

Analysis of deaths related to “Anaphylaxis caused by Injections”

Overview of Recommendations

This material was prepared by extracting the contents that would become points from the Recommendations for preventing the recurrence of medical accidents (Notice 3) "Analysis of deaths related to Anaphylaxis caused by injections" published by the Medical Accident Investigation and Support Center.

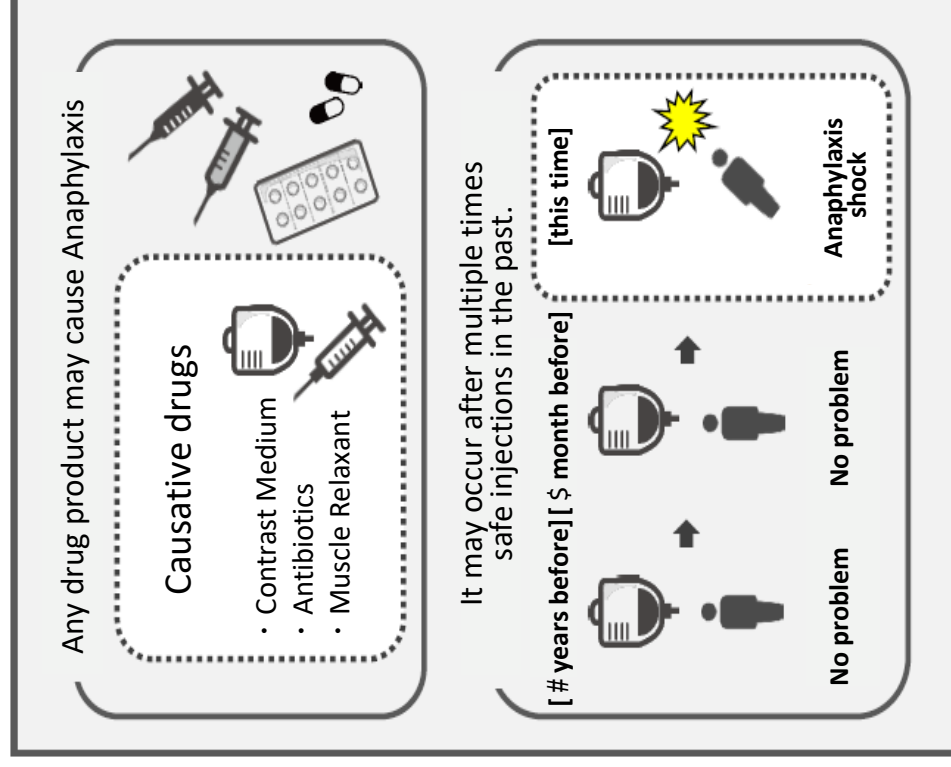
We hope this material will be used for training in medical institutions and widely disseminated.

Medical Accident Investigation and Support Center
Japan Medical Safety Research Organization
[Medsafe Japan]

[Recognition of Anaphylaxis]

Recommendation 1

Anaphylaxis may occur by any drug, and the drug products that could be safely used multiple times in the past.



- Anaphylaxis may be caused by any drug product.
 - Injections, especially Contrast Medium, Antibiotics and Muscle Relaxant are causes in many cases.
 - Even the drugs used safely multiple times in the past may cause fatal Anaphylaxis shock.
- ※ Four among 12 target cases had a history of the same Contrast Medium injected in the past.

POINTS

It is important to recognize that


- the drug products that could be safely used multiple times in the past and
- the drug products of which the specific antibodies were negative may cause the onset of Anaphylaxis.

Reference


Diagnostic criteria for Anaphylaxis

1. There are either of skin symptoms (systemic rash, itching or flush) or mucosal symptoms (swelling of the lips, tongue, palatine uvula, etc.), it rapidly occurs (within a few minutes to several hours) and is associated with at least one of the following a, b.


