

Adverse Events Following Immunisation



2020 Immunisation Update

Slides prepared by:
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Health
Illawarra Shoalhaven
Local Health District

Take home messages...

- Vaccines are safe - tried and tested
- Severe reactions are uncommon
- Reporting is **IMPORTANT**
- Communication is key



What is an AEFI??

“An adverse event following immunisation (AEFI) is any negative reaction that follows vaccination. It does not necessarily have a causal relationship with the vaccine.

The adverse event may be any:

- unfavourable or unintended sign or symptom
- disease
- abnormal laboratory finding

These events may be caused by the vaccine(s) or may occur by chance (that is, the event would have occurred regardless of vaccination).”

What should you report??

- Any AEFI that is serious or unexpected
- Any event that is suspected of being related to vaccination can be reported
- All identifying information relating to the reporter and patient is kept strictly confidential
- Notifying an adverse event does not imply a causal association with vaccination



A little bit about causality...

➤ Causal - biologically & temporally plausible

- Fever 12-24 hours after vaccination
- Hives 5 mins after vaccination

➤ Temporal (coincidental)

- Linked in time - alternative diagnosis more likely
- SIDS

➤ Can be difficult to determine




??
— — — — —>
temporal
vs causal



How do you report an AEFI??

- Contact your local Public Health Unit (PHU) on 1300 066 055
- Complete the AEFI Reporting Form and fax/email it to your local PHU:
 - available through the NSW Health website
- Anyone can report an AEFI



Australian Government
Department of Health
Therapeutic Goods Administration

TGA use only
Date report received:
Notification ID:

This form, when completed, will be classified as 'For official use only'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

National Adverse Events Following Immunisation (AEFI) reporting form

Vaccinated person's details	
Personal details	
Surname:	
First name:	
Gender:	<input type="checkbox"/> Male <input type="checkbox"/> Female <input type="checkbox"/> Unknown
Date of Birth:	or
Age:	Months or Years
Street address:	
Suburb:	
State:	
Postcode:	
Name of parent/guardian: (if relevant)	
Phone: Landline (inc. area code) or mobile	

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au <https://www.tga.gov.au>

TGA Health Safety Regulation

How do you lower the risk of AEFI??

- Prevention is key!!
- USE the pre-screening tool prior to EVERY dose
 - available from the AIH
- Check the AIR as well as the Blue Book if vaccination history is unclear
- Use the '5 rights':
 1. Right patient
 2. Right drug
 3. Right dose
 4. Right route
 5. Right time

10/21/2020

Table. Pre-vaccination screening checklist | The Australian Immunisation Handbook

This checklist helps decide about vaccinating you or your child today. Please fill in the following information for your doctor/nurse.

Name of person to be vaccinated:

Date of birth:

Age today:

Name of person completing this form:

Please indicate if the person to be vaccinated:

- is unwell today
- has a disease that lowers immunity (eg leukaemia, cancer, HIV) or is having treatment that lowers immunity (eg oral steroid medicines such as cortisone and prednisone, DMARDs [disease-modifying anti-rheumatic drugs], radiotherapy, chemotherapy)
- is an infant of a mother who was receiving highly immunosuppressive therapy (eg bDMARDs [biologic disease-modifying anti-rheumatic drugs]) during pregnancy
- has had a severe reaction following any vaccine
- has any severe allergies (to anything)
- has had any vaccine in the past month
- has had an injection of immunoglobulin, or received any blood products or a whole-blood transfusion within the past year
- is pregnant
- has a history of Guillain-Barré syndrome
- was a preterm infant
- has a severe or chronic illness
- has a bleeding disorder
- identifies as an Aboriginal or Torres Strait Islander person
- does not have a functioning spleen
- is planning a pregnancy or anticipating parenthood
- is a parent, grandparent or carer of an infant ≤ 6 months of age
- lives with someone who has a disease that lowers immunity (eg leukaemia, cancer, HIV) or lives with someone who is having treatment that lowers immunity (eg oral steroid medicines such as cortisone and prednisone, DMARDs [disease-modifying anti-rheumatic drugs], radiotherapy, chemotherapy)
- is planning travel
- has an occupation or lifestyle factor(s) for which vaccination may be needed (discuss with doctor/nurse)

Please specify:

How do you lower the risk of AEFI??

