

Supportive care of patients with anaphylaxis – options and shortcomings: an assessment on behalf of the working group on anaphylaxis training and education (AGATE), Germany

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Abstract

Background: Anaphylaxis is an acute-onset, life-threatening, systemic hypersensitivity reaction. The acute reaction occurs due to a permanently immunologically altered response, which can result in mild to severe reactions and, in isolated cases, to fatal reactions upon allergen contact. The avoidance strategies required lifelong in affected individuals significantly impair quality of life.

Objective and methods: An expert analysis of the supportive care situation of anaphylaxis patients.

Results: The trigger of the reaction – mostly food, insect venom, or drugs – can normally be identified by means of allergy diagnostics. However, allergy workups unfortunately are not always performed in anaphylaxis patients. Unequivocal diagnosis and/or causal classification of the trigger is not always easy, particularly in the presence of

summation factors, such as physical exertion or the use of analgesics or alcohol. Complex cases present too rarely in allergy centers with appropriate experience. Following anaphylaxis patients are given guidance on allergen avoidance and after obligatory instruction from a medical expert, receive a prescription for an emergency self-medication kit. However, studies show that allergen avoidance often fails and patient self-medication is frequently not performed. Therefore, the German working group on anaphylaxis training and education (Arbeitsgemeinschaft Anaphylaxie Training und Education, AGATE) formulated a structured written interdisciplinary educational training program that is currently used in 24 registered centers in Germany. In a multicenter study using control groups, the anaphylaxis training program

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showed significant efficacy in terms of practical emergency management and reduced anxiety. The nationwide implementation of the training program and cost-coverage by statutory health insurances appear reasonable given the potentially life-threatening nature of this disease. Since statutory health insurances have not guaranteed cost-coverage to date, it is not possible to offer the training program to all patients in need.

Conclusion: Subject to region and center, there are good treatment options for anaphylaxis patients in Germany. However, these options are not always sufficiently implemented.

Introduction

Anaphylaxis is a systemic or generalized, life-threatening hypersensitivity reaction of acute onset [1, 2]. It differs from an organ-specific allergy in that it often simultaneously affects several organs systemically and is generally severe. However, there is no fully standardized definition of anaphylaxis in the literature as yet. Internationally, anaphylaxis is generally understood to refer to an allergic hypersensitivity reaction involving two or more organ systems following contact with a known allergic trigger. The German-language guideline refers more to the mechanism of a systemic immediate-type reaction as anaphylaxis and, as such, potentially also one that is a generalized immediate-type reaction limited only to the skin (e.g., generalized flushing symptoms or generalized urticaria following an insect bite) [2, 3]. Anaphylaxis can also be triggered by non-allergic mechanisms, for instance non-steroidal antiinflammatory drug hypersensitivity. Since the same principles apply to these non-allergic reactions as compared to the more common allergic reactions, they are not specifically discussed below.

Strictly speaking, anaphylaxis (anaphylactic reaction) itself refers to a systemic hypersensitivity reaction of short duration. However, the underlying allergy persists for months to years, sometimes lifelong, i.e., in chronic form. The underlying disease is thus the susceptibility to anaphylaxis as a result of an aberrant immune system, involving a permanently altered response in affected patients. This situation can be equated to that of patients with chronic epilepsy, which also involves ongoing susceptibility to acute epileptic reactions.

Acute management of anaphylaxis

Depending on stage, the acute management of severe anaphylaxis comprises: discontinuation of allergen intake, prompt initiation of emergency

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treatment involving the administration of intramuscular adrenaline, as well as antihistamines, glucocorticosteroids, and volume replacement, the immediate discontinuation of allergen contact, and appropriate positioning. The current treatment guideline provides instructions on the symptom-specific treatment of anaphylaxis [2]. With action structures involving different tasks performed by various helpers, treatment is complex and requires the treating physician and team to possess excellent organizational skills. Therefore, the importance of prompt intramuscular administration of adrenaline has been prioritized in the treatment guideline for the first responder [2]. Unfortunately, it cannot be assumed that physicians have the skills to perform optimal treatment; significant deficits still exist in this regard [4]. As in “blue-light professions” such as the fire service and police, smooth functioning is usually only achieved through regular practice. The fact that an “anaphylaxis” module taught by experts has now been introduced in emergency services training should be seen as a significant step forward. Although the training of practice or hospital teams is the responsibility of physicians, it is unfortunately only seldom carried out and appropriate training courses only rarely offered. Needs and/or demand exceed supply in this regard.