In addition, it is associated with at least one as shown on the right.



a. Skin and mucosal symptoms
 (Systemic rash, itching, flush, edema)




a. Respiratory symptoms
 (Dyspnea, airway narrowing, wheezing, hypoxemia)




b. Cardiovascular symptoms
 (Lowered blood pressure, disturbed consciousness)


2. It is associated with two or more of the following symptoms, which rapidly occur (within a few minutes to several hours) after exposure to a substance that is generally an allergen.




a. Skin and mucosal symptoms
 (Systemic rash, itching, flush, edema)



b. Respiratory symptoms
 (Dyspnea, airway narrowing, wheezing, hypoxemia)



c. Cardiovascular symptoms
 (Lowered blood pressure, disturbed consciousness)




d. Persisting gastrointestinal symptoms
 (abdominal colic, vomiting)

3. Rapidly lowered blood pressure (within a few minutes to several hours) after exposure to allergens in the patient.

Definition of lowered systolic blood pressure:
 Less than 70% of normal blood pressure or followings

| | |
|----------------------------------|-----------------------|
| 1 month to 11 months after birth | < 70 mmHg |
| 1 to 10 years old | < 70 mmHg + (2 × age) |
| 11 years old - adult | < 90 mmHg |



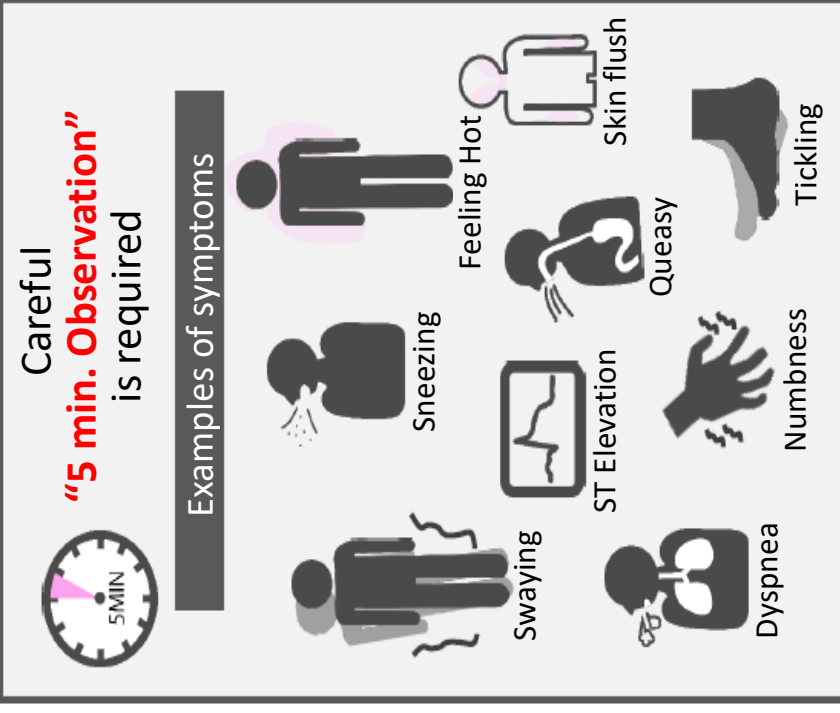
Lowered blood pressure

- Diagnostic criteria for Anaphylaxis due to various causes including food.
- According to the diagnostic criteria, if it falls into one of the three items on the left, it will be diagnosed as Anaphylaxis.
- Particular attention should be paid to the fact that Anaphylaxis caused by injections often occur within five minutes

[Observation at the time of drug use]

Recommendation 2

Careful observation is required when drugs with the high risk of onset were used



➤ When drug with the high risk of Anaphylaxis onset (Contrast Medium, Antibiotics and Muscle Relaxants, etc.) were used via intravenous injection, carefully observation of the patient for at least “Five Minutes” from the start of drug administration.

- In the target cases of analysis, the symptoms were detected during the administration of the drug or within five minutes from the start of administration.