- Discuss what to expect post vaccination with the parent/patient
 - this should be done PRIOR to vaccination as part of the consent process
- Provide some written information to refer to when they are at home
- Ensure they stay for 15 mins post vaccination
- Be prepared to give adrenaline if required

Vaccines given on ___ / ___ / 20 **Time given:** _____ (Please wait a minimum of 15 minutes after immunisation)

Indicate injection sites by circling appropriate box: LA = Left Arm, RA = Right Arm, LL = Left Leg, RL = Right Leg

Hepatitis B vaccine (H-B-Vac® II Paediatric or Engerix® B Paediatric)	Diphtheria, tetanus, whooping cough, hepatitis B, polio, Haemophilus influenzae type b vaccine (Infanrix® hexa)	Pneumococcal vaccine (Prevenar 13®)	Rotavirus vaccine (Rotarix®)
• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'
LL RL LA RA	LL RL LA RA	LL RL LA RA	BY MOUTH
Meningococcal B vaccine (Bexsero®)	Meningococcal ACWY vaccine (Nimenrix®)	Measles, mumps, rubella vaccine (MMR® or Priorix®)	Hepatitis A vaccine (Vagla® Paediatric)
• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'
LL RL LA RA	LL RL LA RA	LL RL LA RA	LL RL LA RA
Haemophilus influenzae type b vaccine (Act-HB®)	Measles, mumps, rubella, chickenpox vaccine (Priorix-Tetra® or ProQuad®)	Diphtheria, tetanus, whooping cough vaccine (Infanrix® or Tripartix®)	Diphtheria, tetanus, whooping cough, polio vaccine (Infanrix® IPV or Quadracel®)
• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'
LL RL LA RA	LL RL LA RA	LL RL LA RA	LA RA
Pneumococcal vaccine (Pneumovax 23®)	Human papillomavirus (HPV) vaccine (Gardasil®9)	Shingles vaccine (Zostavax®)	Influenza vaccine
• See 'Common reactions'	• See 'Common reactions'	• See 'Common reactions'	
LA RA	LA RA	LA RA	

Last updated August 2020

Following vaccination— what to expect and what to do

All vaccinations may cause the following reactions:

- Where the needle was given: Sore, red, burning, itching or swelling for 1–2 days and/or a hard lump for a few weeks
- Grizzly, unsettled, unhappy and sleepy
- Teenagers/adults fainting and muscle aches

ADDITIONAL COMMON REACTIONS SPECIFIC TO EACH VACCINE

- Give frequently extra fluids
- Put a cold wet cloth on the injection site if it is sore
- For fever or pain give paracetamol. Follow instructions on the packaging

The reactions are bad, not going away or getting worse or if you are worried at all

Any of the rare reactions below are experienced

Order this resource

Order ID: IT0303

You can order this resource by contacting National Mailing and Marketing:

- Email - health@nationalmailing.com.au
- Phone - [02 6269 1080](tel:0262691080)

Quote the order ID number above, the quantity of the resource you wish to order and provide your delivery address.



Food allergies & vaccination



- Most vaccines do not contain food allergens
- Vaccines contain no traces of:
 - Dairy products, peanut, tree nuts, wheat, soy, seeds or seafood
- The following vaccines can be given to any patient with food allergy, even those with food-induced anaphylaxis:
 - MMR (Measles, Mumps, Rubella)*
 - DPT (Diphtheria, Tetanus, Pertussis)
 - IPV (Inactivated Polio Vaccine)
 - HiB (Haemophilus influenzae type B)
 - Pneumococcus
 - Meningococcal C
 - Chickenpox (Varicella)
 - Rotavirus

* **Note:** The MMR vaccine is cultured on chicken fibroblast cell cultures, contains **no** residual egg allergen and has been safely administered to large numbers of egg-allergic individuals. The rare allergic reactions to MMR vaccination that have occurred have been attributed to non-egg ingredients such as gelatin.

