Department has developed specifications for a standard allergy band that is used hospital wide for all inpatients during their stay; this is to prevent safety incidents and near misses. In addition, the Quality Department has also developed the Operating Theatre Guidelines for Latex Allergic Patients. The Floor Charge Registered Nurse and the nurse in charge of the operating room are responsible for ensuring that the guidelines are followed strictly.

After the initiation of the anaphylaxis protocol, a supplementary detailed education was given to 90 nurses after the pre-test questionnaire, and their knowledge was retested anonymously by the same questionnaire immediately after the education program.

The questionnaire was a self-administered 10-item questionnaire measuring overall knowledge about allergic diseases and anaphylaxis.

The education covered the following: the general definition of anaphylaxis; the burden of anaphylaxis in the world; the epidemiology of anaphylaxis; the symptoms and the management of food; drug and latex allergy; AAI (through demonstration with trainer pens); the risk of nurses for a latex allergy; the cross-reactivity between drugs, and their potential to provoke a drug allergy in a sensitized person; the cross-reactivity between some foods and latex, and their potential to provoke a latex allergy in a sensitized person; the role of nurses in drug allergy; and drug desensitization. Overall knowledge of allergy and anaphylaxis was low (35%). The least correctly answered questions were about the rapidity of anaphylaxis onset, the route of adrenaline administration and the method of AAI administration. However, we found an important difference between the initial test scores and the average overall knowledge according to the post-test results, which was high (94.5%).

This education program is now scheduled to be administered at regular two-year intervals.

#### Pharmacy's contribution to the protocol

According to the strategies of our Pharmacy and Therapeutic Committee, each prescription and newly prescribed medication must be reviewed by a licensed pharmacist or technician for appropriateness.

The process for reviewing an order or prescription prior to dispensing includes evaluation by a trained professional of the following:

- a) The appropriateness of the drug, dose, frequency, and route of administration;
- b) Therapeutic duplication;
- c) Real or potential allergies or sensitivities;
- d) Real or potential interactions between the medication and other medications or food;
- e) Variation from organization criteria for use;
- f) Patient's weight and other physiological information; and
- g) Other contraindications.

Prescribed and administered medications are monitored by the caregivers for adverse drug reaction. When adverse drug reactions are observed, they are immediately reported to the Pharmacy to be assessed by the Pharmacy and Therapeutic Committee. After the assessment, the Pharmacy and Therapeutic Committee may decide to remove the reported medication from the Hospital Formulary, to continue monitoring, and/or to take preventative actions. In addition, all observed adverse drug reactions are reported to the Minister of Health as federal laws demand.

#### Diet team's contribution to the protocol

With the purpose of avoiding food allergy, some precautions have already been taken by the hospital kitchen. Patient information is checked closely during the process, portion and food service phases to provide "the correct diet for the correct patient," which is particularly relevant for the patients who have food allergy/intolerance. Allergic patients' foods are prepared in a "diet kitchen", which is a separate part of the hospital kitchen. Materials (knives, gloves, counter, etc.) that may cause allergy and/or contamination during food preparation are used carefully and cleaned before every food preparation process.

The education program was administered to 45 people from the hospital kitchen staff after they filled out the pre-test questionnaire. Their knowledge was then retested anonymously by the same individual, immediately after the education program. The education program covered the general definition of anaphylaxis; the burden of anaphylaxis in the world; the epidemiology of anaphylaxis; the symptoms and the management of food allergy; the cross-reactivity between foods, and their potential to provoke a food allergy in a sensitized person; the role of kitchen staff and nurses with food allergy; and oral allergy syndrome.

The questionnaire was a self-administered 10-item questionnaire measuring overall knowledge about allergic diseases, anaphylaxis and especially food allergy.

Overall knowledge of allergy and anaphylaxis was moderate (60%). However, we found an important difference between the average preand post-test results, which showed a high (90%) overall knowledge.

This education program is now scheduled to be administered at regular two-year intervals.

# Prevention of mortality from anaphylaxis in the emergency or hospital plan

For anaphylaxis diagnosis, the Biochemistry Laboratory has begun to measure the level of tryptase, a mast cell neutral protease, which is a marker of mast cell degranulation and a helpful blood test for the confirmation of diagnosis.

For the accurate management of anaphylaxis, the template for the management algorithm of anaphylaxis, as recommended by the World Allergy Organization, was placed in a visible location in all nurses' stations [12].

The hospital began to use AAI in pediatric and adult forms (0.15 mg [0.15 mL, 1:1000] and 0.3 mg [0.3 mL, 1:1000], respectively) in addition to the usual adrenaline ampoules.