[The examples of symptoms]

Swaying feeling, Throat Itching, Numbness, Tickling sensation, Queasy, Dyspnea, Sneezing, Feeling Hot, Skin flush, Rolling of the Eyes, Convulsion, Rapid Ventilation Deterioration, Elevated ST on ECG, etc.

POINTS

- Observation on the occurrence of Anaphylaxis related symptoms is necessary for five minutes from the start of drug administration.
- Skin symptoms are not essential for the diagnosis of Anaphylaxis.

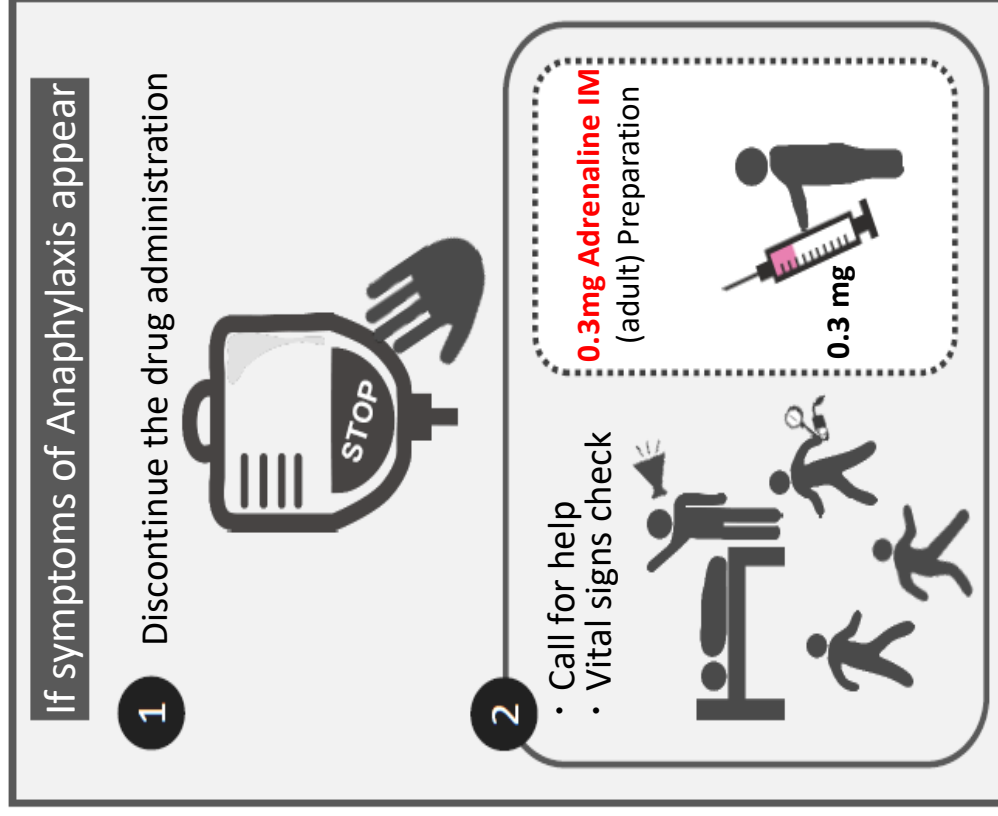
[Understanding of the symptoms and preparation of Adrenaline] Recommendation 3

If symptoms appear, discontinue the drug administration and prepare “Adrenaline”