The following vaccines may contain residual egg protein...

- Yellow Fever vaccine (important for travellers)
- Q fever vaccine (important in the occupational setting)

Higher level of egg protein than influenza vaccines ∴ patients should be referred to allergy/immunology specialist for assessment



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The following vaccines may contain residual egg protein...

➤ Seasonal/Pandemic inactivated influenza vaccines

- Research has shown that egg allergy does not increase the risk of allergic reaction
- Vaccine can be administered in any vaccination setting including GP clinics and community settings (incl settings without direct medical supervision)
- If there is significant provider or parental anxiety - a post vaccination waiting period of 30 mins can be observed
- All staff involved with vaccination should be familiar with the recognition and treatment of anaphylaxis
- If the patient has had anaphylaxis after a previous dose of influenza vaccine, they should be assessed in a specialist clinic



Case Studies



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Injection Site Reactions (ISRs)



- 4yr male old post DTPa-IPV left deltoid
- Developed day post vaccination
- Did not effect range of movement
- Treated with paracetamol and cold compress

ISRs cont...

- Common, expected side effect
- Usually occur within 24 hours of vaccination
- Experienced by up to 34% of vaccinees
- Symptomatic relief is recommended
- Severe ISR or extensive limb swelling occurs less commonly - swelling of entire limb between 2 joints
- Severe ISR usually occur within 24 - 72 hours post vaccination and resolve within a week
- **NOT** a contraindication for further doses
- **NOT** cellulitis - no need for antibiotics
- **NOT** an allergic reaction



Hypotonic/Hyporesponsive Events (HHEs)

- 6 week old female
- Cried and vomited post vaccination
- Went pale, floppy, sleepy within 5 minutes of vaccination
- Colour briefly returned and then went pale, floppy and clammy
- Colour returned in 2 minutes but was “not quite herself”
- Sent home 30min post vaccination
- Still more sleepy for rest of day
- Generally quite *unsettling* for parents and immunisation providers



HHEs cont...

- Classic characteristic symptoms: pale, floppy, unresponsive
- 2018 - 235 (1997-2014) HHE cases from Melbourne and Sydney AEFI Clinics studied
- 67% (157/235) occurred following vaccines given at 6 - 8 weeks
- 2 types:
 - immediate (0-30mins post vaccination)
 - delayed (up to 14 days post vaccination)
 - median time 2 hours
- 3% recurrence rate (7/235)
- Immediate HHEs are consistent with a vasovagal stimulus following a painful event
- Give subsequent vaccines in supine position