Diagnostic methods

The diagnostic work-up of anaphylaxis corresponds largely to that of other hypersensitivity reactions. Due to the particular hazard posed by anaphylaxis, urgent attempts must be made to: identify the trigger by means of an allergy diagnostic work-up, consistently avoid this trigger [5, 6, 7], and, in the case of insect venom allergy, provide specific immunotherapy. Patient history, the identification of sensitization by means of skin or laboratory tests, as well as challenge testing represent the diagnostic meth-

ods of choice; having said that, not all centers have adequate experience with challenge testing and it is often only offered in centers with particular experience. Relevant risk factors (e.g., mastocytosis, bronchial asthma, infections) need to be investigated [2, 8].

A good diagnostic work-up for anaphylaxis requires experience with and knowledge of the typical anaphylaxis triggers, as well as the differential diagnoses. It is essential that this complex diagnosis is performed by an allergist. In most cases, anaphylaxis can be identified by typical clinical symptoms in close temporal relation to contact with a typical trigger. Referral to a university outpatient department with allergy expertise is advisable in complex cases, particularly if differential diagnoses (e.g., somatoform diseases) need to be excluded, special test methods are required, or if the trigger cannot be identified or only identified in conjunction with co-factors. Some anaphylactic reactions, such as wheat-dependent exercise-induced anaphylaxis, only occur when food intake is combined with other co-factors, e.g., physical exertion, analgesic or alcohol use, and infections, and require complex allergy investigations to identify the cause [9]. It is still true to say that anaphylaxis patients all too rarely undergo allergological investigation [10, 11]. It is particularly important to improve the counseling of patients with anaphylactic reactions presenting to emergency outpatient departments and rescue services (particularly referral to an allergist following an acute reaction and, where appropriate, the prescription of an emergency kit).

Hazards posed to anaphylaxis patients

Approximately one in 300 people in Europe will develop at least one severe anaphylactic episode during their lifetime [12], and the incidence of anaphylaxis appears to be rising [13]. Fatalities due to anaphylaxis are estimated at less than 0.1%–1% of all cases of anaphylaxis [1]. The number of annual fatalities due to food-induced anaphylaxis in the US has been put at around 150 [14]. Patients that have already experienced an anaphylactic episode are at greater risk of developing recurrent anaphylactic reactions. Patients, or their parents/guardians, find it challenging to avoid allergens (e.g., cow's milk, hen's eggs, peanut in the case of food-induced anaphylaxis, and insect bites in hymenoptera-venom anaphylaxis). Even in patients with drug-induced anaphylaxis, avoidance is not always successful despite allergy testing, counseling, and the issuing of an allergy passport [15]. It is not possible to reliably prevent bee and wasp stings. Studies show that patients with food-induced anaphylaxis do not always manage complete trigger avoidance or emergency drug administration [16, 17]. The majority of pa-

tients with food-induced anaphylaxis had reacted to the eliciting food in the past [16, 18]. Also in the case of fatal reactions, all patients were aware of their food allergy, but were nevertheless unable to sustain long-term avoidance of the relevant food [17, 19]. Patients often find the required avoidance strategies highly restrictive, particularly in the case of high-grade hypersensitivity where even small amounts of a covertly occurring trigger can elicit severe symptoms. This can be seen as an invisible handicap. On the other hand, patients that remain healthy over a long period of time as a result of successful avoidance encounter skepticism and ignorance in relation to their requirements, thereby putting them at additional risk and further impairing their quality of life.

The interval between allergen exposure and fatal anaphylaxis is generally shorter in the case of parenteral administration of noxious substances compared with oral food intake: the median time interval between allergen contact and clinical death is 30 min in food-induced anaphylaxis, 15 min in insect venom-induced anaphylaxis, and 5 min in medication-induced anaphylaxis [17]. Bronchial asthma is the main risk factor for fatal food-induced anaphylaxis [19]. Fatal reactions generally occurred (with the exception of medication-induced anaphylaxis) at locations where immediate medical care was not available, e.g., insect venom-induced anaphylaxis in the outdoors and food-induced anaphylaxis [17] in restaurants/bars, at take-away stands, at home, in the canteen, or at school. Since patients require immediate treatment in the case of recurrent anaphylaxis, it is essential that they are also trained to initiate treatment themselves.

