

A guide for healthcare professionals

in filing an adverse event (AE) report associated with **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.**

Why is it important to recognise anaphylaxis?

Anaphylaxis may be under-diagnosed and under-treated partly due to a failure in recognising anaphylaxis which presents itself without obvious cutaneous symptoms or hypotension. The diagnosis of anaphylaxis is clinical and based on a detailed description of the acute episode including preceding activities. The number of symptoms can vary from a few to many involving virtually all body systems. There are three criteria for the diagnosis of anaphylaxis:

1. Acute onset (minutes to a few hours) of symptoms and signs (with involvement of the skin, mucosal tissue, or both (e.g. generalised urticaria, pruritus or flushing, swollen lips-tongue-uvula) and at least one of the following:
 - a. Respiratory compromise (e.g. dyspnea, wheeze-bronchospasm, stridor, cyanosis)
 - b. Reduced blood pressure (BP) or associated symptoms of end-organ dysfunction (eg, hypotonia [collapse], syncope, incontinence)
2. Two or more of the following that occur rapidly after exposure to a likely allergen for that patient (minutes to a few hours):
 - a. Involvement of the skin-mucosal tissue (e.g. generalised urticaria, itch, flushing, swollen lips-tongue-uvula)
 - b. Respiratory compromise (e.g. dyspnea, wheeze-bronchospasm, stridor, cyanosis)
 - c. Reduced BP or associated symptoms (e.g. hypotonia [collapse], syncope, incontinence)
 - d. Persistent gastrointestinal symptoms (e.g. crampy abdominal pain, vomiting)
3. Reduced BP after exposure to known allergen for that patient (minutes to a few hours):
 - a. Infants and children: low systolic BP (age specific) or > 30% decrease in systolic BP
 - b. Adults: systolic BP < 90 mm Hg or > 30% decrease from that person's baseline

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.

How do I report a suspected case of anaphylaxis caused by a drug/vaccine?

Please fill in the blue Vaccine Adverse Event (VAE) reporting form (for vaccines) or the yellow Adverse Drug Reaction reporting form (for other health products) and submit it to:

Vigilance Branch/Health Products Regulation Group

Health Sciences Authority

Phone: (65) 6866 1111

Fax: (65) 6478 9069

OR Email to HSA_productsafety@hsa.gov.sg

OR Online Reporting at http://www.hsa.gov.sg/ae_online

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

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 vulva 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

Acknowledgement

The above diagnostic guide was developed by the Health Sciences Authority in consultation with Prof. Chng Hiok Hee, Senior Consultant, Department of Rheumatology, Allergy and Immunology, TTSH.

References

- 1) Brighton collaboration: <https://brightoncollaboration.org/public>
- 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