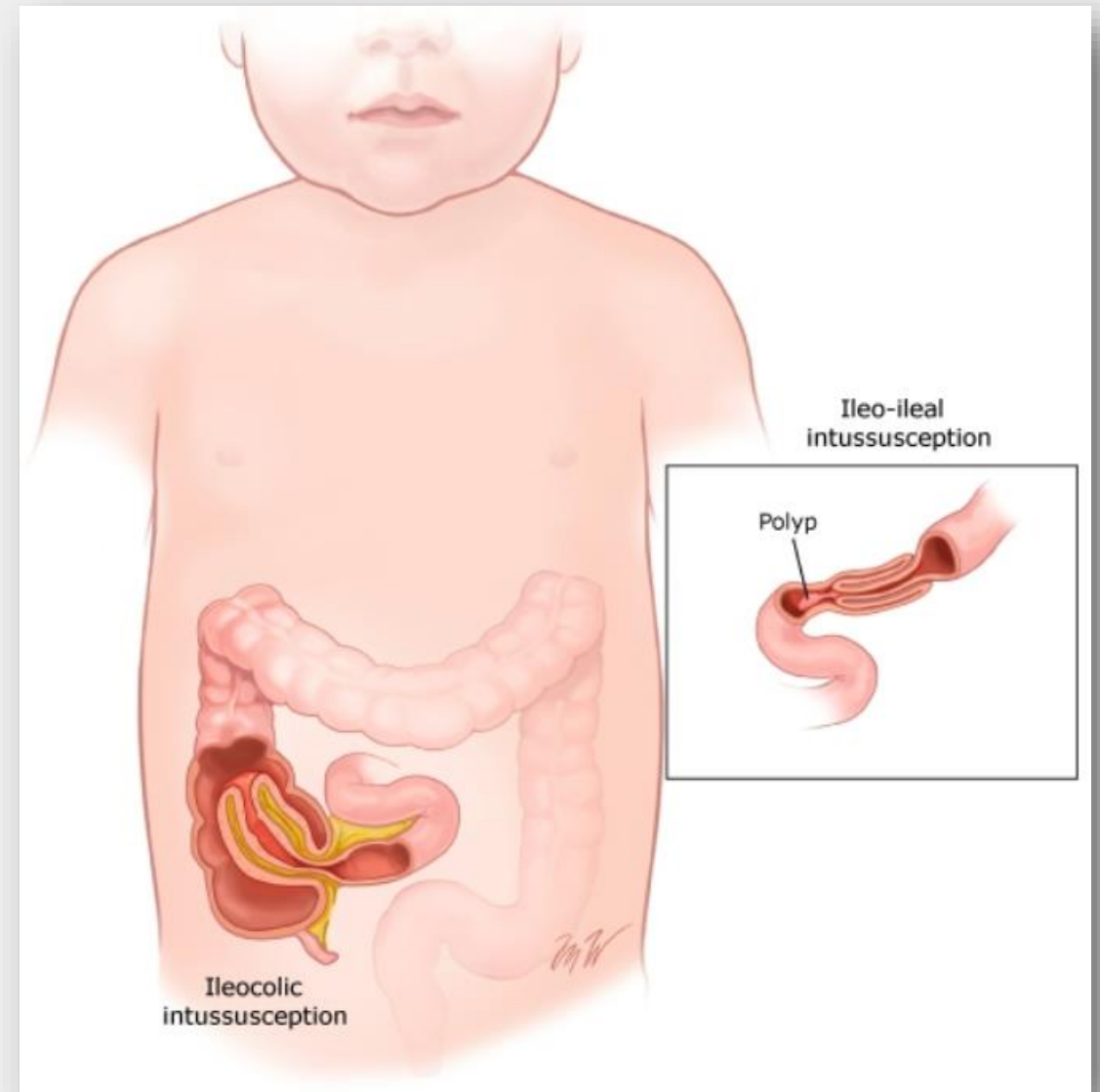
Intussusception (IS)

- 4 month old female - nil medical history
- 4 days post 4 month vaccinations woke screaming and thrashing - settled with paracetamol
- During the day BO x12 - loose, green with light red spots
- Difficult to console but well between episodes
- Presented to ED → abdo ultrasound confirmed transient ileoileal IS
- Symptoms resolved without treatment



Intussusception cont...

- Rare - 200 cases per year in Aus
- Typically presents between 6 and 36 months of age
 - 60% of cases are <1 year old
- Most have no known cause, some are preceded by a virus
- Rotavirus vaccine has been linked to a slight increased risk of IS in the first 1-7 days post vaccination
 - Increase of 2 additional cases per year related to vaccination



Intussusception cont...