Self-medication and long-term management

In order to ensure immediate treatment, patients are prescribed an emergency self-medication kit, which should be used by the patient or other persons present prior to the arrival of the emergency physician. Since it is a known fact that delaying adrenaline administration represents a significant risk factor for a fatal outcome [17], it is essential for the prescribing physician to show the patient how to use the emergency kit and for the patient to practice its use. Ideally, the emergency kit should be a „self-medication kit“ designed to avoid emergency situations. When all those involved experience an improvement in (and the potential to influence) physical symptoms, this helps prevent further chronification caused by unfavorable learning histories and the negative impact of physical and interactive processes. **Tab. 1** lists the medications usually included in a kit.

Moreover, following anaphylaxis associated with the risk of recurrence, individual counseling on how

to deal with risks and hazards should be given and an anaphylaxis passport provided. In the case of insect venom-induced anaphylaxis, it is important to initiate allergen-specific immunotherapy (hyposensitization) promptly. Patients with food allergy-induced anaphylaxis should receive qualified counseling from a nutritionist experienced in allergies. Patients need to be informed about the current regulations on and gaps in allergen labeling in order to minimize risks when food shopping and enable the safe consumption of foods outside the home environment. Nutritionists with allergy expertise are available through the German working group on dietetics in allergology (Arbeitskreis Diätetik in der Allergologie, AK-DiDa) or the German Allergy and Asthma Association (Deutscher Allergie- und Asthmabund, DAAB), which, as a patient organization, also provides information materials and support for those affected.

Problems prescribing and implementing self-medication

Experience has shown that non-allergists in particular harbor considerable uncertainty about the measures required for anaphylaxis patients (e.g., the indication to prescribe an adrenaline autoinjector). As such, not all patients in this patient group are offered appropriate treatment. Conversely, it is not uncommon for adrenaline autoinjectors to be prescribed even in the absence of an indication. Unnecessary precautions and alertness of this kind can also diminish quality of life. For this reason, anaphylaxis patients should be treated by allergists. **Tab. 2** lists the indications for the prescription of an adrenaline autoinjector.

Numerous studies in recent years have shown that patients at risk of anaphylaxis, as well as their families, have significantly impaired quality of life [20]. The situation is exacerbated by incorrect information provided by inadequately informed physicians. In actual fact, patients' expectations, and thus also their anxieties, are influenced more by the information they receive than by the anaphylactic reactions they experience. The information they receive from qualified allergists and the information exchange, moderated by a psychologist, with other affected individuals is often of far greater value. Support with everyday management in the form of information materials and advice from patient organizations such as the DAAB can also be highly beneficial.

Self-medication requires knowledge and skills that cannot be mediated by a treating physician in a brief individual training session and demonstration of the emergency set [21]. Patients' lack of understanding for the need to carry their emergency medication (including an adrenaline autoinjector), as well as their lack of knowledge about the appropriate use of the

Tab. 1: Emergency self-medication kit for patients (modified from [2])

Component	Mode of administration and dose
Adrenaline	Autoinjector for intramuscular administration, weight-adjusted: > 7.5–15 kg: 150 µg adrenaline* > 25–30 kg: 300 µg adrenaline* > 50 kg: 300 or 500 µg adrenaline**
H1 antihistamine agent	Orally in liquid or (dissolvable) tablet form according to patient age and preference. The permitted daily dose of the antihistamine agent can be used as a single dose, e.g., in the case of dimetinden drops as with a weight-adjusted dose of the i. v. formulation, to be taken as an oral dose.
Glucocorticoids	According to patient age and preference, rectal or oral (in liquid or tablet form) with 50–100 mg prednisolone equivalent
Optional	In the case of known bronchial asthma: β-2 agonists If upper airway obstruction is anticipated: inhalative adrenaline preparation with a spray nozzle for pharmaceutical vials (to be specially requested from the pharmacist)***
Note:	The emergency self-medication shall include a written instruction on how to use the contents (e.g. anaphylaxis pass or anaphylaxis emergency plan)

*Approved depending on preparation; **from 25–30 kg up to 50 kg, 300µg adrenaline is prescribed, from 50kg 300µg or 500µg; ***off-label use, not approved for this indication.

