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| Anaphylaxis notifications under the *Public Health and Wellbeing Act 2008*Victoria State Government Department of Health and Human Services  *A Guide for Victorian hospitals* |
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Department of Health

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To receive this publication in an accessible format phone 1300 364 352, using the National Relay Service 13 36 77 if required, or email [Food Safety Unit](mailto:foodsafety@dhhs.vic.gov.au) <foodsafety@dhhs.vic.gov.au>

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# Purpose of document

A 2018 amendment to the Victorian *Public Health and Wellbeing Act* *2008* (the Act) introduced a requirement for Victorian hospitals to notify the Department of Health and Human Services (the department) when a person presents for treatment for anaphylaxis.

This guidance document aims to provide Victorian hospitals with the information they require to meet their statutory obligations and the process that must be followed to submit a notification of an anaphylaxis presentation to the department, in accordance with the Public Health and Wellbeing Regulations 2009 (the Regulations).

Copies of the relevant content in the Act and Regulations are provided at Appendix 1 and 2, respectively. The legislation can be found online at [Victorian Legislation and Parliamentary Documents](http://www.legislation.vic.gov.au/) <www.legislation.vic.gov.au>

# Background

Legislative amendments to require notification of anaphylaxis were introduced by the Minister for Health, the Hon Jill Hennessy MP, in response to a Victorian Coronial report regarding the death of a 10-year-old Victorian boy in 2013. The boy was allergic to dairy products and drank a can of imported coconut drink which failed to declare the presence of milk as an ingredient on its label, in breach of Australian food labelling law.

Without adequate warning of the contents of the drink, the boy’s parents unwittingly gave the drink to their son, who, shortly after consuming it, suffered an anaphylactic reaction that ultimately claimed his life. At the time, the responding hospital was not required to and did not notify the department of the suspicions that this beverage was the likely cause of the boy’s anaphylactic reaction. As a result, the product remained in the marketplace for six weeks before being recalled from the shelves, putting other milk-allergic consumers at risk.

### Further information

More information on the background to this scheme as well as a link to the Coronial findings can be found on the department’s anaphylaxis notifications website at: [Anaphylaxis Notifications](https://www2.health.vic.gov.au/public-health/anaphylaxis-notifications) <https://www2.health.vic.gov.au/public-health/anaphylaxis-notifications>

# Purpose of notifying anaphylaxis presentations

The primary purpose of the anaphylaxis notification scheme is to **allow the department to take swift action where a notification reveals a broader public health risk**, such as a food which contains an allergen but does not declare it on the label or poor allergen management at a food business. Action may include a food recall to remove an offending food product from the marketplace or addressing poor allergen management in food businesses.

Presentations to hospitals of anaphylaxis, where the suspected cause is a packaged food, are considered the highest priority and the Regulations require these to be notified immediately. For anaphylaxis notifications, the department considers this to be as soon as practicable, but within 24 hours.

In addition, data collected will enable the department to better understand the burden of anaphylaxis in Victoria and, where possible, inform public health policy, service provision, interventions and research.

# Understanding the Act: your requirement to notify

It is **mandatory for Victorian public and private hospitals to report all cases of anaphylaxis presenting for treatment** to the department.

It is vital that hospitals familiarise themselves with the legislative requirements, and their obligations, as anaphylaxis reporting bodies.

The *Public Health and Well Being Act 2008* (Appendix 1) places the onus to notify on an **anaphylaxis reporting body**, defined as:

* a public hospital,
* a denominational hospital,
* a private hospital,
* a multi-purpose service, or
  + a privately-operated hospital within the meaning of the *Health Services Act 1988*.

Notification to the department is required **if a registered medical practitioner employed at, or otherwise engaged by the anaphylaxis reporting body, has reasonable grounds to believe that a person presenting for treatment at the anaphylaxis reporting body has anaphylaxis** (section 130B(1)). Note, the legislation permits other clinical staff to notify cases of anaphylaxis if a registered medical practitioner is overseeing the care of the patient. In situations where a registered medical practitioner is not involved in managing patients presenting to the hospital (for example in nurse-led urgent care settings), clinical staff are still encouraged to notify the Secretary of any cases of anaphylaxis to ensure that any mislabelled food does not remain in the marketplace placing other allergic consumers at risk.