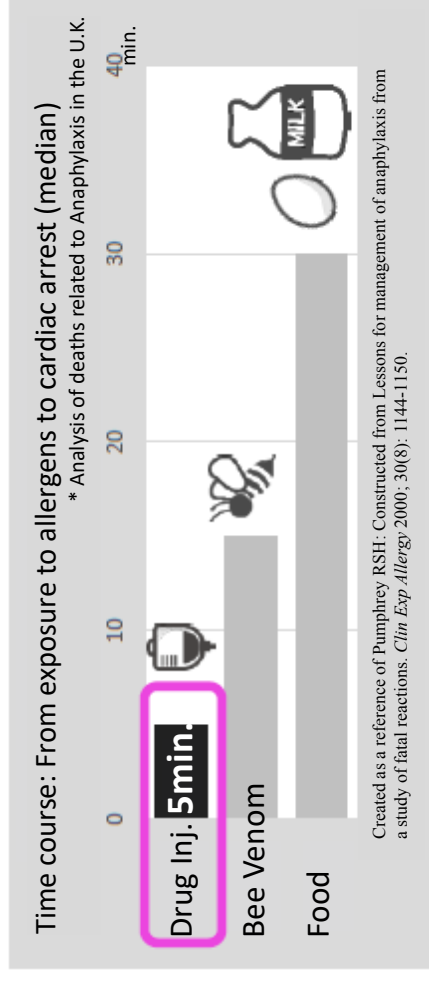
- If symptoms appear, regardless of the skin symptom, within five minutes from the start of drug administration, suspect Anaphylaxis.
- Respond
 - ➊ Discontinue drug administration, if Anaphylaxis is suspected
 - ➋ Prepare Adrenaline intramuscular injection in parallel with call for help and measure vital signs

POINTS

- If Anaphylaxis is suspected due to some drug products start immediately an initial response.



IM : Intramuscular Injection



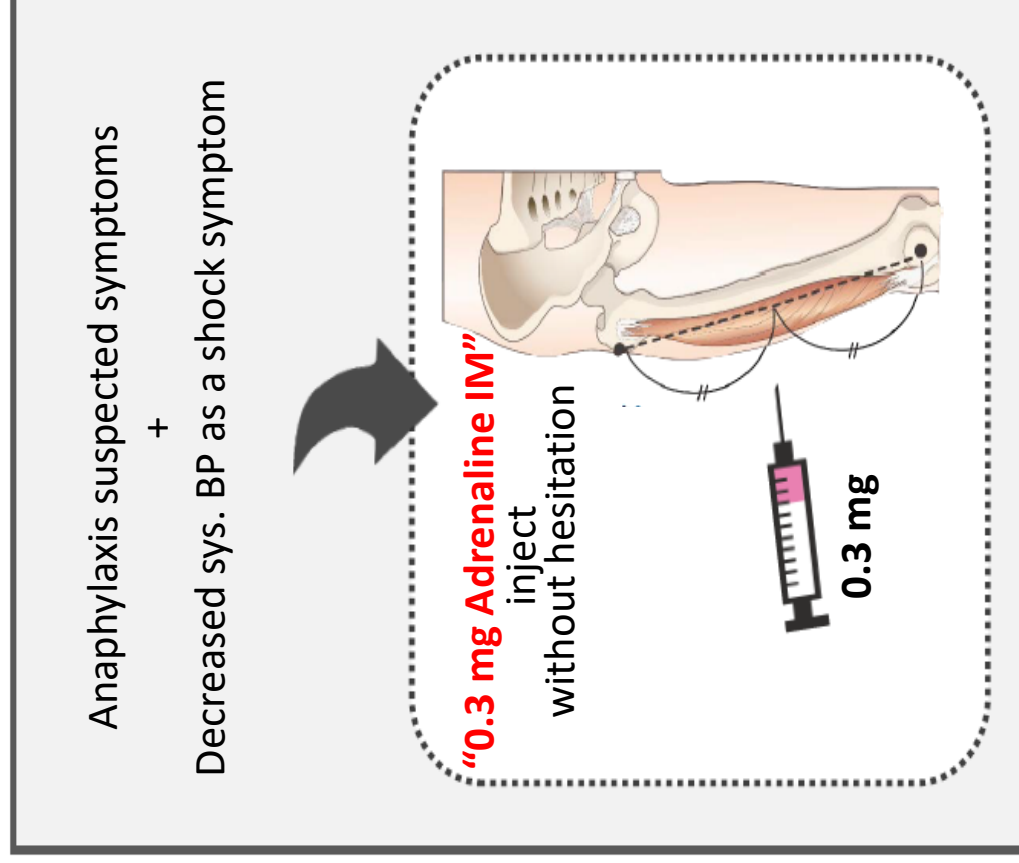
[Intramuscular injection of Adrenaline] Recommendation 4

