

Advice regarding medication and equipment that should be available at all centres providing the COVID-19 Pfizer BioNTech vaccine

Background

An anaphylactic reaction is a potential risk when administering any vaccine. Following two cases of anaphylactoid reaction to the Pfizer/BioNTech vaccine very early on in the programme the MHRA issued additional advice. This states the following:

- Any person with a history of immediate-onset anaphylaxis to a vaccine, medicine or food should not receive the Pfizer/BioNTech vaccine. A second dose of the Pfizer/BioNTech vaccine should not be given to those who have experienced anaphylaxis to the first dose of Pfizer/BioNTech vaccine.
- Vaccine recipients should be monitored for 15 minutes after vaccination, with a longer observation period when indicated after clinical assessment.
- A protocol for the management of anaphylaxis and an anaphylaxis pack must always be available whenever the Pfizer/BioNTech vaccine is given. Immediate treatment should include early treatment with 500 micrograms intramuscular adrenaline (0.5ml of 1:1000 or 1mg/ml adrenaline), with an early call for help and further IM 1:1000 adrenaline every 5 minutes if no better.
- The health professionals overseeing the immunisation service must be trained to recognise an anaphylactic reaction and be familiar with techniques for resuscitation of a patient with anaphylaxis.

Drugs

The Resuscitation Council (UK) include the following list of drugs that should be used in the treatment of anaphylaxis:

- 1 Intramuscular (IM) 1:1000 adrenaline
- 2 Oxygen
- 3 Fluids; 500-1000ml given IV. 0.9% sodium chloride (normal saline) or Hartmann's solution
- 4 Antihistamines (after initial resuscitation); chlorphenamine given IM or slow IV
- 5 Steroids (after initial resuscitation); hydrocortisone given IM or slow IV

The latter two drugs are not part of immediate treatment of a case of anaphylaxis.

All vaccine sites must consider the possibility of needing to manage more than one anaphylactoid response at once or in quick succession. Sites must therefore ensure that they have adequate supplies available at all times to manage multiple episodes. The size and throughput of site should be considered when determining the stock levels and availability of each product. The ability to restock items quickly is essential to reduce the risk of having to suspend vaccination, particularly given the short shelf life of the Pfizer/BioNTec vaccine.

Vaccination should not be administered at a site if a complete anaphylaxis kit is not available.

Oxygen should be available at every vaccination site.

Fluids – these should be available at every site as they are part of the supplies provided nationally. It is recognised that not every site will have staff available at all times who are competent and experienced in the administration of IV fluids.

Equipment

The MHRA guidance quoted above includes the need for a protocol and appropriate pack for the management of anaphylaxis for centres giving the Pfizer/BioNTech vaccine. It does not specifically mention the requirement for equipment to manage cardio-respiratory arrest. The Resuscitation Council (UK) includes cardiac ischaemia and cardiac arrest as potential consequences of anaphylaxis.

The Resuscitation Council (UK) has a list of equipment that it recommends is available in primary care facilities for the management of cardiac arrest, reproduced below:

Primary Care - Minimum suggested equipment

Item	Suggested availability	Comments
Protective equipment - gloves, aprons, eye protection	Immediate	
Pocket mask (adult) with oxygen port	Immediate	May be used inverted in infants
Oxygen cylinder (with key where necessary)	Immediate	
Oxygen tubing	Immediate	
Automated external defibrillator (AED)	Immediate	Preferably with facilities for paediatric use as well as use in adults. Type of AED and location determined by a local risk assessment. AEDs are not intended for use in infants (less than 12 months old) and this should be considered at risk assessment.
Adhesive defibrillator pads	Immediate	Spare set also recommended
Razor	Immediate	
Stethoscope	Immediate	
Absorbent towel	Immediate	To dry chest if necessary

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The Supply Inventory List for local vaccination services and for vaccination centres includes the provision of an automated electronic defibrillator so it is assumed that all vaccination locations will have access to an AED

Access to an AED is not required for a roving model of service provision.

New national guidance of management of anaphylaxis in a vaccination setting

The Resuscitation Council (UK) published on Tuesday 15th December revised guidance on the management of anaphylaxis in a vaccination setting. This guidance is available here:

<https://www.resus.org.uk/about-us/news-and-events/rcuk-publishes-anaphylaxis-guidance-vaccination-settings>

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