- Inform parents/carers of rare risk of IS post vaccination and what to look for
- Do not give rotavirus vaccine outside recommended age limits
 - 1st dose upper age limit = 14 weeks (+ 6 days)
 - 2nd dose upper age limit = 24 weeks (+ 6 days)
- Do not give rotavirus vaccine to a baby with history of IS
- Report cases to PHU



Australian Government
Department of Health and Ageing

Rotavirus Immunisation

INFORMATION FOR PARENTS AND GUARDIANS

What is rotavirus and how serious is it?

Rotavirus is the most common cause of severe gastroenteritis in infants and young children in Australia and worldwide.

The severity of the illness ranges from mild, watery diarrhoea of limited duration to severe, dehydrating diarrhoea with vomiting, fever and shock. Rotavirus infections are often more severe than other causes of diarrhoea, are more likely to be associated with dehydration and are more likely to require treatment in hospital.

Prior to the introduction of rotavirus vaccination in Australia, almost every child was infected with rotavirus by the age of 5 years, and there was approximately 10,000 hospitalisations due to rotavirus in children less than 5 years of age each year. In addition to hospitalised children, an estimated 115,000 children under 5 years of age visited a GP, and 22,000 children required an emergency department visit. On average, there was one childhood death from rotavirus each year.

Children can be infected with rotavirus several times during their lives, and without vaccination almost every child will suffer from at least one infection by the age of 3 years. The disease is easily spread from one child to the next. Confirmation of rotavirus infection can only be made by laboratory testing of faecal specimens.

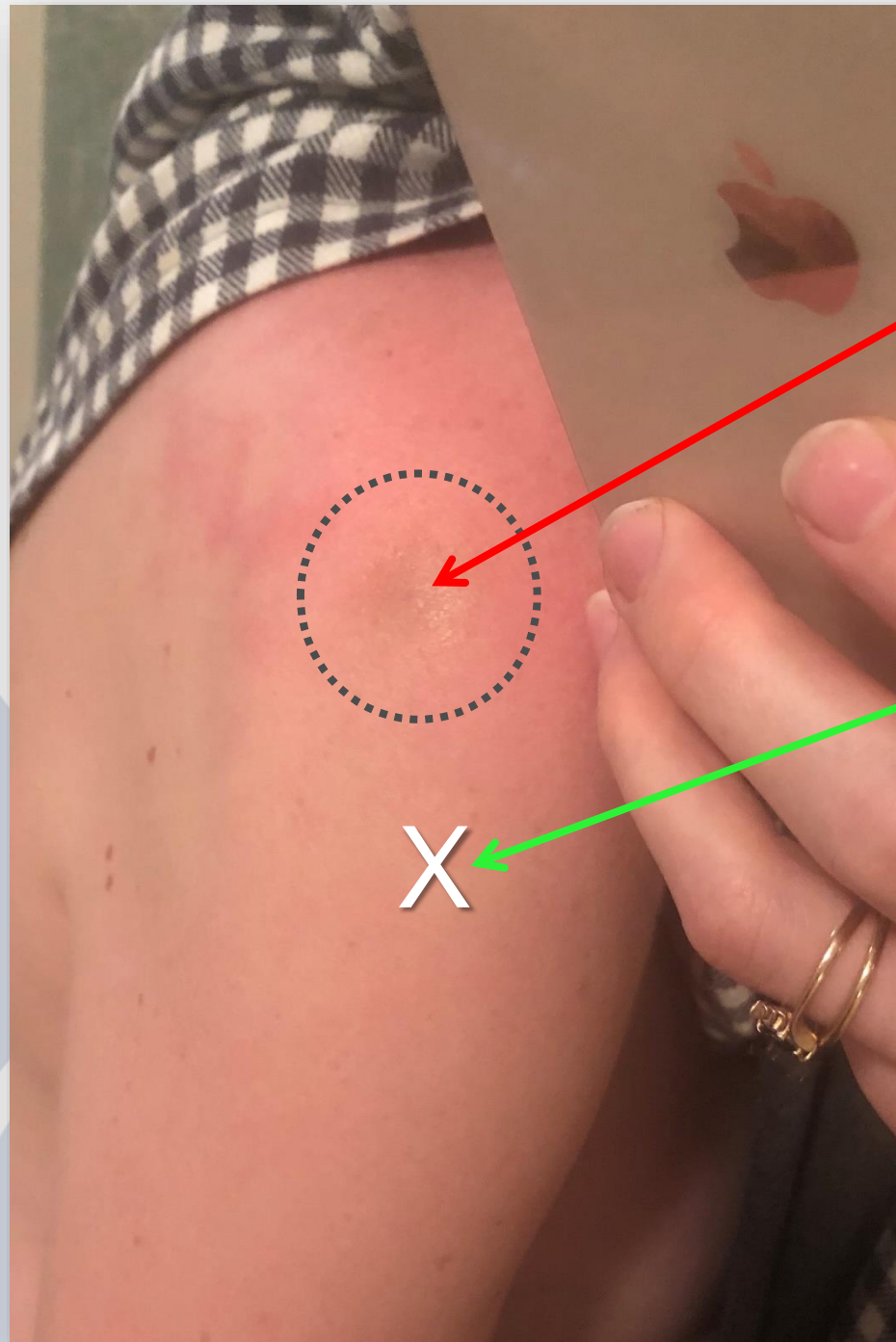
When is rotavirus vaccine given?

