ASSESSMENT AND MANAGEMENT OF POTENTIAL ANAPHYLAXIS POST COVID-19 VACCINATION

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BACKGROUND

Anaphylaxis, an acute and potentially life-threatening allergic reaction, has been reported in rare instances following COVID-19 vaccination. This document, developed by DHMOSH Public Health (dos-dhmosh-public-health@un.org) and adapted from CDC guidelines¹, provides information on preparing for the initial assessment and management of anaphylaxis following COVID-19 vaccination.

In all cases, appropriate medical treatment for severe allergic reactions must be immediately available in the event that an acute anaphylactic reaction occurs following administration of a COVID-19 vaccine. Note that all recommendations below should be considered alongside local health authorities’ regulations.

OBSERVATION PERIOD FOLLOWING COVID-19 VACCINATION

We recommend that persons be observed after vaccination for the following time periods:

- **30 minutes observation time**: Persons with a history of an immediate allergic reaction² of any severity to a vaccine or injectable therapy and persons with a history of anaphylaxis due to any cause.
- **15 minutes observation time**: All other persons

EARLY RECOGNITION OF ANAPHYLAXIS

Because anaphylaxis requires immediate treatment, diagnosis is primarily made based on recognition of clinical signs and symptoms, including:

- **Respiratory**: sensation of throat closing, stridor (high-pitched sound while breathing), shortness of breath, wheeze, cough
- **Gastrointestinal**: nausea, vomiting, diarrhoea, abdominal pain
- **Cardiovascular**: dizziness, fainting, tachycardia (abnormally fast heart rate), hypotension (abnormally low blood pressure)
- **Skin/mucosal**: generalized hives, itching, or swelling of lips, face, throat

Symptoms often occur within 15-30 minutes of vaccination, though it can sometimes take several hours for symptoms to appear.

Early signs of anaphylaxis can resemble a mild allergic reaction, and it is often difficult to predict whether initial, mild symptoms will progress to become an anaphylactic reaction. In addition, not all symptoms listed above are necessarily present during anaphylaxis. Most people will present with skin manifestations. Symptoms are considered generalized if there are generalized hives and more than one body system (e.g., cardiovascular, gastrointestinal) is involved. If a patient develops itching and swelling confined to the injection site, the patient should be observed closely for the development of generalized symptoms (beyond the recommended observation periods noted above, if necessary).

If symptoms are generalized, epinephrine should be administered as soon as possible, emergency medical services should be contacted, and patients should be transferred to a higher level of medical care. In addition, patients should be instructed to seek immediate medical care if they develop signs or symptoms of an allergic reaction after their observation period ends and they have left the vaccination site.

¹ CDC: Managing Anaphylaxis After COVID-19 Vaccination
² Please note that for individuals with a history of any immediate allergic reaction to any other vaccine a risk assessment should be conducted to determine the type and severity of reaction. These individuals can still receive vaccination but should be counselled that risk of developing a severe allergic reaction should be balanced against benefit of the vaccination.
MEDICATIONS AND SUPPLIES FOR ASSESSING AND MANAGING ANAPHYLAXIS

The following medications and supplies are important for evaluating and managing of anaphylaxis and are recommended for all COVID-19 vaccination sites. Further guidance for creating “epinephrine kits” for emergency use can be found in the Annex.

The following emergency equipment should be immediately available to the clinical team assessing and managing anaphylaxis.

<table>
<thead>
<tr>
<th>Should be available at all sites</th>
<th>To include at all sites if feasible</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine (autoinjector or prepared at time of event/from kit – see Annex)*</td>
<td>Pulse oximeter</td>
</tr>
<tr>
<td>H1 antihistamine (e.g., diphenhydramine)†</td>
<td>Oxygen with delivery device (e.g. nasal cannula, face mask etc)</td>
</tr>
<tr>
<td>Blood pressure cuff</td>
<td>Bronchodilator (e.g., albuterol, salbutamol etc)</td>
</tr>
<tr>
<td>Stethoscope</td>
<td>H2 antihistamine (e.g., famotidine, cimetidine)</td>
</tr>
<tr>
<td>Timing device to assess pulse</td>
<td>Intravenous fluids</td>
</tr>
<tr>
<td></td>
<td>Intubation kit</td>
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<tr>
<td></td>
<td>Pocket mask with one-way valve (also known as cardiopulmonary resuscitation (CPR) mask)</td>
</tr>
</tbody>
</table>

*COVID-19 vaccination sites should have at least 3 doses of epinephrine on hand at any given time.

†Antihistamines may be given as adjunctive treatment but should not be used as initial or sole treatment for anaphylaxis. Additionally, caution should be used if oral medications are administered to persons with impending airway obstruction.

MANAGEMENT OF ANAPHYLAXIS AT A COVID-19 VACCINATION SITE

If anaphylaxis is suspected, take the following steps:

- Rapidly assess airway, breathing, circulation, and mentation (mental activity).
- Call for emergency medical services.
- Place the patient in a supine position (face up), with feet elevated, unless upper airway obstruction is present, or the patient is vomiting.
- Epinephrine (1 mg/ml aqueous solution [1:1000 dilution]) is the first-line treatment for anaphylaxis and should be administered immediately into the lateral thigh.
  - In adults, administer a 0.3 mg intramuscular dose with the maximum adult dose is 0.5 mg per dose.
  - For children, administer dose at 0.01 mg/kg per dose (to maximum 0.5 mg per dose)
  - Epinephrine dose may be repeated every 5-15 minutes (or more often) as needed to control symptoms while waiting for emergency medical services.
  - Because of the acute, life-threatening nature of anaphylaxis, there are no contraindications to epinephrine administration.