Tab. 2: Indications for the prescription of an emergency self-medication kit containing an adrenaline autoinjector (modified from [2])

Indicated in the case of:

1. A previous history of anaphylaxis caused by a trigger that cannot be reliably avoided
2. Patients with severe systemic allergic reactions (e.g., generalized urticaria following allergen exposure) and a risk factor for the manifestation of future anaphylaxis
 - Patients with systemic allergic reactions and bronchial asthma
 - Progressively severe symptoms due to the systemic allergic reaction
 - Systemic allergy to potent allergens, such as peanuts, tree nuts, sesame
 - High degree of sensitization, e.g., patients that react to minute quantities of the allergen
3. Adults with mastocytosis (also in the absence of known anaphylaxis)

autoinjector, creates a significant breach of safety [17]. In the case of an anaphylactic reaction, patients have difficulties judging reaction severity. They feel emotionally inhibited about using the autoinjector, which often results in their failure to use adrenaline or in its delayed use. Many patients have inadequate knowledge about possible triggers and their avoidance, insufficient awareness of the typical symptoms of anaphylaxis to differentiate these from anxiety re-

actions, and poor practical skills in terms of self-medication [15, 16, 17, 18, 19].

Anaphylaxis: instruction and training

It is incumbent upon treating physicians to ensure that all their anaphylaxis patients receive an individual instruction session. This includes information on the symptoms of anaphylaxis, how it is triggered, and how to avoid triggers; where necessary, patients should be referred to a nutritionist experienced in allergies and instructed on how to use emergency medication, including a practical demonstration. However, this procedure is often inadequately implemented in everyday medical practice, particularly among non-allergists; no provision is made in their remuneration concept for the individual, time-consuming counselling and instruction of anaphylaxis patients. Particularly the self-injection of adrenaline in the thigh muscle using an autoinjector often fails due to patients' inability to overcome their inhibitions – inhibitions that can only be overcome by repeated practical or simulated practice using an adrenaline autoinjector trainer. In addition, many patients feel overtaxed by the demands put on them by allergen avoidance and dealing with a potentially fatal disease, which often leads to excessive reactions such as irrational anxiety or a disregard of their anaphylaxis risk. Special, structured training can help patients to protect

from further severe anaphylactic episodes, relieve them of additional stress, and improve their social participation [22]. **Tab. 3** shows the differences between individual instruction and training as complementary treatment measures.

AGATE anaphylaxis educational training

In 2007, members of the German working group on anaphylaxis training and education (Arbeitsgemeinschaft Anaphylaxie Training und Education, AGATE) drew up a standardized, interdisciplinary, and target-oriented group-training concept structured as a self-contained program for anaphylaxis patients and the parents/guardians of children and adolescents. This concept includes a manual, participation documents, and sample timetables [23]. Training is indicated in those patients or parents/guardians of affected children for whom an adrenaline autoinjector has been prescribed, in line with indications (see **Tab. 2**), since the treating physician assumes that there is a high risk of anaphylaxis. Patients that are able to avoid their anaphylaxis trigger, e.g., the vast majority of drug-allergic individuals carrying an allergy passport, are not included in the training program (**Fig. 1**).

One focus of the training program is to enable patients to perform appropriate emergency management in the form of initial treatment before the emergency physician arrives. This includes recognizing anaphylactic reactions and using emergency medication, in particular the adrenaline autoinjector, in a manner appropriate to the situation and symptoms. Allergen avoidance strategies, support in coping with chronic hazards in everyday life, and the options for risk management are discussed in such a way that, besides knowledge on how to respond appropriately, affected individuals also gain a sense of social and emotional security that helps them master life with anaphylaxis on a day-to-day basis, as well as improve and minimize the limitations they experience. The AGATE anaphylaxis educational training program takes place on 2 days, each comprising two 45-min training sessions, generally at a 1-week interval. The training sessions are designed for around six to eight patients (or parents/guardians of six to eight affected children). For teaching purposes, the patient's personal situation in terms of symptoms, acute management, and allergen avoidance take the foreground and are worked-through. Against this background, it is necessary as part of the program to recognize individual problems and expectations. The practical use of the emergency kit is demonstrated using training autoinjectors and practiced by the patients themselves; using role playing, patient behavior in various emergency situations is analyzed and corrected. Patients are given a practice phase, as well

