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REC

Primary Care Immunisation Update Webinar Series

November 2023: Adverse Events Following Immunisation

Welcome to the webinar. This webinar will commence at the scheduled time.

Before then please take a moment to read through the tips below



- All delegate's lines are muted throughout the presentation
- If at other times you are in a noisy environment please mute your line by pressing the mute button on your screen (this can be found at the bottom)
- If you would like to ask a question please use the message function
- There will be an opportunity at the end for questions, at this point microphones will be un-muted – you will need to unmute yourself though to be heard
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- If you are having any technical problems please send a message to the host via the message function or email immstraining@ukhsa.gov.uk

Webinar Essentials

Today's webinar

- Trainer is Pauline MacDonald
- 30 minutes Pauline talking with slides
- 15 minutes for questions and answers from delegates

Access to slides

- Copy of slides will be emailed to delegates
- Underlined text on the slides are hyperlinks – click to go straight to the link

Following the webinar

- You will be emailed a link to an electronic evaluation (Select Survey)
- Your feedback is essential to support the development of the webinar series
- A certificate will be emailed once the evaluation is completed



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Primary Care Immunisation Update Webinar Series

November 2023: Adverse Events Following Immunisation

Presenter – Pauline MacDonald

Learning outcomes

- Classify the types of adverse events that can follow immunisation
- Discuss how understanding and managing adverse events supports quality practice
- Consider how explaining adverse events following immunisation can increase vaccine confidence
- Consider lessons learnt for your future practice

Role of immunisers

Successful immunisation programmes rely on public trust and confidence

This includes trust and confidence in:

- The immunisation programme – including processes such as monitoring safety
- The vaccines being administered
- The immuniser who needs to be knowledgeable, promotes and administer the vaccines correctly



Classification of Adverse Events Following Immunisation (AEFI) -

- Defined in Green Book Chapter 8
- Programmatic errors
 - Incorrect doses or routes, out of date etc
- Vaccine-induced AEFI
 - Induced direct effects of vaccine or vaccine component and/or due to underlying medical condition or idiosyncratic response in recipient
- Coincidental events
 - Chance happening
- Related to administration
 - Due to injection or delivery system, not the vaccine e.g. pain, anxiety, fear
- Unknown
 - Cause cannot be determined

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Vaccine safety and the management of adverse events following immunisation

Introduction

Vaccines induce protection by eliciting active immune responses to specific antigens. There may be predictable adverse reactions (side effects): most are mild and resolve quickly. However, it is not always possible to predict individuals who might have a mild or serious reaction to a vaccine. The advice in this chapter uses the World Health Organization (WHO) classification of adverse events following immunisation (AEFIs). It gives an overview of common side effects associated with vaccines and of the management of serious adverse reactions such as anaphylaxis. The process of vaccine safety monitoring in the UK and the reporting of suspected vaccine-induced adverse drug reactions (ADRs) via the Yellow Card scheme are described in Chapter 9.

Adverse events following immunisation

AEFIs may be true adverse reactions that are intrinsic to the vaccine, or may be caused by the way it is administered or be related to an underlying condition in the recipient. Other AEFIs may be coincidental and would have occurred regardless of vaccination.

WHO classifies AEFIs according to four main categories:

- programme-related
- vaccine-induced
- coincidental
- unknown.