The emergency service staff, doctors and nurses received an education covering the general definition of anaphylaxis; the burden of anaphylaxis in the world; the epidemiology of anaphylaxis; the diagnosis, grading, symptoms and management of anaphylaxis; the cross-reactivity between foods and between drugs in a sensitized person; and the prompt usage of adrenaline auto-injectors.

This education is now scheduled to be administered at regular twoyear intervals.

The standard follow-up period after a recovery from an anaphylaxis event was decided to be 4 hours after a mild (grade one or two) anaphylaxis. However, patients with moderate or severe anaphylaxis, e.g., with respiratory or cardiovascular symptoms and signs, would be observed and monitored for at least 6 hours or would be hospitalized.

Because of the inability to promptly provide an adrenaline autoinjector by prescription in our country, our emergency staff did not prescribe it. Therefore, calling an ambulance and coming to the emergency department was advised for subsequent anaphylaxis events. The AAI can only be prescribed by an allergist and can only be sold under government observance in government pharmacy offices.

Allergist consultation is critically important for those at risk for any form of anaphylaxis to ensure proper education and discussion of prevention strategies [13]. However, the worldwide rates of receiving subsequent follow-up care from an allergist/immunologist after an anaphylaxis event are inadequate. Therefore, the allergist of our hospital prepared an informative leaflet for the patients experiencing an allergic reaction at emergency. This leaflet covered the general epidemiology and causes of anaphylaxis, the rates of the disease and the importance of finding its trigger, the importance of strictly avoiding suspected triggers, the risk of experiencing subsequent anaphylaxis events after an initial one, advice for handling other potential anaphylaxis events and the importance of arranging a consultation with an allergist.

A written anaphylaxis emergency action plan and an emergency wallet card listing relevant confirmed triggers, concomitant diseases, and concurrent medications has been given to all the patients after allergy consultation for the prevention of secondary events.

To monitor protocol compliance, the allergist planned to analyze hospital data for outcomes annually. Any unanticipated events in our hospital resulting in death or serious physical or psychological injury to a patient or patients, not related to the natural course of the patient's illness, are reported immediately. The reported cases related to allergy will be sent to the allergist. The allergist will analyze that data to detect any protocol compliance problems, and a report will be prepared by the Quality Management Office in cooperation with the allergist's findings to be submitted to the general management office of the hospital.

## **Results and Discussion**

Strategies and policies for improving anaphylaxis awareness among caregivers and patients are required to manage the increasing number of severely allergic patients. Because of its rapid onset, unpredictability and life-threatening nature, delayed or incorrect treatment strategies for this condition can be fatal [14].

The limitations of anaphylaxis management include the lack of anaphylaxis symptom recognition, underuse of adrenaline as the first-line treatment, insufficient knowledge regarding AAI and lack of follow-up care instructions and other prevention strategies [15].

The majority of anaphylaxis deaths occur in a hospital [16]. Therefore, it is important to render hospitals safe places for severe allergic reactions. Consequently, this protocol was planned with multidisciplinary collaborations, including the allergy, emergency medicine, nursing, nutrition and pharmacy departments. We herein detailed our hospital anaphylaxis protocol based on current guidelines.

Intramuscular adrenaline is the first-line treatment for anaphylaxis, and delays in its administration or dosing errors have been associated with anaphylaxis fatalities [12,17]. Therefore, for the more rapid and accurate administration of adrenaline, we preferred to use AAI in addition to the usual adrenaline ampoules. The main aim of this strategy was to reduce the administration time and possible dosing or administration errors and to save lives. The secondary aim was to show the patient how to use an AAI in a real-life setting. With this knowledge, patients experiencing an anaphylaxis event are more prone to a recurrence; we expected to see a secondary prophylaxis [18]. Despite the usefulness of AAI, the usage of these prefilled intramuscular dose syringes among hospitals is extremely rare, most likely due to

the increased cost [17]. However, Manivannan et al. have found a significant increase in adrenaline administration after the introduction of a protocol and the inclusion of AAI in hospital stock [19].

Our pre- and post-test questionnaire evaluation demonstrated that education is very important among all caregivers and even for the hospital kitchen staff. The least correctly answered questions were about the rapidity of the occurrence of anaphylaxis, the route of adrenaline administration and the method of AAI administration.

The major suggestions for an anaphylaxis protocol are as follows: to prepare a protocol according to guidelines drafted by a multidisciplinary team that are appropriate for the hospital's capabilities, to educate all caregivers, to standardize general management and the length of follow-up, and to prevent subsequent anaphylaxis by patient education.

In conclusion, as the diagnosis of anaphylaxis is based on clinical criteria, accurate diagnosis is mandatory for proper management. More effort is required for the education of patients and health care workers that adrenaline is the first-line treatment for anaphylaxis. Hospital anaphylaxis protocols are therefore important for assessing strategies and preventing death from anaphylaxis.

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