Notifications must be **submitted in accordance with the Regulations**, which prescribe when and how a notification for anaphylaxis should be made and the details that need to be included (see section below, and appendix 2).

The Act also requires the **person in charge of the anaphylaxis reporting body** to implement processes to ensure that it complies with the requirement to notify. For the purposes of anaphylaxis notification, the person in charge of a:

* public hospital, denominational hospital, multi-purpose services or privately-operated hospital is the Chief Executive Officer, and
  + private hospital is the proprietor of the private hospital.

# What to notify under the scheme?

Hospitals are required to report to the department **all cases presenting to the hospital with anaphylaxis to any allergen, known or unknown.**

|  |
| --- |
| Definition of anaphylaxis A case of anaphylaxis should be notified to the department when a registered medical practitioner has reasonable grounds to believe that a person presenting for treatment has anaphylaxis. This includes situations where one or more symptoms of their anaphylaxis has resolved at the time of presentation.  Anaphylaxis has no universally accepted definition but can be defined as a severe, potentially life-threatening systemic hypersensitivity reaction characterised by[[1]](#footnote-1):  • rapid onset of a life-threatening airway, breathing or circulatory problems  • (usually, but not always) skin and mucosal changes.  Note: Vomiting and abdominal pain are symptoms of anaphylaxis to insect venom and systemically administered allergens |

### Common symptoms and signs of anaphylaxis[[2]](#footnote-2)

#### Dermatological/skin and mucous membrane features

* Urticarial rash.
* Erythema/flushing.
  + Angioedema.

#### Respiratory/chest features (most common in children)

* Persistent cough.
* Wheeze.
* Tongue swelling.
* Stridor.
* Hoarse voice or change in character of the cry.
* Subjective feeling of swelling or tightness/tingling in the throat.
  + Dysphagia.

#### Cardiovascular features

* Pale and floppy (infant).
* Palpitations.
* Tachycardia.
* Bradycardia.
* Hypotension.
* Collapse with or without unconsciousness.
  + Cardiac arrest.

#### Gastrointestinal features

* Nausea.
* Vomiting.
* Diarrhoea.
  + Abdominal/pelvic pain.

#### Neurological features

* Headache (usually throbbing).
* Dizziness.
  + Altered consciousness/confusion.

## What does not need to be notified under the scheme?

The following clinical presentations are **not required to be notified under this scheme**:

**Persons presenting only with:**

* **Urticaria:** pruritic, elevated skin lesions surrounded by erythematous base commonly described as “hives”, or
  + **Angio-oedema:** a much less common form of allergic reaction that involves deeper subcutaneous extension. It involves face (eyelids, lips, tongue), hands and feet, and sometimes other areas (trunk, genitalia, mucous membranes).

Although these cases are not required to be reported **under this scheme**, whenever a potentially mislabelled packaged food is thought to be the cause of an allergic reaction in an allergic individual, the hospital or members of the public are advised to report the matter to the department’s Food Safety Unit via [email](mailto:foodsafety@dhhs.vic.gov.au) <foodsafety@dhhs.vic.gov.au> or 1300 364 352.

**In-hospital anaphylaxis**

Anaphylactic reactions that occur while receiving care in a hospital do not need to be notified. Only **presentations** to hospital emergency departments for treatment for anaphylaxis should be notified.

Health services should continue to observe internal incident reporting and management processes, such as where a food-allergic person is mistakenly given the food they are allergic to while receiving care in hospital.

Appendix 4 provides questions and answers to support decision making around what to notify.

# Understanding the regulations

The Regulations (Appendix 2) specify how and when according to the suspected cause of anaphylaxis.

## When to notify

### Where the suspected cause is a packaged food:

Notify as soon as practicable, but within **24 hours** of diagnosis

### Where the suspected cause is anything other than packaged food:

Notify as soon as practicable, but within **five days** of diagnosis of anaphylaxis.

## How to notify

All notifications of anaphylaxis are to be made **electronically** via the online form through the department’s website: [Online form](https://www2.health.vic.gov.au/public-health/anaphylaxis-notifications) <https://www2.health.vic.gov.au/public-health/anaphylaxis-notifications>.