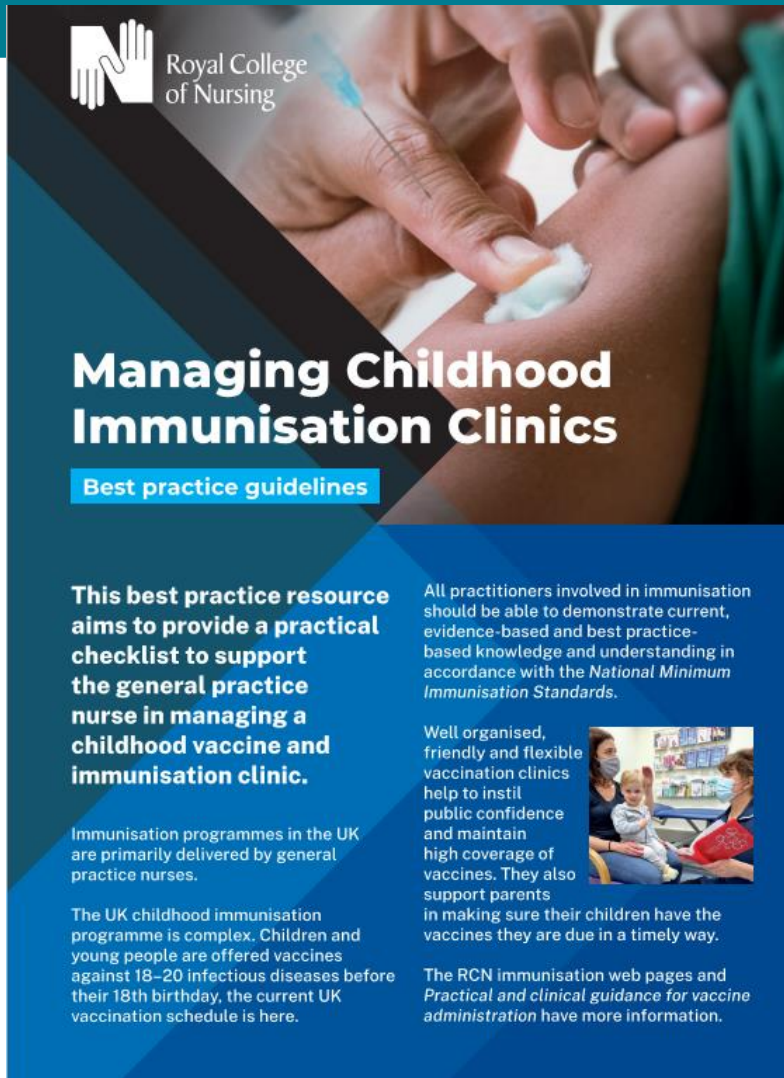
Programme-related AEFIs

These are adverse events that result from inappropriate practices in the provision of vaccination. These may include:

- wrong dose of vaccine administered
- inappropriate route, site or technique of administration
- vaccine prepared incorrectly
- vaccines used beyond expiry date
- vaccine stored incorrectly
- wrong type or amount of diluent used
- vaccines used at inappropriate intervals
- reconstituted vaccine kept beyond the recommended period
- contraindications not elicited or ignored
- mixing into inappropriate combinations
- vaccine or diluent contaminated



Avoiding programmatic errors



Royal College of Nursing

Managing Childhood Immunisation Clinics

Best practice guidelines

This best practice resource aims to provide a practical checklist to support the general practice nurse in managing a childhood vaccine and immunisation clinic.


Immunisation programmes in the UK are primarily delivered by general practice nurses.

The UK childhood immunisation programme is complex. Children and young people are offered vaccines against 18–20 infectious diseases before their 18th birthday, the current UK vaccination schedule is here.

All practitioners involved in immunisation should be able to demonstrate current, evidence-based and best practice-based knowledge and understanding in accordance with the *National Minimum Immunisation Standards*.

Well organised, friendly and flexible vaccination clinics help to instil public confidence and maintain high coverage of vaccines. They also support parents in making sure their children have the vaccines they are due in a timely way.

The RCN immunisation web pages and *Practical and clinical guidance for vaccine administration* have more information.



<https://www.rcn.org.uk/professional-development/publications/managing-childhood-immunisation-clinics-uk-pub-009-860>

Before giving a vaccine always check the 8Rs

(based on *Pediatric vaccination errors: Application of the “5 Rights” framework to a national error reporting database* (Shore et al., 2009).

- 1 Right patient.
- 2 Right vaccine and diluent (where applicable).
- 3 Right to give (ie, no contraindications).
- 4 Right time (including correct age and interval, as well as before the product expiration date).
- 5 Right dose.
- 6 Right route (including correct needle gauge and length and technique).
- 7 Right site.
- 8 Right documentation (to ascertain what the patient has already had/needs).

Dealing with programmatic errors

- Principles of managing vaccine storage incidents and interruption of the cold chain
 - Vaccine storage incident checklist
- Responding to errors in vaccine preparation and administration
 - Considerations and general principles for revaccination
 - Revaccination tables and advice
- Example letter to patients or carers offering revaccination
- Duty of candour and patient consent



<https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>

Vaccine-induced AEFIs

- Specifically caused by a particular vaccine or a component in a vaccine
- Direct effects
 - Local and systemic reactions
- Due to underlying medical conditions
 - E.g. Varicella zoster infection after giving Shingles vaccine to an immunocompromised patient
- Idiosyncratic responses
 - Idiopathic thrombocytopaenic purpura (ITP) within 30 days of MMR vaccine
 - Anaphylaxis after vaccination



Common vaccine-induced adverse events

- Adverse reactions generally start within a few hours of the injection and are usually mild and self-limiting
- Local Reactions
 - *pain, swelling or redness at the site of injection*
- Systemic Reactions
 - *Fever, malaise, headache, loss of appetite, irritability, achy muscles and joints*
- Each vaccine's commonly known side effects are described in the relevant chapter of the [Green Book](#)
- Additionally the Summary Product Characteristic (SPC) sheet for each vaccine will list common and less common adverse reactions noted in vaccine trials
 - SPCs can all be found at [Electronic Medicines Compendium](#)



