Adverse events following Immunisation and Anaphylaxis
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 Irish Medicines Board

www.immunisation.ie
Training in management of anaphylaxis

• Individuals giving vaccinations must receive appropriate training

• Regular updates every 2 years
Adverse events following Immunisation

Frequency of reactions classified as

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

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WHO classification of AEFIs

– Programme related
  • Wrong vaccine/incorrect storage or administration

– Vaccine-induced
  • Direct effect of the vaccine or its component parts

– Coincidental
  • Chance event e.g. URTI post influenza vaccination

– Unknown
  • Undetermined cause

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Vaccine Induced AEFIIs

- 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

<table>
<thead>
<tr>
<th>Vaccine</th>
<th>Local reaction</th>
<th>Fever</th>
<th>Irritability, malaise</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCG</td>
<td>Common</td>
<td>Rare</td>
<td>Rare</td>
</tr>
<tr>
<td>DTP/IPV</td>
<td>Common</td>
<td>Common</td>
<td>Common</td>
</tr>
<tr>
<td>MMR</td>
<td>Common</td>
<td>Common</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Hib</td>
<td>Common</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Men C</td>
<td>Common</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Hep B</td>
<td>Common</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
<tr>
<td>Pneumococcal</td>
<td>Common</td>
<td>Uncommon</td>
<td>Uncommon</td>
</tr>
</tbody>
</table>

Source: Summary of Product Characteristics

[www.immunisation.ie](http://www.immunisation.ie)
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°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.

www.immunisation.ie
# Signs and symptoms of anaphylaxis

<table>
<thead>
<tr>
<th>Clinical Progression</th>
<th>Signs and Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild early warning signs</td>
<td>Itching of skin, rash and swelling around the injection site. Dizziness and general feeling of warmth</td>
</tr>
<tr>
<td>Life threatening symptoms</td>
<td>Painless swelling in parts of the body e.g. face or mouth. Flushed, itchy skin, nasal congestion, sneezing tears</td>
</tr>
<tr>
<td></td>
<td>Hoarseness, feeling sick, vomiting</td>
</tr>
<tr>
<td></td>
<td>Swelling in the face, difficulty breathing, abdominal pain</td>
</tr>
<tr>
<td></td>
<td>Wheezy, difficulty breathing, collapse, low blood pressure, weak pulse</td>
</tr>
</tbody>
</table>
## Anaphylaxis and other common reactions to vaccination.

<table>
<thead>
<tr>
<th></th>
<th>Faint</th>
<th>Anxiety attack</th>
<th>Breath holding episode</th>
<th>Anaphylaxis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>• Good central pulses but may be bradycardic</td>
<td>• May appear fearful</td>
<td>• Mainly in young children</td>
<td>• Poor central pulses, usually sinus tachycardia</td>
</tr>
<tr>
<td></td>
<td>• Respiration continues</td>
<td>• Usually tachypnoeic</td>
<td>• Generally distressed/ crying prior to episode</td>
<td>• Possible apnoea, especially in children</td>
</tr>
<tr>
<td></td>
<td>• Pallor</td>
<td>• Hyperventilation</td>
<td>• Facial flushing and cyanosis</td>
<td>• Upper airway oedema, sneezing</td>
</tr>
<tr>
<td></td>
<td>• Warm skin</td>
<td>• Pallor</td>
<td>• Can briefly become unconscious during which breathing returns</td>
<td>• Hive like (Urticarial) lesions &amp; itching</td>
</tr>
<tr>
<td></td>
<td>• Unusual in pre-school children</td>
<td>• Tingling of face and extremities</td>
<td></td>
<td>• Sense of impending doom</td>
</tr>
<tr>
<td></td>
<td>• No upper airway oedema</td>
<td>• Complains of feeling light-headed, dizzy or numb</td>
<td></td>
<td>• Flushed sweating cold skin</td>
</tr>
<tr>
<td></td>
<td>• No itching</td>
<td></td>
<td></td>
<td>• Patient does not revive when lying down</td>
</tr>
<tr>
<td></td>
<td>• Patient regains consciousness when lying down</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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
- <6 months    0.05ml (50µcg)
- 7-18 months  0.1ml (100µcg)
- 18-36 months 0.15ml (150µcg)
- 4-7 years    0.2ml (200µcg)
- 8-10 years   0.3ml (300µcg)
- 11-12 years  0.4ml (400µcg)
- > 12 years   0.5ml (500µcg)

Adult: 0.5ml (500µcg)
Those ≥ 100 kgs can be given 1mg IM (use green needle, 37mm)
Reporting of AEFI

• Report all suspected adverse reactions to the Irish Medicines Board
  
  Kevin O’ Malley House
  Earlsfort Terrace,
  Dublin 2,

• Use the Adverse Reaction Report (Yellow) Card System
  – “Freepost” system (cards from the IMB or from www.imb.ie
  – on-line version of the report form is available from www.imb.ie

• Give as much detail as possible

• Pharmaceutical companies are obliged to also submit adverse reaction reports to the IMB.
Useful Resources


• 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 2008 and updates. Available at www.rcpi.ie or www.immunisation.ie or www.hpsc.ie

• World Health Organisation. Adverse events following immunisation http://www.who.int/immunization_safety/aefi/en/


www.immunisation.ie