If Anaphylaxis is suspected, do not hesitate Intra-Muscular injection of Adrenaline

- If the symptoms of Anaphylaxis are detected and shock symptoms or lowered systolic BP are observed, immediately inject 0.3 mg of Adrenaline intramuscularly into the antero-lateral thigh.
 - Lowered systolic blood pressure:
As a guide, • less than 90 mmHg or • obviously lower than normal blood pressure
- The “0.3 mg Adrenaline IM” is very unlikely to cause adverse events.

POINTS

- In the initial response of Anaphylaxis, an immediate intramuscular injection into the antero-lateral region of the thigh is effective.
- Antihistamines and corticosteroids are the secondary choice of drugs, and there is no evidence of contribution to the saving of lives.



[For Adrenaline deployment, instruction and rapid response system]

Recommendation 5

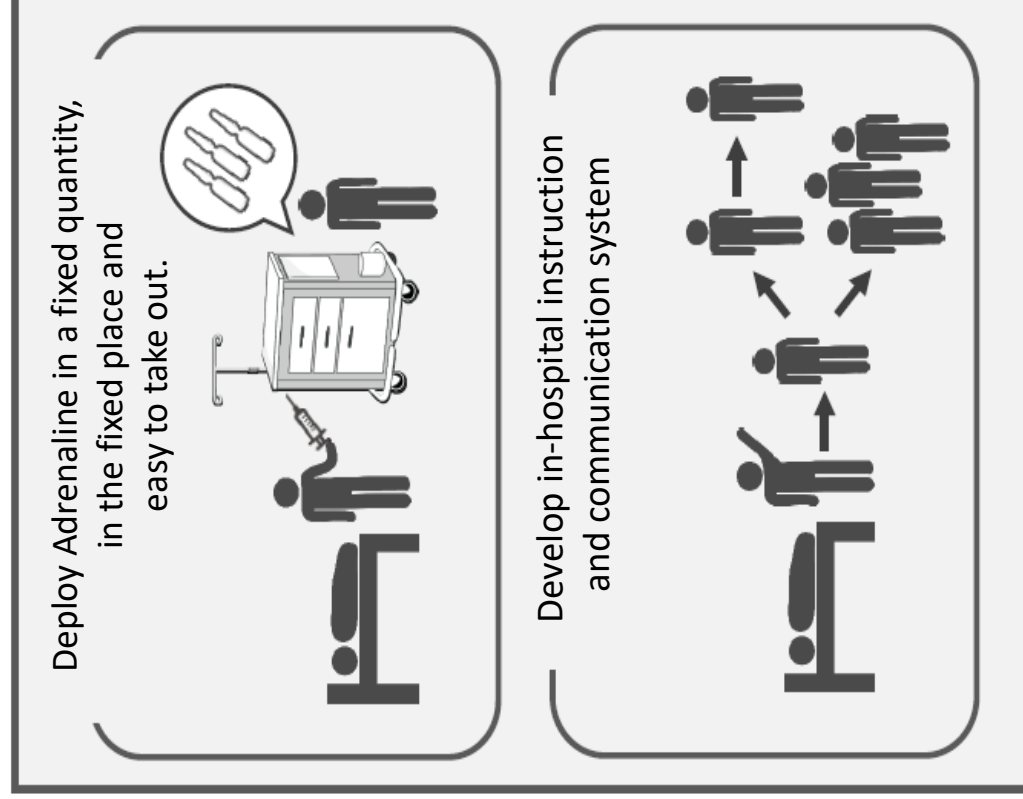
The system development where immediate “Adrenaline IM” available

- In the places where the causative drugs are used, such as Contrast Medium, Antibiotics, Muscle Relaxant, etc., deploy Adrenaline so that it can be administered at any time.
 - Deploy Adrenaline in order not to be confused with the 1.0 mg for resuscitation by measures, such as specifically describing that “0.3 mg of Adrenaline” is used for Anaphylaxis in the places where Adrenaline is deployed.

