Management of food allergy in Europe

An overview using Germany as an example
Disclosure

In relation to this presentation, I declare that there are no conflicts of interest.
Allergy Societies in Europe and Germany

The European Academy of Allergy and Clinical Immunology (EAACI) is the largest medical association in Europe in the field of allergy and clinical immunology.

The Academy includes 49 National Allergy Societies.

The German Member Society in the EAACI is the German Society for Allergology and Immunology (DGAKI).
EAACI Food Allergy and Anaphylaxis Guidelines

- 2-year project of six task forces within the EAACI Food Allergy and Anaphylaxis Guidelines Group
- Use of comprehensive systematic reviews and meta-analysis of the literature, where appropriate
- Joint work of health care professionals, scientists, patient groups and regulators

1. **Primary prevention of food allergy in children and adults**
2. **Diagnosis and management of food allergy**
3. **Anaphylaxis**
4. **Managing patients with food allergies in the community**
5. **Protecting consumers with food allergies**
6. **Food Allergy health-related quality of life measures**

*Muraro et al. Allergy. 2014. and available at www.eaaci.org*
The Association of the Scientific Medical Societies in Germany (AWMF) is the umbrella organisation of the more than 150 German medical societies.

The AWMF advises the German government in all topics of scientific medicine and co-ordinates the national programm of medical guidelines.

The AWMF guidelines take current scientific evidence, practically proven methods as well as economic aspects in account.

Duration of validity of guidelines: ≈ 5 years

www.awmf.org
National Guidelines in Germany (AWMF)

1. Guideline for acute therapy and management of anaphylaxis
2. Guideline for the management of food allergies due to crossreactivity to inhalative allergens
3. Guideline for in vitro diagnostics for IgE-mediated food allergies
4. Guideline for standardisation of food challenges in the diagnostic of food allergy
5. Guideline for the treatment of IgE-mediated food allergy

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Under revision and will be combined to **one single guideline for the management of IgE-mediated food allergy** (planned for November 2015)

www.awmf.org
German healthcare system

How is the German health system covering the cost of food allergies for individuals and their families?
German healthcare system

- The world’s oldest national social health insurance system
- Funded by a statutory contribution system that ensures free healthcare for all via health insurance funds
- Health insurance is compulsory for the whole population.

Efficiency principle:
Treatment costs are covered under the maxim that the services are “sufficient, appropriate and cost-effective and are not allowed to exceed a measure of necessity”. (Code of Social Law V)
German healthcare system

Medical services that are recommended by the German guidelines should be provided to the (food allergic) patients and are predominantly payed by the health insurance companies.

What approaches are recommended and used for the diagnosis, management and treatment of food allergy in Germany?
Diagnosis of food allergy

- Patient’s clinical history and examination
- Measurement of specific serum IgE (including component-resolved diagnostic tests)

and/or

Skin prick testing

- Oral food challenges
  - In patients with atopic eczema, subjective or suspected psychological symptoms double-blind and placebo-controlled challenges should be performed.

www.awmf.org
Long-term management strategies

- **Elimination diet**

- **Nutritional counseling by an experienced nutritionist:**
  - Identification and possible avoidance from the eliciting food
  - Information regarding alternative food choices and preventing potential nutritional deficiencies
  - Information about recent food declaration regulations in order to allow for the low risk purchase of foods at the supermarket and when eating out

- **Re-evaluation of patients at regular intervals** (depending on specific food allergen) to assess development of tolerance

www.awmf.org
### Ingredients of an "emergency set for self-help" for patients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Route of application and dosage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenaline</td>
<td>Autoinjector for intramuscular application, adapted to body weight:</td>
</tr>
<tr>
<td></td>
<td>&gt; 15 kg 150 µg adrenaline</td>
</tr>
<tr>
<td></td>
<td>&gt; 30 kg 300 µg adrenaline</td>
</tr>
<tr>
<td>H&lt;sub&gt;1&lt;/sub&gt; antihistamine</td>
<td>According to age and preference of patients as liquid or fast-melt tablet. The licensed daily dose of the respective antihistamine is recommended as single dose. Dimetindene drops can be taken orally in a dosage adapted for bodyweight and corresponding to the intravenous dose.</td>
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<tr>
<td>Glucocorticosteroid</td>
<td>According to age and preference of the patient oral or rectal (tablets or liquid) with 50–100 mg Prednisolone equivalent.</td>
</tr>
<tr>
<td>Optional</td>
<td>In patients with bronchial asthma: β&lt;sub&gt;2&lt;/sub&gt; adrenoceptor agonists</td>
</tr>
<tr>
<td></td>
<td>When airway obstruction can be expected an adrenaline preparation for inhalation with spray head (to be ordered especially from the pharmacist)</td>
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*Note: “The emergency set for self-help” should contain written instructions for the application of its constituents (e.g. anaphylaxis-passport and/or anaphylaxis-emergency plan)*

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**Patient management and self-medication**

„emergency set for self-help“  
(AWMF-Guideline for acute therapy and management of anaphylaxis)  

www.awmf.org
## Patient management and self-medication

### Ingredients of an "emergency set for self-help" for patients

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| H₁ antihistamine| According to age and preference of patients as liquid or fast-melt tablet. The licensed daily dose of the respective antihistamine is recommended as single dose. Dimetindene drops can be taken orally in a dosage adapted for bodyweight and corresponding to the intravenous dose. |
| Glucocorticosteroid | According to age and preference of the patient oral or rectal (tablets or liquid) with 50–100 mg Prednisolone equivalent. |
| Optional        | In patients with bronchial asthma: β2 adrenoceptor agonists  
|                 | When airway obstruction can be expected an adrenaline preparation for inhalation with spray head (to be ordered especially from the pharmacist) |