The online form is intended to be intuitive and simple to use. Please let us know of any problems using the online form by sending an [email](mailto:anaphylaxis@dhhs.vic.gov.au) <anaphylaxis@dhhs.vic.gov.au> and we will respond as soon as possible.

**In Summary:**

Notify anaphylaxis cases:[www2.health.vic.gov.au/notify](https://www2.health.vic.gov.au/notify)

Packaged food – as soon as practicable but **within 24 hours**

All other cases – as soon as practicable but **within 5 days**

## Notification details

The Regulations prescribe the details required when notifying all anaphylaxis presentations. These are:

* **case information** – name, date of birth, sex, Aboriginal or Torres Strait Islander status, residential address and person/parent/guardian contact details (vital for enabling the department’s Food Safety Unit to follow-up and take required action to remove risk foods).
* **clinical information** – morbidity or mortality details, history of allergies reported by the person and date of presentation for treatment for anaphylaxis.
* **details of the anaphylaxis reporting body** – name and address, telephone number and email address, name and telephone number of the registered medical practitioner who formed the reasonable belief that the person had anaphylaxis.
  + **suspected cause of anaphylaxis** – the suspected cause must be provided from a defined list, and additional notification details are to be provided to the extent known.

### Suspected cause of anaphylaxis

#### Packaged food

Select this option if the suspected cause possibly involves a packaged food.

Definitions for ‘food’ and ‘package’ are based on the Victorian *Food Act 1984* (see Appendix 3). For the purposes of this scheme:

* **‘food’** includes beverages and chewing gum, and
  + **‘package’** refers to any food which has been sold in any sort of outer covering and does not include foods which have been packaged at home, not intended for commercial purposes (e.g., a home-made sandwich wrapped in cling-wrap).

Encourage patients to keep details of the implicated packaged food, where possible, to aid follow-up.

For example:

* + a person known to be allergic to milk has had an anaphylactic reaction after consuming a number of foods, including some made at home and some packaged foods, all of which they have eaten safely before. You suspect food is the cause, but which particular food is unclear.
  + A person consumes a packaged food that contains a relevant allergen in error, for example incorrectly reading a packaged food label.

#### Unpackaged food from a food premises

Select this option if the suspected cause was unpackaged food from a commercial premises that sells or provides foods to customers or clients. Examples include:

* a meal purchased from a café or restaurant,
* a meal provided to a child by a child-care facility,
* a meal or snack provided to a child by a school canteen, or after school hours care program,
  + a meal provided to a client by an aged care facility.

#### Consumption of any other food

Select this option if the suspected cause was any other food-related anaphylactic reaction, where the suspected food is NOT a packaged commercial food, nor from a food premises such as a restaurant or child care centre, which has provided a suspected allergen-contaminated food to an allergic person.

For example:

* accidental cross-contamination in the home whilst cooking a meal,
* accidental cross-contamination during a private party where, for example, the peanut-containing brownies were in direct contact with the nut-free muffins.

#### Drugs and blood-derived products

Anaphylactic reactions to a drug or pharmaceutical (including prescription medicines, over-the-counter medicines and complementary medicines) are to be notified to the department.

In addition, hospitals are requested to continue to report these reactions to the Therapeutic Goods Administration (TGA) as part of its adverse events monitoring scheme (as the relevant authority with jurisdiction over drugs, pharmaceuticals and blood-derived products).

The TGA adverse events online notification form is available on the TGA website: [Adverse events reporting](https://aems.tga.gov.au/) <https://aems.tga.gov.au/>.

#### Vaccine

Anaphylactic reactions to vaccines are to be notified to the department.

In addition, immunisation providers are requested to continue to report these and other reactions to the Adverse Events Following Immunisation – Clinical Assessment Network (AEFI-CAN), previously the Surveillance of Adverse Events Following Vaccination in the Community (SAEFVIC), which collects and acts on these reports. You will need to register to lodge a report. This can be accessed at:[Adverse Events Following Immunisation](https://www.aefican.org.au/Home/Info/VIC) <https://www.aefican.org.au/Home/Info/VIC>

#### Other

For anaphylactic reactions which are suspected to have been caused by something other than the causes listed above.