Rotavirus vaccination is only recommended for children up to 6 months of age. The first dose of vaccine is recommended to be given with your child's 2 month old vaccines and it is most important that the vaccine is given on time. It is possible that the risk of intussusception, a rare side effect of vaccination discussed below, may be increased if the vaccine is delayed past the scheduled time. The vaccine is given orally (by the mouth).

Shoulder Injury Related to Vaccine Administration (SIRVA)

- 31 year old healthy female - currently 29 weeks pregnant
- Afternoon of dTpa vaccination developed pain at the injection site that worsened over time accompanied by decreased shoulder movement
- Waking at night with pain
- GP diagnosed bursitis - confirmed by ultrasound
- Treated with massage and TENS machine as unable to have anti-inflammatories
- Patient stated that she felt that the vaccine was given “very high”





Actual
injection
site

Recommended
injection site



SIRVA cont...

- Rare complication caused by incorrect vaccine administration
- When given too high, the vaccine can go into the shoulder joint causing pain and restricted movement
- Diagnoses include bursitis, tendinitis & rotator cuff tears
- Correct technique & positioning will avoid SIRVA

Injection too high



Injection too low

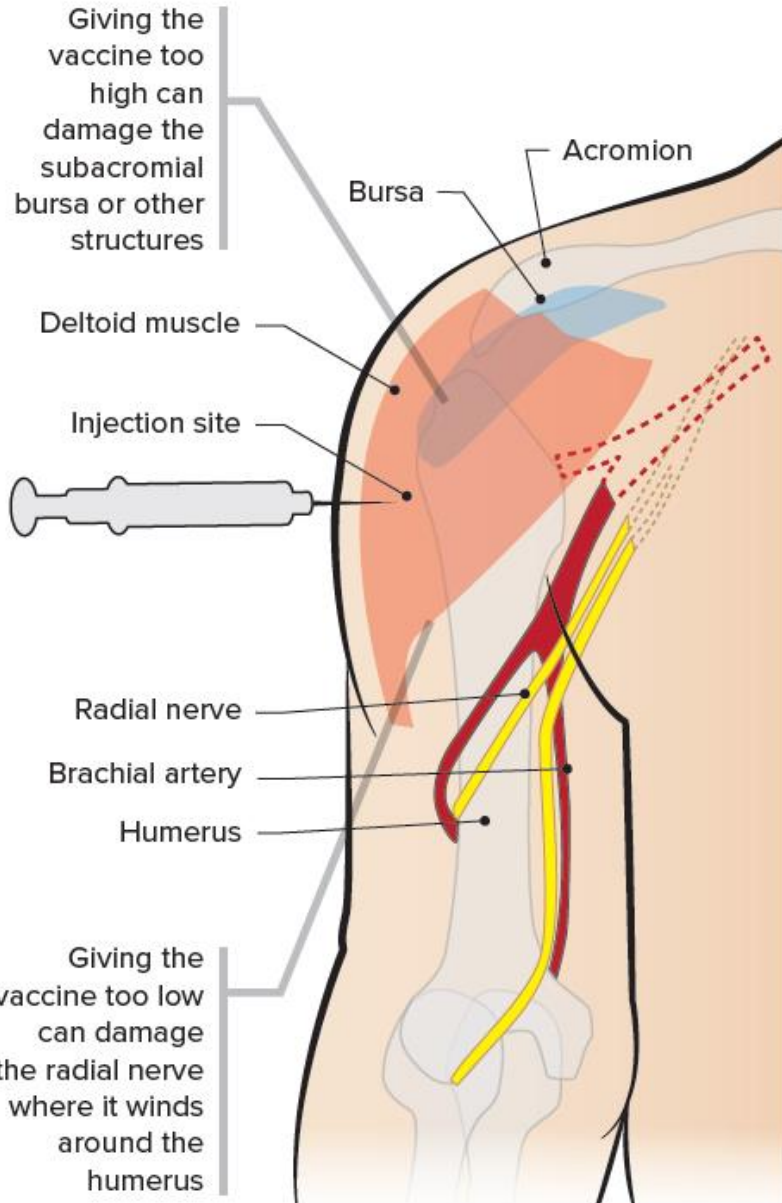


Correct site for injection



3

Find the correct injection site



Triangle method



Acromion

- ▶ Measure 2 finger widths down from the acromion process (the knobby top of the arm).
- ▶ Imagine an inverted triangle starting from this point (the width of the arm).
- ▶ The injection site is the centre of the triangle.

Fingertips method



- ▶ Place your index finger on the acromion process (the knobby top of the arm).
- ▶ Place your thumb at the bottom of the deltoid muscle (about halfway along the upper arm).
- ▶ The injection site is midway between these points.

Giving 2 vaccines into the deltoid muscle



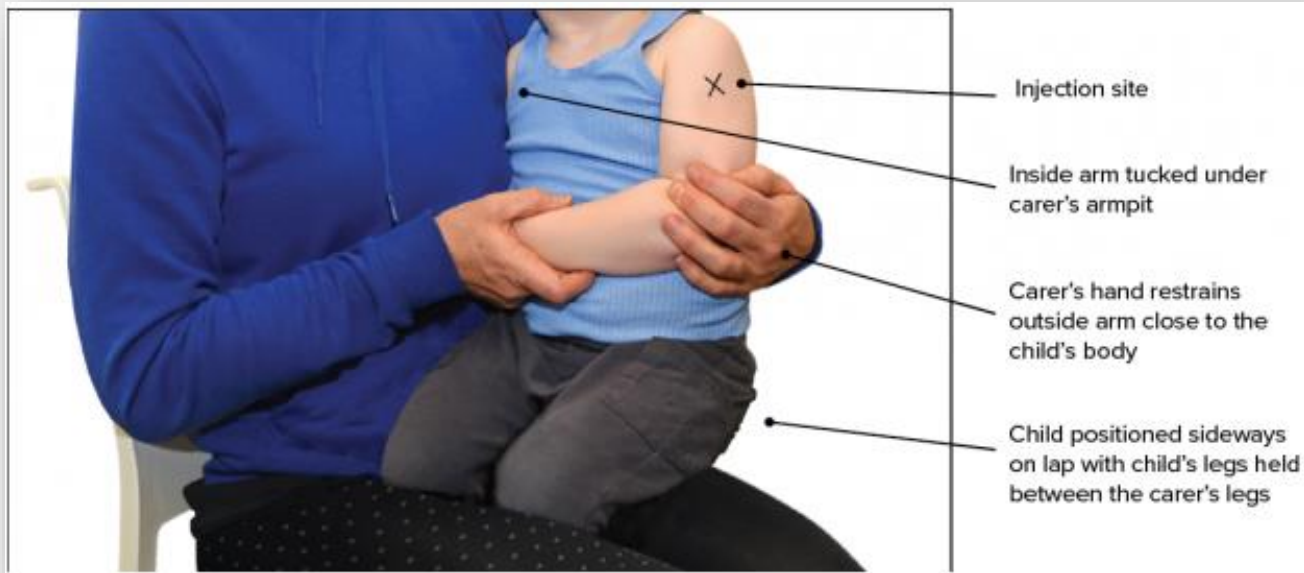
- ▶ Leave 2.5 cm between injection sites.