Cause of most local and systemic adverse events

- The patient's own immune response
- Important to be able to warn patients' of the common symptoms after a vaccine
- Reassure the patient or parent that this is normal and to be expected
 - We want their immune system to respond to the vaccine
- Give advice on how to self care and when to return for advice

Rare vaccine-induced AEFIs

- Neurological or immune-mediated.
 - Examples include seizures, hypotonic-hyporesponsive episodes (HHE), idiopathic thrombocytopaenic purpura (ITP), acute arthropathy, allergic reactions and anaphylaxis.
- Anaphylaxis
 - Can be rapid within minutes or hours later
 - 1.3 - 1.6 per million doses
 - Vaccine-Associated Anaphylaxis, Michael M McNeil (2019) - <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6896995/>
 - Very rare <1 - 3 per million doses of vaccine
 - Bohlke *et al.* Risk of Anaphylaxis After Vaccination of Children and Adolescents *Pediatrics* 2003; 112:815-820 <https://pubmed.ncbi.nlm.nih.gov/14523172/>
 - COVID vaccines initially rate seemed to be higher (8-11 per million) – although heightened vigilance and mis-reporting
 - Sometimes confused with other allergic reactions, fainting, hyperventilation or panic attacks
- All immunisers must to be update with basic life support and management of anaphylaxis training
 - <https://www.resus.org.uk/>



**Resuscitation
Council UK**

Coincidental AEFIs

- Not true adverse reactions to immunisations or vaccines
- Linked because timing of their occurrence
 - Cold or flu-like symptoms after an inactivated flu vaccine
 - Cold virus are common in the winter when people receive a flu vaccine
 - Death of a young girl after HPV vaccine (2009)
 - Malignant tumour in her chest infiltrated her heart and left lung
- These events are important since they can undermine confidence in vaccines and vaccination programmes

Adverse reaction related to delivery system

- Fear, anxiety and distress
- Needle phobia, reluctance to have nasal spray (Fluenz tetra for children)
 - Reports of children who have had lateral flow tests for COVID infection are more worried about nasal vaccine
- Can result in refusal, anxiety, fainting, panic attack
- Reducing impact:
 - Carefully listen to concerns, give time for them to feel comfortable and safe, give a simple explanation of what will happen
 - Distraction techniques are useful for all ages:
 - Talk about TV, the news, their journey or future plans
 - For children parents bring favourite toy or book, something sweet to eat or drink, offer stickers

Unknown AEFIs

- Defined as unknown when there is insufficient evidence to classify as one of the other AEFIs

Managing common vaccine-induced AEFIs

- Most important element is to warn vaccine recipients and carers about common adverse events, why they occur and how to manage them
- Give any relevant leaflets on what to expect after vaccination
 - [For children aged 0-5](#)
 - [COVID vaccination](#) programme
 - [Paracetamol after MenB vaccination](#)
- Fevers over 37.5°C are common in children and usually mild
- Local discomfort or aches are usually mild
- If necessary advise on appropriate dose of paracetamol or ibuprofen if symptoms occur

What to expect after vaccinations

This leaflet tells you about the common side effects of vaccinations that might occur in babies and young children up to five years of age.

After a vaccination, your baby may cry for a little while, but that usually settles soon with a cuddle or a feed. Most babies don't have any other reaction.

Reactions at the site of the injection

Some babies have some swelling, redness or a small hard lump where the injection was given and it may be sore to touch. This usually only lasts two to three days and doesn't need any treatment.

Fevers

A fever is a temperature over 38°C. Fevers are quite common in young children, but are usually mild. If your child's face feels hot to the touch and they look red or flushed, he or she may have a fever. You can check their temperature with a thermometer.

If your baby has a fever:

- don't put them in a bath
- don't sponge them down
- don't put a fan on them

After vaccination with MenB

Fever can be expected after any vaccination, but is very common when the MenB vaccine is given with the other routine vaccines at two and four months. The fever shows the baby's body is responding to the vaccine, although not getting a fever doesn't mean it hasn't worked. The level of fever depends on the individual child and does not indicate how well the vaccine has worked. Giving paracetamol will reduce the risk of fever, irritability and general discomfort (including pain at the site of the injection) after vaccination.