#### Unknown

This is for reactions where the suspected cause is not known. This selection may also be an appropriate choice if multiple factors were suspected to have led to the reaction, but not packaged food. Any details able to be submitted on the suspected cause of anaphylaxis will assist the department in determining any next steps.

**The following table summarises the requirements of the Regulations with examples of useful details:**

|  |  |  |
| --- | --- | --- |
| Suspected cause of anaphylaxis | Additional notification details (if known to the hospital) | Example |
| **Consumption of packaged food** | * Type of food product * Brand of food product * Date and time of consumption | * Canned coconut drink * ABC brand * 7:30pm, 20/9/18 |
| **Unpackaged food from a food premises** | * Details of the food consumed * Name of food premises * Date and time of consumption | * Lasagne * ABC Café, Collingwood * 8pm, 20/9/18 |
| **Consumption of any other food** | * Details of the food consumed | * Cake made at home |
| **Drug** | * Type of drug * Name of drug | * Anaesthetic * ABC brand |
| **Blood-derived products** | * Name of product * Batch number | * Serum * XXX123 |
| **Vaccine** | * Type of vaccine * Name of vaccine | * Childhood immunisation * MMR brand name |
| **Insect venom** | * Type of insect | * Jack jumper ant and geographical location |
| **Other** | * Details of the suspected cause of anaphylaxis | * Known to be anaphylactic, suspected to be triggered by exercise |
| **Unknown** | * Any relevant details | * First time reaction, unsure of trigger, referred to allergist |

# Departmental response

## Anaphylaxis due to food

The department will follow up all notifications of anaphylaxis presentations where:

* the suspected cause is the consumption of a packaged food, or
  + the suspected cause is a council registered food premises,

This may involve a phone conversation with the notifying doctor and/ or the case to clarify aspects of the information about the reaction and what was consumed.

**It is important to include contact details for the case when notifying and advise the case (or their parent/guardian) that the department may contact them for further details to help action to reduce food allergen risks.**

Such incidents are potential breaches of food laws and require follow up to prevent future mislabelling or contamination events. Such follow up may include laboratory testing of food and could result in a national or international food recall to remove the product from the marketplace.

Notifications involving unpackaged food from food businesses which suggest poor allergen management will be referred to the relevant local council, as the food regulator, for assessment of allergen management practices, education and potential enforcement action.

## Anaphylaxis due to drugs, blood-derived products and vaccination

Notifications of anaphylaxis caused by drugs, blood products and vaccines will be collected by the department, and forwarded periodically to appropriate bodies (TGA, Adverse Events Following Immunisation – Clinical Assessment Network).

**Hospitals should continue to report these drugs reactions directly to TGA and AEFI-CAN to ensure appropriate and timely action can be taken by these bodies where necessary.**

## Anaphylaxis due to insect venom

Notification data will be retained for possible future interrogation, for example of seasonal and geographical incidence of anaphylaxis, to contribute to the knowledge base and aid in policy development and service provision.

## Data storage, analysis and reporting

All information about anaphylaxis presentations collected by the department is health information for the purposes of the *Health Records Act 2001*. This Act aims to protect the privacy of an individual’s health information and how this information is managed. The department complies with this Act in dealing with any information collected.

The data collected through the anaphylaxis notification scheme will be monitored to determine trends over time and descriptive epidemiological analysis will be undertaken where possible. This information will be used to inform public health policies and planning and provide reports to stakeholders, including hospitals.

# Further assistance

For any questions about the scheme, phone notifications and the online notification process please contact 1300 364 352 or [email](mailto:anaphylaxis@dhhs.vic.gov.au) <[anaphylaxis@dhhs.vic.gov.au](mailto:anaphylaxis@dhhs.vic.gov.au)>.

# Appendices

## Appendix 1 – *Public Health and Wellbeing Act 2008*

**Division 3A—Notification of anaphylaxis presentation**

**130A Definitions**

In this Division—

***anaphylaxis reporting body*** means—

(a) a public hospital; or

(b) a denominational hospital; or

(c) a private hospital; or

(d) a multipurpose service; or

(e) a privately-operated hospital within the meaning of the **Health Services** **Act 1988**;

***person in charge*** means—

(a) in the case of an anaphylaxis reporting body that is a public hospital, denominational hospital, multipurpose service or privately-operated hospital, the chief executive officer of the body; and

(b) in the case of an anaphylaxis reporting body that is a private hospital, the proprietor of the private hospital.