Tab. 3: Differences between anaphylaxis instruction and educational training

	Instruction	Educational training
Number of participants	Individual instruction	Group training
Aimed at	The individual	Groups
Duration	Brief	2 × 3 Hours
Training personnel	Physician/allergist	Interdisciplinary training team (allergist, psychologist, nutritionist)
Source of information	Specialist knowledge	Multiprofessional specialist knowledge, experiences of affected individuals
Standardization	None	Structured manual
Content	Allergen avoidance, emergency kit use	Allergen avoidance, anaphylaxis recognition, self-medication options, emergency kit use, support with self-medication, risk management, promoting empowerment, reducing emotional and social barriers in everyday life (e.g., anxieties)

as the task of relaying the use of emergency treatment to their social environment, as homework between training sessions.

As part of their quality assurance measures, AGATE monitors the conditions that need to be fulfilled for training: certification requires a multiprofessional team and a predefined structure (e.g., premises, teaching materials, training materials) in an anaphylaxis training center. At least one team member needs to be a certified physician with additional qualifications in allergology and practical experience with anaphylaxis. The training team should also include a nutritionist specialized in allergies, as well as a psychologist, pedagogue, or medical psychotherapist. As of February 2016, 106 individuals had obtained their qualification as AGATE trainers and are now working in 24 registered training centers in Germany (Fig. 2). The AGATE trainers in virtually all training centers are also trainers in atopic dermatitis and/or asthma education. The training program falls under the auspices of the KomPaS concept (www.kompetenznetz-patientenschulung.de). Thus, training obtained at a recognized instructor training center, certification (or acquisition) of basic training skills, as well as a specialist seminar and supervision, are prerequisites for obtaining a training certificate.

The efficacy of the AGATE anaphylaxis training program was investigated in a multicenter, randomized study conducted at 12 training centers with 100 adult patients and parents/guardians of 96 children. A significant increase in practical knowledge and a marked improvement in emergency response behavior and anxiety in parents/guardians was seen in the training (but not in the control) groups compared with the situation prior to training [21].

Practical problems in the implementation of anaphylaxis group training (Tab. 4)

Trainers currently receive instructor training at five active academies and 12 training centers. Although patient anaphylaxis training centers can be found throughout Germany, there are still areas where training is in short supply. Added to this is the fact that, although there are 24 registered centers in Germany, only a small number of training courses are held. Many centers currently offer only one or two training courses per year or are forced to cancel these for reasons of cost, since no cost coverage is provided for. The costs of patient training programs are borne by only a handful of statutory health insurances, subject, moreover, to regional differences. As a result, the training centers that are active, as well as the DAAB, receive numerous inquiries from affected individuals about the training courses on offer. This demand is met with an extremely limited supply offered by only a handful of active, region-