After each of the two-month and four-month vaccinations you will need to give your baby a total of three doses of paracetamol (2.5ml of infant paracetamol 120mg/5ml suspension) to prevent and treat any potential fever. You should give the first dose of paracetamol as soon as possible after your two-month vaccination visit. You should then give the second dose four to six hours later and the third dose four to six hours after that. You will need to follow the same steps after

Immunisation

the safest way to protect your child's health

Using paracetamol to prevent and treat fever after MenB vaccination

My baby has just had the MenB vaccine, what should I expect now?

Fever can be expected after any vaccination, but is more common when the MenB vaccine (Bexsero) is given with the other routine vaccines at 2 and 4 months. Without paracetamol, more than half of infants will develop a temperature after these vaccines. The fever tends to peak around 6 hours after vaccination and is usually only mild (less than 38.5°C). The fever shows the baby's immune system is responding to the vaccine, although the level of fever will depend on each child and does not show how well the vaccine will protect your baby.

How can I reduce the risk of fever?

Giving paracetamol soon after vaccination – and not waiting for a fever to develop – will reduce the risk of your child having a fever (with paracetamol, fewer than 1 in 5 children will get a fever and nearly all of these are mild below 38°C). The paracetamol will also reduce the chance of your baby being irritable or suffering discomfort (such as pain at the site of the injection).

Which paracetamol product should I use?

You should use the infant paracetamol suspension. This kind of paracetamol comes in liquid form for use in babies and young children. It has a strength of 120mg/5ml. If you have not already got some paracetamol suspension for infants at home, you should get some from your local pharmacy or supermarket so that you can give the first dose of paracetamol when you first see the vaccine. There are various brands to choose from (Mylan, Dorel, and others), but the type needed is infant paracetamol suspension (120mg/5ml).

(Note: Junior paracetamol (5 plus) is stronger than infant paracetamol (120mg/5ml) and must not be used in babies.)

After which vaccinations should I give my baby paracetamol?

Paracetamol is advised for your baby following the MenB vaccine. The MenB vaccine is usually given at your baby's first and third immunisation appointments at 2 months and 4 months of age.

Paracetamol is not routinely needed after the 1st B booster vaccine given at 12 months of age. By this age the baby's risk of fever is the same as after other vaccines.

How much paracetamol should I give?

A total of 5 doses of 2.5ml (50mg) of paracetamol are recommended following MenB vaccination. You should give the first dose at the time of vaccination or as soon as possible afterwards. You should then give the second dose of paracetamol around 4 to 6 hours after the first dose (4 to 6 hours after the first dose if possible afterwards). The 2.5ml dose should be measured and given either using a syringe or with a 2.5ml spoon. This is usually the size of the spoon that comes in the packet. For very premature babies (born before 32 weeks gestation), paracetamol should be prescribed by your doctor according to the baby's weight at the time of vaccination. You should check with your doctor and follow the instructions on the prescription.

Dosage and timing of infant paracetamol suspension (120mg/5ml) for use after primary MenB vaccinations (usually at 2 and 4 months of age)

Age of baby	Up to 6 months (usually at 2 and 4 months)
Dose 1	One 2.5ml (50mg) dose as soon as possible after vaccination
Dose 2	One 2.5ml (50mg) dose 4 to 6 hours after first dose
Dose 3	One 2.5ml (50mg) dose 4 to 6 hours after second dose

Immunisation

The safest way to protect the health of your baby

What to expect after your

COVID-19 vaccination



Information for people who just had a COVID-19 vaccination



Find out more at [nhs/CovidVaccine](#)

Surveillance and monitoring for vaccine safety

- [Green book chapter 9](#)
- Testing before being licensed in clinical trials
 - However not all rare side effects can be identified in trials
- Post marketing safety studies by both Public Health authorities and manufacturers
- Epidemiological databases
- Clinician's reports
- Medical literature and World-wide reporting
- In UK the Medicines and Healthcare products Regulatory Agency (MHRA) are responsible for monitoring safety of all medicines and medical devices
 - Yellow Card scheme – voluntary reporting system

Coronavirus yellow card reporting scheme



Welcome to the Yellow Card reporting site

Report suspected side effects to medicines, vaccines, e-cigarettes, medical device incidents, defective or falsified (fake) products to the Medicines and Healthcare products Regulatory Agency to ensure safe and effective use.

Find the medicine / vaccine / device you wish to report.

Start report

Use the [Coronavirus Yellow Card reporting site](#) to report suspected side effects to medicines and vaccines or medical device and diagnostic adverse incidents used in coronavirus treatment.

Reporting as a manufacturer, marketing authorisation holder or other non-patient or health professional for a medical device adverse incident, fake or defective healthcare product? See our [reporting guidance page](#).

Worried about your health?