**130B Notification by anaphylaxis reporting body**

(1) This section applies if a registered medical practitioner employed at, or otherwise engaged by, the anaphylaxis reporting body has reasonable grounds to believe that a person presenting for treatment at the anaphylaxis reporting body has anaphylaxis.

(2) An anaphylaxis reporting body must notify the Secretary in the prescribed manner of the prescribed notification details within the prescribed period.

(3) The person in charge of an anaphylaxis reporting body must implement processes to ensure that the anaphylaxis reporting body complies with subsection (2).

**130C Secretary may provide anaphylaxis reporting information**

If the Secretary considers that it is in the public interest to do so, the Secretary may provide information obtained under this Division to a person or class of person prescribed for the purposes of this section.

## Appendix 2 – *Public Health and Wellbeing Regulations 2009*

**Division 2A—Notification of anaphylaxis**

**76A Definitions**

In this Division—

1. ***food*** has the same meaning as it has in section 4(1) of the **Food Act 1984**;
2. ***package*** has the same meaning as it has in section 4(1) of the **Food Act 1984**.

**76B Prescribed notification details for a person having anaphylaxis**

For the purposes of section 130B(2) of the Act, the prescribed notification details are the details specified in Schedule 6A.

**76C Prescribed manner and period for notification of anaphylaxis**

For the purposes of section 130B(2) of the Act—

(a) the prescribed manner for notification is electronically through the Department’s website; and

(b) the prescribed period for notification is-

1. if the suspected cause of anaphylaxis is the consumption of packaged food, immediately upon the initial diagnosis of anaphylaxis; and
2. in any other case, within 5 days of the initial diagnosis of anaphylaxis.

**Schedule 6A—Anaphylaxis—prescribed notification details**

**1 Notification details—case information**

1.1 Family name

1.2 Given name(s)

1.3 Date of birth

1.4 Sex

1.5 Aboriginal or Torres Strait Islander status

1.6 Residential address

1.7 Contact details of the person/parent/guardian

**2 Notification details—clinical information**

2.1 Mortality details

2.2 Morbidity details

2.3 Allergies or other history of anaphylaxis reported by the person

2.4 Date of presentation for treatment for anaphylaxis

**3 Notification details—details of anaphylaxis reporting body**

3.1 Name and address of anaphylaxis reporting body

3.2 Telephone number and email address of anaphylaxis reporting body

3.3 Name and telephone number of registered medical practitioner who formed the reasonable belief that the person had anaphylaxis

3.4 Report date

**4 Notification details—suspected cause of anaphylaxis**

The notification details are to include one of the causes listed in column A of the Table as the suspected cause of the anaphylaxis of the person presenting for treatment, and the details in column B of the Table to the extent known to the anaphylaxis reporting body.

**Table**

|  |  |
| --- | --- |
| **Column A** | **Column B** |
| **Suspected cause of anaphylaxis** | **Additional notification details** |
| Consumption of packaged food | * Type of food product |
|  | * Brand of food product |
|  | * Date and time of consumption |
| Unpackaged food from a food premises | * Details of the food consumed. |
|  | * Name of the food premises. |
|  | * Date and time of consumption. |
| Consumption of any other food | * Details of the food consumed. |
| Drug | * Type of drug. |
|  | * Name of drug. |
| Blood-derived products | * Name of product. |
|  | * Batch number. |
| Vaccine | * Type of vaccine. |
|  | * Name of vaccine. |
| Insect venom | * Type of insect. |
| Other | * Details of the suspected cause of anaphylaxis. |
| Unknown | * Any relevant details. |

## Appendix 3 – Statutory definitions of ‘food’ and ‘package’

4A Meaning of *food* (Victorian Food Act 1984)

1. In this Act, food includes—
   1. any substance or thing of a kind used, or represented as being for use, for human consumption (whether it is live, raw, prepared or partly prepared);
   2. any substance or thing of a kind used, or represented as being for use, as an ingredient or additive in a substance or thing referred to in paragraph (a);
   3. any substance used in preparing a substance or thing referred to in paragraph (a) (other than a substance used in preparing a living thing) if it comes into direct contact with the substance or thing referred to in that paragraph, such as a processing aid;
   4. chewing gum or an ingredient or additive in chewing gum, or any substance used in preparing chewing gum;
   5. any substance or thing declared to be a food under a declaration in force under section 3B of the Australia New Zealand Food Authority Act 1991 of the Commonwealth.
2. A substance, thing, chewing gum or ingredient or additive in chewing gum described in subsection (1) is food regardless of whether or not it is in a condition fit for human consumption.