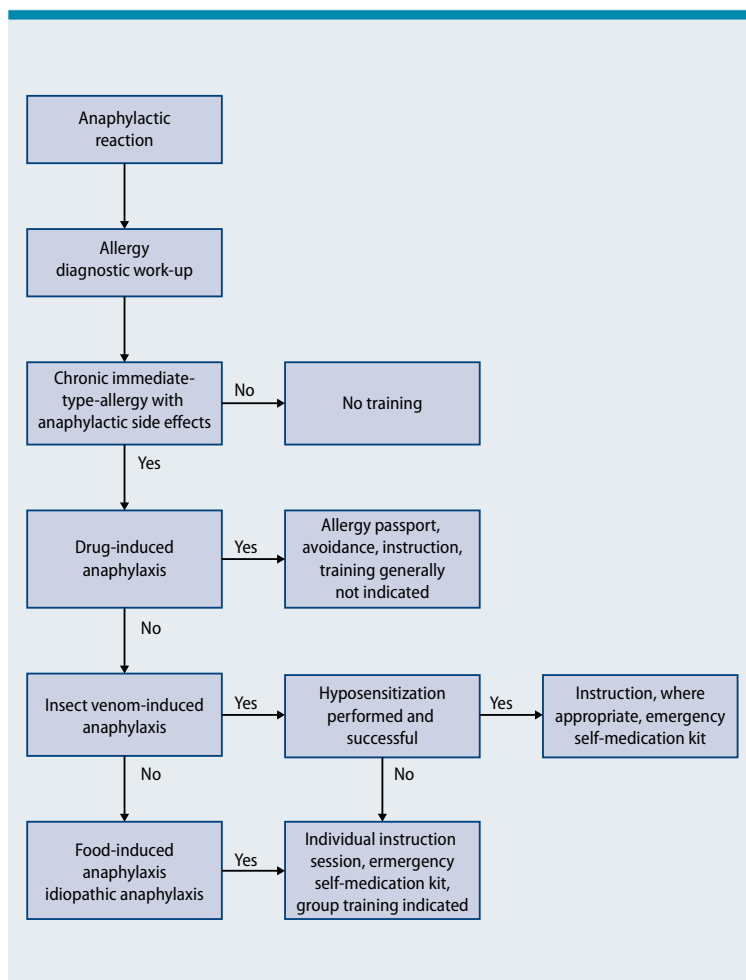


Fig. 1: Algorithm for anaphylaxis educational training

al training centers, to the extent that there is significant supply deficit. In order to remedy this situation, the statutory health insurances need to give their basic consent to covering the costs of the AGATE anaphylaxis training course.

Food-induced anaphylaxis often affects pre-school and school children. It is important to ensure that at-risk children in crèches, nursery schools, other childcare facilities, and schools are provided with allergen-free food and that personnel are willing and prepared to administer emergency treatment. However, this requires significantly more time, effort, and responsibility for staff at care facilities. Clear arrangements between parents and carers on special treatment often break down due to ambivalence and a lack of knowledge on both sides. As a result, children are still being refused places in day-care facilities, although the overall situation has improved in recent years.

Due to a lack of knowledge about the disease and its treatment, combined with the fear of possible le-

