Adverse events following Immunisation Common and Uncommon

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Health Service Executive

Objectives

- To define of adverse events that can occur following immunisation (AEFI)
- To identify minor, rare and serious adverse reactions
- To define “anaphylaxis” and recognise signs and symptoms of anaphylaxis and appropriate management
- To outline the reporting of adverse reactions to the Health Products Regulatory Authority (formerly the Irish Medicines Board)

Training in management of anaphylaxis

- Individuals giving vaccinations must receive appropriate training
- Updates as required to maintain individual competence

Adverse Event Following Immunisation

- Any untoward medical occurrence which follows immunisation and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease

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Adverse events following Immunisation

Frequency of reactions classified as

- Very common > 1 in 10
- Common > 1 in 100 and < 1 in 10
- Uncommon > 1in 1,000 and < 1 in 100
- Rare > 1/10,000 and < 1 in 1,000
- Very rare < 1/10,000

Adverse Events Following Immunisation

1. Vaccine Product-Related AEFI
2. Vaccine Quality Defect-Related AEFI
3. Immunisation Error-Related Reaction AEFI
4. Immunisation Anxiety-Related Reaction AEFI
5. Coincidental Event AEFI

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Vaccine Induced AEFIs

- Local reactions
  - common *(redness, fever and swelling at the injection site)*
- General reactions
  - usually occur within 24-48 hours of vaccination *(fever, irritability, loss of appetite)*
- Anaphylaxis
- Later reactions
  - post MMR ("mini measles" after 7-10 days)

Local reactions

- Not surprising
- Occur within hours of receiving the vaccine
- Usually mild and self limiting
- Reduced by using correct needle length
- **Do not contraindicate** the administration of this vaccine subsequently.

Minor reactions following immunisation

Frequency of minor reactions			
	Local reaction	Fever	Irritability, malaise
BCG	Common	Rare	Rare
DTP/IPV	Common	Common	Common
MMR	Common	Common	Uncommon
Hib	Common	Uncommon	Uncommon
Men C	Common	Uncommon	Uncommon
Hep B	Common	Uncommon	Uncommon
Pneumococcal	Common	Uncommon	Uncommon

Source: Summary of Product Characteristics

Systemic reactions

Timing varies according to the type of vaccine received.

- Tetanus containing vaccines - fever within a few hours
- MMR vaccine - rash 7-10 days later.

– **Do not contraindicate** the administration of this vaccine subsequently

Management of common reactions

- Inform parents verbally and with information leaflets
  - expected common events post-vaccination –
  - how to treat them.
    - paracetamol or ibuprofen (pyrexia>39.5^{0}C)
    - no aspirin or aspirin-containing medication if under 18 years of age (Reye's syndrome).
- BCG vaccination
  - 3 – 6 weeks after vaccination, in almost all cases small red pustule (s) will appear at the site of the injection
  - remain for a number of weeks and may discharge slightly
  - normal reaction and will resolve leaving a flat scar

Anaphylaxis

Severe systemic (whole body) allergic reaction.

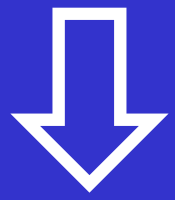
The key issues in the management

- Awareness that anaphylaxis though rare can occur
- Early recognition
- Early treatment.
- Extremely rare event 1/1,000,000 doses of vaccine given
- Most vaccinators will never see an anaphylactic reaction.

BUT it can be a life threatening event

must be diagnosed and treated appropriately.

Signs and symptoms of anaphylaxis

Clinical Progression	Signs and Symptoms
Mild early warning signs	Itching of skin, rash and swelling around the injection site. Dizziness and general feeling of warmth
	Painless swelling in parts of the body e.g. face or mouth. Flushed, itchy skin, nasal congestion, sneezing tears
	Hoarseness, feeling sick ,vomiting
Life threatening symptoms	Swelling in the face, difficulty breathing, abdominal pain
	Wheezy, difficulty breathing, collapse, low blood pressure, weak pulse

Anaphylaxis and other common reactions to vaccination.

Faint	*Anxiety attack*	*Breath holding episode*	*Anaphylaxis*
• Good central pulses but may be bradycardic • Respiration continues • Pallor • Warm skin • Unusual in pre-school children • No upper airway oedema • No itching • Patient regains consciousness when lying down	• May appear fearful • Usually tachypnoeic •Hyperventilation • Pallor • Tingling of face and extremities • Complains of feeling light-headed, dizzy or numb	• Mainly in young children • Generally distressed/ crying prior to episode • Facial flushing and cyanosis • Can briefly become unconscious during which breathing returns	• Poor central pulses, usually sinus tachycardia • Possible apnoea, especially in children • Upper airway oedema, sneezing • Hive like (Urticarial) lesions & itching • Sense of impending doom • Flushed sweating cold skin • Patient does not revive when lying down

Management of anaphylaxis

- Send for additional medical assistance
- Dial 999 OR 112 and state that there is a case of anaphylaxis
- Lie patient, ideally with legs raised unless the patient has breathing difficulties
- Administer oxygen if available
- If the patient is unconscious an airway should be inserted
- If the patient stops breathing, mouth to mouth resuscitation should be performed but preferably bag valve mask ventilation should be performed

Dose of adrenaline

1:1000 (1mg(1000µcg)/ml) IM

Child: Dose by weight (0.01ml/kg) or age

- 0 - 5 years 0.15ml (150µcg)
- 6 -12 years 0.3ml (300µcg)
- >12 years 0.5ml (500µcg)

Adult: 0.5ml (500ucg)

Those ≥ 100 kgs can be given 1mg IM (use green needle, 37 - 40mm)

Reporting of AEFI

- Report all suspected adverse reactions to the Health Products Regulatory Authority (formerly Irish Medicines Board)

  Kevin O' Malley House
  Earlsfort Centre,
  Earlsfort Terrace,
  Dublin 2,

- Use the on-line reporting system at www.hpra.ie

  - **A downloadable version of the form is also available, which can be filled in manually and sent to the HPRA by freepost.**

  - **By calling the HPRA on (01) 676 4971.**

- Give as much detail as possible
- Pharmaceutical companies are obliged to also submit adverse reaction reports to the HPRA.

Useful Resources

- **Health Products Regulatory Authority www.hpra.ie**
- **American Academy of Paediatrics. 2012 Report of the Committee on Infectious Diseases – The Red Book. http://aapredbook.aappublications.org/**
- **Department of Health UK. November 2013. Immunisation against infectious disease. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/266583/The_Green_book_front_cover_and_contents_page_December_2013.pdf**
- **Ewan P.W. ABC of allergies: Anaphylaxis. BMJ1998 (316) 1442-1445**
- **Health Protection Surveillance Centre, Ireland. www.hpsc.ie**
- **Royal College of Physicians of Ireland. Immunisation Guidelines for Ireland 2013 and updates. Available at www.immunisation.ie**
- **World Health Organisation. Adverse events following immunisation http://www.who.int/immunization_safety/aefi/en/**
- **World Health Organisation. Global Advisory Committee on Vaccine Safety http://www.who.int/vaccine_safety/en/index.html**

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