However, food does not include a therapeutic good.

To avoid doubt, food may include live animals and plants.

**Package** includes any container or wrapper in or by which food intended for sale is wholly or partly encased, covered, enclosed, contained or packed and, in the case of food carried or sold or intended to be carried or sold in more than one package, includes every such package;

## Appendix 4 – Questions and answers

### Do I notify anaphylaxis to food only or other allergens as well?

Yes, you are required to notify all confirmed cases of anaphylaxis to **all** allergens.

### What if I’m not sure what caused the anaphylaxis or there were several possibilities?

* You are still required to notify all cases of anaphylaxis, whether due to known and unknown allergens.
  + Please provide as much information as possible to help us make a risk assessment and take any necessary public health action.

### My patient received adrenaline prior to arriving at hospital and now has mild symptoms, so does not meet all the criteria for the clinical definition of anaphylaxis, do I still notify?

Yes, notify the case. For the purposes of this scheme, a case is considered confirmed even if one or more symptoms have resolved.

### My patient has had an allergic reaction, but not anaphylaxis. Should I notify?

There is no legal obligation to notify in this situation, however, if you think the cause of the allergic reaction may be (mislabelled) packaged food or mishandling (e.g. cross-contamination) at a food premises such as a restaurant or child care centre, please report the matter for investigation to the Food Safety Unit at [foodsafety@dhhs.vic.gov.au](mailto:foodsafety@dhhs.vic.gov.au) or 1300 364 352.

### What if my patient developed anaphylaxis on the ward while an inpatient and was sent to ED for observation, assessment or treatment, do I notify then?

Yes, if a patient is sent to ED, even from within the hospital, for treatment of anaphylaxis, you should notify.

### What about patients who present to outpatients for follow up and testing for allergies and anaphylaxis, do I notify those?

* There is no legal obligation to notify in this situation, as only presentations in the acute setting (e.g. emergency departments) need to be notified.
* If, however, the patient develops anaphylaxis whilst in clinic and is then sent to the ED for treatment, you should notify.

### Do I only have to notify people who have a previous history of anaphylaxis (known anaphylaxis) or those presenting with anaphylaxis for the first time?

All individuals presenting to hospital with anaphylaxis symptoms should be notified whether they have a history of anaphylaxis or have developed anaphylaxis for the first time.

### Should I still notify TGA for anaphylaxis due to drugs, pharmaceuticals or blood and blood-derived products? What about SAEFVIC for vaccine attributable anaphylaxis?

Yes, please continue to notify through these routes to ensure the organisations with responsibility in this area are aware and can take any action, as necessary.

### What if I have more questions?

* More information is available at [Anaphylaxis notifications](https://www.health.vic.gov.au/public-health/anaphylaxis-notifications) <https://www.health.vic.gov.au/public-health/anaphylaxis-notifications>
  + Alternatively, please contact 1300 364 352 or [email](mailto:anaphylaxis@dhhs.vic.gov.au) <anaphylaxis@dhhs.vic.gov.au>

1. Anaphylaxis Clinical Care Standard – Safer Care Victoria. February 2019 [↑](#footnote-ref-1)
2. Adapted from: Anaphylaxis definitions, Australian Society of Clinical Immunology and Allergy *ASCIA Guidelines - Acute management of anaphylaxis*, [ASCIA Guidelines - Acute management of anaphylaxis](https://www.allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines) <https://www.allergy.org.au/hp/papers/acute-management-of-anaphylaxis-guidelines> and The Royal Children’s Hospital Clinical Practice Guidelines, [Anaphylaxis Clinical Practice Guideline](https://www.rch.org.au/clinicalguide/guideline_index/Anaphylaxis) <https://www.rch.org.au/clinicalguide/guideline\_index/Anaphylaxis/> [↑](#footnote-ref-2)