Safety updates

[See all safety updates](#)

<https://yellowcard.mhra.gov.uk/>

Safety

- All medicines have the potential to cause adverse reactions in a recipient
- Vaccines have higher levels of testing and safety standards than other medicines since they are given to healthy people
- No vaccine is 100% safe for every recipient but have been given to millions of recipients with a good safety profile.
- Vaccines have higher safety profiles compared to other drugs
- Very rarely an individual might suffer a severe mental or physical disablement as a result of immunisation
 - Vaccination: rare side effects
<https://www.gov.uk/government/collections/vaccination-rare-side-effects>
 - Green Book Chapter 10 - [Vaccine Damage Payment Scheme](#)

Additional resources

- [Vaccine Safety Net](#), **WHO**:
 - help internet users find reliable vaccine safety information tailored to their needs
- [Vaccine Confidence Project](#)
 - project monitoring confidence in vaccine programmes internationally – useful for current myths and controversies
- [Vaccine Knowledge Project](#), **Oxford Vaccine Group**:
 - a source of independent information about vaccines and infectious diseases
 - content is aimed at the general public and designed to help people make informed decisions about vaccine issues
- [British Society for Immunology – public information](#):
 - Information on vaccines/safety and basic immunology presented in interesting and understandable formats – good for immunisers and the public

Summary

Confidence and trust in immunisation programmes is supported by skilled immunisers who:



1. prevent and reduce the risk of adverse events through best practice in immunisation
2. are confident in addressing concerns and providing accurate advice on the risks and benefits of each vaccine
3. identify any safety/quality issues and utilise appropriate reporting mechanisms

Immunisation and health protection advice (London)

NHS E London Immunisation Clinical Advice Response Service (ICARS) for Immunisation queries from primary care. Email: london.immunisationqueriescars@nhs.net

North East and North Central London HPT

UK Health Security Agency 10
South Colonnade, Canary Wharf,
London, E14 4PU

Email:

necl.team@ukhsa.gov.uk
phe.nenclhpt@nhs.net

Telephone

0300 303 0450

Out of hours advice:

0300 303 0450

North West London HPT

UK Health Security Agency
61 Colindale Avenue
London NW9 5EQ

Email:

phe.nwl@nhs.net

Telephone

020 3326 1658

Out of hours advice:

01895 238 282

South London HPT

UK Health Security Agency 10
South Colonnade, Canary
Wharf, London E14 4PU

Email:

slhpt@ukhsa.gov.uk
phe.slhpt@nhs.net

Telephone

0300 303 0450

Out of hours advice:

0300 303 0450

March to July

September to
January 2024

Vaccine ordering, storage & handling

Incomplete immunisation schedules

Vaccination of individuals with
underlying medical conditions

Vaccine administration – best
practice

Child and adolescent immunisation
update

Addressing concerns around vaccines
– supporting acceptance

Primary care
immunisation update
webinar series
2023 2024

Influenza and Covid-19

Shingles and pneumococcal (adult)
vaccines

Adverse events following
immunisation

Current Issues vaccine schedule
changes.

Legal issues Consent and medicines
management

Webinar Series - booking

	Date	Start time	Link to register
November			Adverse events following immunisation
1	09/11/2023	09:30	https://Nov23-Webinar1-AdverseEventsFollowingImmunisation.eventbrite.co.uk?aff=odtdtcreator
2	28/11/2023	09:30	https://Nov23-Webinar2-AdverseEventsFollowingImmunisation.eventbrite.co.uk?aff=odtdtcreator
3	28/11/2023	14:00	https://Nov23-Webinar3-AdverseEventsFollowingImmunisation.eventbrite.co.uk?aff=odtdtcreator
December			National Immunisation Programme schedule changes and horizon scanning
1	05/12/2023	09:30	https://Dec23-Webinar1-NationalImmsProgrammeScheduleChanges.eventbrite.co.uk
2	05/12/2023	13:00	https://Dec23-Webinar2-NationalImmsProgrammeScheduleChanges.eventbrite.co.uk
3	14/12/2023	09:30	https://Dec23-Webinar3-NationalImmsProgrammeScheduleChanges.eventbrite.co.uk
January			The legal issues to consider for safe vaccine administration relating to: Consent and medicines administration
1	11/01/2024	09:30	https://Jan24-Webinar1-TheLegalIssuesConsentAndMedicinesAdministration.eventbrite.co.uk
2	16/01/2024	09:30	https://Jan24-Webinar2-TheLegalIssuesConsentAndMedicinesAdministration.eventbrite.co.uk
3	16/01/2024	13:00	https://Jan24-Webinar3-TheLegalIssuesConsentAndMedicinesAdministration.eventbrite.co.uk