Antihistamines (e.g., H1 or H2 blockers) and bronchodilators do not treat airway obstruction or hypotension, and thus are not first-line treatments for anaphylaxis. However, they can help provide relief for hives and itching (antihistamines) or symptoms of respiratory distress (bronchodilators) but should only be administered after epinephrine in a patient with anaphylaxis. Because anaphylaxis may recur after patients begin to recover, monitoring in a medical facility for at least several hours is advised, even after complete resolution of symptoms and signs.
CONSIDERATIONS FOR ANAPHYLAXIS MANAGEMENT IN SPECIAL POPULATIONS

**Older adults**

There are no contraindications to the administration of epinephrine for the treatment of anaphylaxis for older adults. Although adverse cardiac events, such as myocardial infarction or acute coronary syndrome, have been reported in some patients who received epinephrine for treatment of anaphylaxis (particularly among older adults with hypertension and/or atherosclerotic heart disease) epinephrine is the first-line treatment for anaphylaxis.

**Pregnant Individuals**

Pregnant people with anaphylaxis should be managed the same as non-pregnant people. They should be closely monitored to ensure adequate perfusion, and their fetus should be closely monitored as well, as appropriate.

**Children**

Anaphylaxis should be managed in children the same way as in adults aside from dosing considerations.

**PATIENT COUNSELING**

Patients who experience anaphylaxis after the first dose of COVID-19 vaccination should be instructed not to receive additional doses. In addition, patients should be referred to an allergist-immunologist for appropriate work-up and additional counselling.

**REPORTING OF ANAPHYLAXIS**

Adverse events following vaccination that are beyond the normal side effect profile and require treatment are to be recorded as part of the clinic visit for that vaccination and is an important part of vaccine post-marketing safety. Please note that in locations where the EarthMed System is used, the diagnosis code T80.5 is to be used for anaphylaxis and T88.1 is to be used to designate other significant adverse reactions. The diagnosis is to be marked ‘Yes/Likely’ for Work Related if the vaccine was given by your clinic, and the details recorded in the clinic visit. Adverse events are not recorded for vaccines given by other providers except where the symptoms are reviewed as a stand-alone clinic visit. This information is also included in the EarthMed COVID-19 User Guide.

**ADDITIONAL RESOURCES**

- [DHMOSH Public Health Video: Management of Potential Anaphylaxis Post-COVID-19 Vaccination](#)
- [UpToDate: Anaphylaxis Emergency Treatment](#)
- [UK NICE: Anaphylaxis Guidelines](#)
- [CDC: Managing Anaphylaxis After COVID-19 Vaccination](#)
ANNEX: PREPARING “EPINEPHRINE KITS” FOR ANAPHYLAXIS

INTRODUCTION

Epinephrine administered intramuscular (IM) is the first-line treatment for the patient experiencing anaphylaxis.

Epinephrine should always be readily available in case of anaphylaxis due to medications and other triggers. Although epinephrine auto-injectors are easy to use and result in less delays in epinephrine administration they are costly. For this reason, we are providing guidance on the logistics of preparing an “epinephrine kit”.

MATERIALS NEEDED FOR PREPARING AN “EPINEPHRINE KIT”

The following items should be part of an “epinephrine kit” and can be easily assembled in the clinic/hospital. Each clinic/hospital should have at least THREE kits available at any given time, or quantities determined by number of people attending vaccination clinic.

Please note that the items below are only for one kit.

<table>
<thead>
<tr>
<th>Item</th>
<th>Picture*</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epinephrine injection 1mg/mL ampule</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Label stating “For IM use only”. This medication should NOT be given Intravenous (IV).</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1 mL syringe</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>1½ inch Safety Glide needle (22-25G depending on what is available)</td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Alcohol swab</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

*Photos included are only examples. Supplies may differ by duty station and/or clinic based on local procurement and availability. Other items which may be required include gloves, scissors to cut clothes.

EPINEPHRINE SYRINGE PREPARATION

Epinephrine should be drawn up at the time of anaphylaxis. Given that epinephrine is sensitive to light and needs to be stored at 15-30 °C, it is not advised that epinephrine is drawn up in advance of a clinic as this can lead to errors and degradation of the medication.

Ensure that the medication is drawn up by those with the correct training and knowledge on how to do so and can do this under pressure, as every minute counts during anaphylaxis.

DELAYS SHOULD BE AVOIDED. Therefore, please practice the process described below if you are not familiar with it.

An epinephrine ampule of 1 mg/mL should be used (see picture above):
Patients weighing >25 to 50 kg can be given 0.3 mg by drawing up 0.3 mL of the 1 mg/mL solution.
Patients who weigh >50 kg can be given 0.5 mg by drawing up 0.5 mL of the 1 mg/mL solution.

**STEP BY STEP INSTRUCTIONS ON EPINEPHRINE SYRINGE PREPARATION**

1. Get the 1mg/mL epinephrine ampule and open it
2. If not already attached, attach the 22G-25G (gauge may vary based on what is available at your duty station) 1 ½ inch needle to the 1 mL syringe
3. Draw the epinephrine to the desired volume (as above) and ensure no air bubbles
4. Administer the dose in the mid- anterior lateral thigh (can be given with or without clothes on).
5. Repeat dosing if necessary, in the opposite side

**ADDITIONAL RESOURCES**

- [Immunization Action Coalition: How to Administer Intramuscular and Subcutaneous Vaccine Injections](#)