



# An AE guide for healthcare professionals

## ANAPHYLAXIS

### What is *anaphylaxis*?

Anaphylaxis is a clinical syndrome characterised by:

- **sudden onset** AND
- **rapid progression of signs and symptoms** AND
- **involvement of two or more organ systems such as the dermatological, cardiovascular and respiratory systems.**

### How to diagnose *anaphylaxis*?

Anaphylaxis may be under-diagnosed and under-treated partly due to a failure in recognising the symptoms which, in some cases, may present without any obvious cutaneous symptoms or hypotension.

The diagnosis of anaphylaxis is clinical and based on a detailed description of the acute episode including preceding activities to identify possible causes of anaphylaxis such as food- or exercise- induced allergic reactions. The number of symptoms can vary from a few to many involving virtually all body systems.

**Anaphylaxis is highly likely when any one of the following two criteria is fulfilled:**

1. Acute onset of an illness (minutes to several hours) with simultaneous involvement of the skin, mucosal tissue, or both (e.g. generalised hives, pruritus or flushing, swollen lips-tongue-uvula)

And at least one of the following:

- i. Respiratory compromise (e.g. dyspnoea, wheeze-bronchospasm, stridor, reduced peak expiratory flow (PEF), hypoxemia)
  - ii. Reduced blood pressure (BP) or associated symptoms of end-organ dysfunction (e.g. hypotonia (cardiovascular collapse), syncope, incontinence)
  - iii. Severe gastrointestinal symptoms (e.g. severe crampy abdominal pain, repetitive vomiting), especially after exposure to non-food allergens
2. Acute onset of hypotension<sup>a</sup> or bronchospasm<sup>b</sup> or laryngeal involvement<sup>c</sup> after exposure to a known or highly probably allergen<sup>d</sup> for that patient (minutes to several hours), even in the absence of typical skin involvement

a. Hypotension defined as a decrease in systolic BP greater than 30% from that person's baseline, OR

i. Infants and children under 10 years: systolic BP less than (70 mmHg + [2 x age in years])

ii. Adults and children over 10 years: systolic BP less than <90 mmHg.

b. Excluding lower respiratory symptoms triggered by common inhalant allergens or food allergens perceived to cause "inhalational" reactions in the absence of ingestion.

c. Laryngeal symptoms include stridor, vocal changes, odynophagia.

d. An allergen is a substance (usually a protein) capable of triggering an immune response that can result in an allergic reaction. Most allergens act through an IgE mediated pathway, but some non-allergen triggers can act independent of IgE (for example, via direct activation of mast cells).

Biphasic reactions, defined as a recurrence of symptoms that develop following the apparent resolution of the initial anaphylactic event, may occur in one to 20 per cent of anaphylactic reactions. They typically occur within eight hours after resolution of the initial symptoms and signs. Thus, patients with anaphylaxis should be observed for several hours, and in the case of severe reactions, the patient should preferably be observed in the hospital for at least 24 hours.

# Important information to include when reporting an adverse event associated with anaphylaxis

The following questionnaire is designed to aid the reporting of anaphylaxis as an AE.

You are encouraged to complete this questionnaire and submit it together with the standard AE report.

## Anaphylaxis Questionnaire

1. How soon did the patient experience the first symptoms or signs following drug or vaccine administration?  
Time to onset: \_\_\_\_\_ minutes/ \_\_\_\_\_ hours/ \_\_\_\_\_ days

2. Did the patient exhibit any of the following symptoms?  
Tick as many as appropriate:

### Dermatologic/mucosal

- generalised erythema
- generalized urticaria (hives)
- angioedema, specify site: \_\_\_\_\_
- generalized pruritus
- localized injection site urticaria
- itchy eyes with or without chemosis

### Cardiovascular

- hypotension
- tachycardia
- feeling faint
- decreased level of consciousness/  
loss of consciousness

### Gastrointestinal

- abdominal pain
- nausea
- vomiting
- diarrhoea

### Respiratory

- wheeze/rhonchi
- stridor
- upper airway swelling (lips, tongue, throat  
uvula or larynx)
- tachypnoea/increased use of accessory  
respiratory muscles
- cyanosis
- grunting
- sudden onset of persistent dry cough
- hoarse voice/dysarthria
- sensation of throat closure
- sneezing and/or rhinorrhoea

### Others

- a sense of impending doom

## How to report a suspected case of anaphylaxis caused by a drug/vaccine?

Please report to the Vigilance and Compliance Branch, HSA via the following reporting channels:

-  The Adverse Drug Reactions/Drug Allergy module in the **Critical Medical Information Store (CMIS)** of the Electronic Medical Records (EMR) of public health institutions
-  Online Reporting at <https://www.hsa.gov.sg/adverse-events>

If in doubt, you need not label the adverse reaction as 'anaphylaxis'. However please indicate all the signs and symptoms observed in the patient.

### Acknowledgement

This guide was developed by the Health Sciences Authority in consultation with Prof. Chng Hiok Hee, Senior Consultant, Department of Rheumatology, Allergy and Immunology, Tan Tock Seng Hospital.

It was updated in 2021 in consultation with Adjunct A/Prof Bernard Thong, Divisional Chairman (Medicine) & Senior Consultant, Department of Rheumatology, Allergy & Immunology, Tan Tock Seng Hospital.

### References

- 1) Brighton collaboration: <https://brightoncollaboration.us/>
- 2) J Allergy Clinical Immunology 2006; 117:391, Second symposium on the definition & management of anaphylaxis: summary report – Second National Institute of Allergy & Infectious Disease/Food Allergy & Anaphylaxis Network symposium
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Vigilance and Compliance Branch, Health Products Regulation Group, Health Sciences Authority

11 Biopolis Way, #11-03, Helios, Singapore 138667  
Tel: (65) 6866 1111 Fax: (65) 6478 9069  
Website: <http://www.hsa.gov.sg> Email: [HSA\\_productsafety@hsa.gov.sg](mailto:HSA_productsafety@hsa.gov.sg)