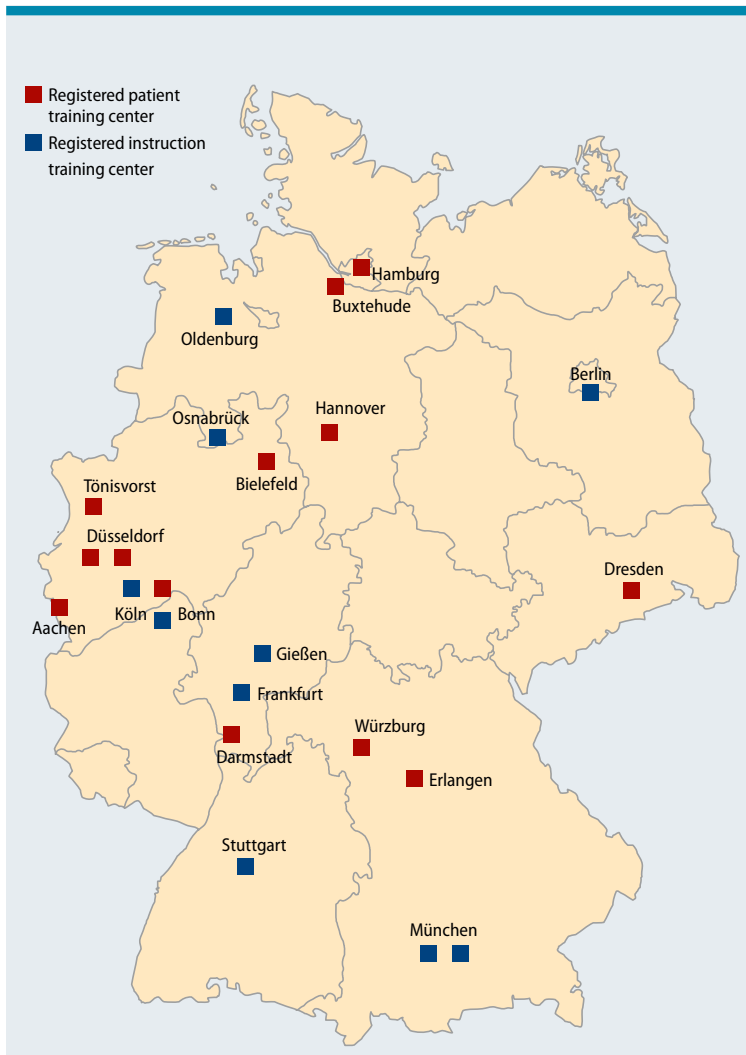


Fig. 2: Landscape of anaphylaxis educational training in Germany

gal liability consequences, teaching and educational staff are to an extent unwilling to assume responsibility for treatment, particularly the use of emergency treatment, or to allow children to participate at mealtimes [24]. A major obstacle here is the legal insecurity surrounding the administration of medication by teaching and educational staff. In this regard, however, the German Statutory Accident Insurance (Deutsche Gesetzliche Unfallversicherung, DGUV) has clarified the overall framework of insurance law for the administration of medication to school children. Limited liability insurance cover is in place for fully-employed teachers and carers. Therefore, fears held by employees and public servants regarding civil liability for damage to health due to the incorrect use of medication are without foundation, unless such damage is caused deliberately.

The ministries of education and cultural affairs in the various German federal states are responsible for setting out the legal framework. A 2015 survey conducted by the DAAB on the treatment of nursery-school and school children at risk for anaphylaxis showed that the respective ministries of education and cultural affairs were unaware of the difficulties parents experience in terms of the care their children receive. Nonetheless, most German federal states set out general provisions for the administration of medications by non-medical childcare staff. As a general rule, drugs can be administered if a medical certificate from a physician, as well as a drug schedule including dose and relevant instructions on administration, is provided (the anaphylaxis emergency plan can serve as documentation here). In addition to these general legal provisions, the second cornerstone of treatment consists of granting a right of care, i.e., a written agreement between parents/guardians and teaching staff on the use of the emergency set for the purposes of self-medication (both free of cost from the DAAB). The third cornerstone comprises training in the use of emergency medication and in contacting an emergency physician. Special training courses of this kind tailored to the needs of childcare staff have also been developed and evaluated under the aegis of AGATE e. V. The courses demonstrate good efficacy and a publication is currently in preparation. Depending on the institution, the costs of this type of training are borne to only a certain extent. The goal is to ensure that all institutions bear training costs. Participation in a training course is optional for childcare personnel. Since there is a serious shortage of qualified anaphylaxis trainers capable of providing training courses for childcare facilities, demand exceeds feasible supply in many areas.

Conclusion

An anaphylactic reaction is the manifestation of a chronic, long-term susceptibility to anaphylaxis that can cause a sudden, severe, and in some cases fatal, shock reaction. The treatment of anaphylaxis patients is challenging in terms of diagnosis, treatment, and prevention. Subject to region and center, there are good treatment options on offer for anaphylaxis patients in Germany. However, these options are not available nationwide and are not always adequately implemented, resulting in shortcomings in the treatment of anaphylaxis patients. Individual instruction is often insufficient for many patients with severe anaphylaxis and should be complemented by anaphylaxis group training. The AGATE group training program for patients and parents/guardians resulted in a significant gain in knowledge and practical self-medication skills, as

Tab. 4: Practical problems in the implementation of the AGATE training program

Limited number of active training centers
Demand for training sharply exceeds supply
Limited number of instructor training centers
Costs of training measures not covered
Lack of a binding framework for (emergency) treatment/ drug administration by teaching and educational staff

well as in a reduction of anxiety among parents/guardians. Nationwide implementation of training courses and cost-coverage by health insurance funds would be beneficial in this potentially life-threatening disease.

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Conflict of interests

The authors Kirsten Beyer, Jörg Fischer, Uwe Gieler, Oliver Giessler-Fichtner, Norbert Gebert, Thilo Jakob, Claudia Kugler, Imke Reese, Franziska Rüeff, Sabine Schnadt, Cäcilia Siemens, Rüdiger Szczepanski, Margitta Worm, Johannes Ring und Lars Lange state that there are no conflicts of interest. Knut Brockow has received fees for lectures or advisory activities for Phadia, Meda, ALK, and Novartis. Ludger Klimek has been working as a board member for Meda and Novartis; as a consultant for ALK-Abelló, Allergopharma, Bionorica, Boehringer Ingelheim, GlaxoSmithKline, Lofarma, Novartis, and Meda, has received grants, payment for lectures including service on speakers bureaus and/or for manuscript preparation from ALK-Abelló, Allergopharma, Bencard, Bionorica, Biomay, HAL, Boehringer Ingelheim, GlaxoSmithKline, Leti, Lofarma, Meda, Novartis, and Roxall. Ernst Rietschel has been working as an advisory board member for Meda and Bauch + Lomb.

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