**Note:** “The emergency set for self-help” should contain written instructions for the application of its constituents (e.g., anaphylaxis-passport and/or anaphylaxis-emergency plan)

+ adrenaline autoinjector trainer (dummy without needle and drug)

### “emergency set for self-help”

(AWMF-Guideline for acute therapy and management of anaphylaxis)

www.awmf.org
Patient management and self-medication

Table 8: Ingredients of an "emergency set for self-help" for patients

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+ adrenaline autoinjector trainer (dummy without needle and drug)

Table 9: Indications for the prescription of an adrenaline autoinjector

- Patients with a systemic allergic reaction and bronchial asthma (even without a history of anaphylaxis)
- Progressive severity of symptoms of a systemic allergic reaction
- History of previous anaphylactic reactions to elicitors which cannot be avoided with certainty
- Systemic allergy to potent allergens e.g. peanuts, tree nuts, sesame
- High degree of sensitization, e.g. patients who react to even minute amounts of allergen
- Adults with mastocytosis (even without a history of anaphylaxis)

„emergency set for self-help“ (AWMF-Guideline for acute therapy and management of anaphylaxis)

www.awmf.org
Patient management and self-medication

Anaphylaxis passport (available at www.daab.de)
Educational programs: „Anaphylaxis training“

Age related structured educational program has been developed by the „Working Group Anaphylaxis Education and Training“ (founded in 2007) for patients and parents of children who are at high risk of anaphylaxis.

→ Adapted from successfully applied patient education programs for atopic eczema and bronchial asthma.

Structured patient education program can bring significant improvement of anaphylaxis-related knowledge and practical emergency management skills. (Brockow et al. Allergy. 2015)

www.anaphylaxieschulung.de

Johanna Bellach, MD – 1 September 2015
Educational programs: „Anaphylaxis training“

Training team:  
**Multidisciplinary team of allergists, nurses, psychologists and dietitians**

Group size: 6 patients or 12 parents / caregivers

Training time: 2 x 3-hour sessions over a 2-week period (+ homework after the first session)

Training contents

- **practical skills** (e.g. administration of an epinephrine auto-injector)
- **disease management** (e.g. recognition of anaphylaxis, daily strategies such as label reading and food preparation)
- **psychosocial interventions** to reduce especially phobic anxieties about anaphylaxis

www.anaphylaxieschulung.de
Educational programs: „Anaphylaxis training“

Further „AGATE“-Activities:

✓ Structured educational programs for childcare workers and teachers → costs only sometimes covered by health insurances

✓ Train-the-trainer seminars for education of „anaphylaxis trainers“ → license to give anaphylaxis training courses

www.anaphylaxieschulung.de
Information materials and helpful tools

„German Allergy and Asthma Union“ (DAAB)

Patient organization funded in 1897

Very active in consumer protection!

www.daab.de
Food Allergen Labelling in the European Union
Food Allergen Labelling in the European Union

COMMISSION DIRECTIVE 2007/68/EC
of 27 November 2007

Mandatory labelling of 14 allergenic foods (and derived products) when used as ingredients for pre-packed foods, regardless of concentration of the potentially allergenic ingredient.

„Directive shall be binding, as to the result to be achieved, upon each Member State to which it is addressed, but shall leave to the national authorities the choice of form and methods.“
(Article 288 of the Treaty of the Functioning of the European Union)
Food Allergen Labelling in the European Union

The 14 allergenic foods with mandatory labelling according to EU legislation
image: www.thefoodlabeller.com
Food Allergen Labelling in the European Union

of 25 October 2011


Extends allergen labelling to non-prepacked foods
→ Effective from December 2014

But: The EU member states can decide upon means through which information about presence of allergens is to be made available to consumers.
→ e.g. Germany: Written and verbal information have to be provided for consumers.

„A regulation shall have general application. It shall be binding in its entirety and directly applicable in all Member States.“
(Article 288 of the Treaty of the Functioning of the European Union)
Food Allergen Labelling in the European Union

of 25 October 2011

on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and

Thresholds for the allergen declaration as well as the presence of allergens due to cross-contamination are not covered in the current EU legislation.

→ Precautionary labelling statements are still neither regulated nor mandatory.
→ This leads to confusion among consumers with food allergy: e.g. variation in statements for precautionary labelling would reflect a hierarchy of risk or reaction.
Food Allergen Labelling in the European Union

Percentage of food allergic consumers that would 'never' buy a product with precautionary allergen labelling according the wording used.

Survey by the EAACI Patient Organisation Committee and the International Food Allergy and Anaphylaxis Alliance (iFAAA) on consumers’ perspective on allergen labelling and thresholds.
Personal communication S. Schnadt.
[DunnGalvin A et al. Precautionary allergen labelling: perspectives from key stakeholder groups. Allergy 2015]
Integrated Approaches to Food Allergen and Allergy Risk Management (iFAAM)

Research Project with 38 partners from 18 countries (including the United States with the University of Nebraska)

Funded by the European Union’s Seventh Framework Programme for research, technological development and demonstration

Aims to:

- Develop evidence-based approaches and tools for management of allergens in food
- Integrate knowledge derived from their application into food allergy management plans and dietary advice
- Develop strategies to reduce the burden of food allergies in Europe

http://www.inflammation-repair.manchester.ac.uk/iFAAM/
Contains 5 modules with 14 work packages with different topics regarding food allergen and allergy risk management

Modules of the iFAAM Project

(1) Early Life Nutrition and Allergy
(2) Risk Factors and Severity
(3) Risk Models
(4) Analysis of Allergens in Food
(5) Food Allergen and Allergy Management Knowledge Base

http://www.inflammation-repair.manchester.ac.uk/iFAAM/
Thank you very much!