- Develop in-hospital instruction and communication system in order to promptly inform the physicians if symptoms concerned occur after the injection.

POINTS

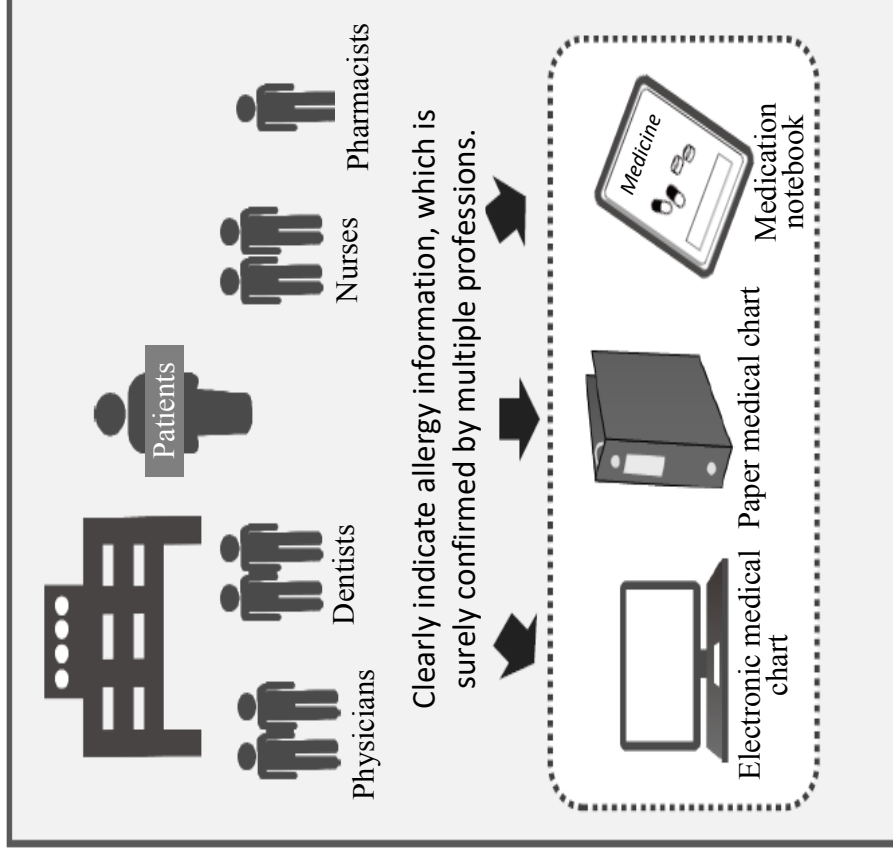
- Have “0.3 mg Adrenaline” always ready in fixed positions such as emergency carts from which Adrenaline is easy to take out.
(“Epipen[®] injection solution 0.3 mg” can be used as a substitute depending on the circumstances in the medical institutions).



[Understanding and sharing of allergy information]

Recommendation 6

Establish the system by which the patients drug allergy information can be understood and shared.



- Understanding and sharing patients' allergy information leads to preventing the onset of Anaphylaxis as much as possible.
- It is important to thoroughly share patients' allergy information among multiple professions

POINTS

- Clearly indicate the rules of the operation of electronic medical charts, etc. because all personnel involved in patient care should share the allergy information.
- Even the same ingredients may have different names (original drugs and generic drugs). It is necessary to make it understood that they are the same ingredients.