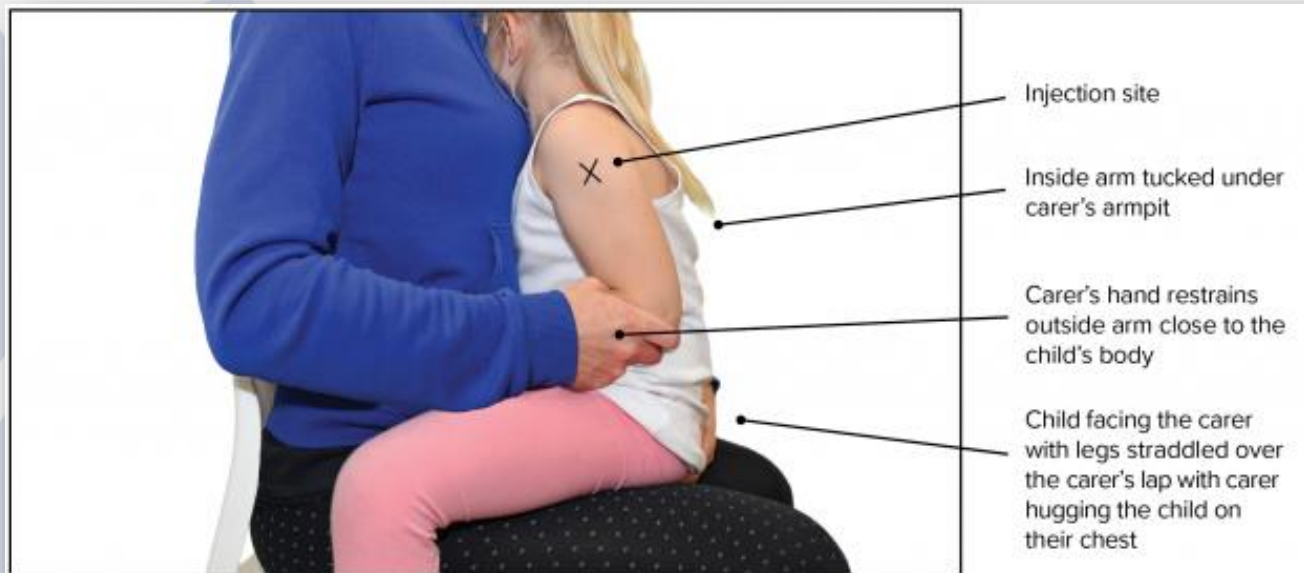
AIH Resources: Publications
‘Avoiding shoulder injury related to vaccine administration’

- 4yr old, dose 5 DTPa-IPV
- Child moved during administration - scratched
- Injection site too low - not IM
- AIH advice on SC vs IM:
 - “If a vaccine that is registered for IM administration is inadvertently given SC, check the vaccine product information and the relevant disease-specific chapters... for more details.”
- Issues:
 - Weakened immune response, ISR
 - Hep B & Rabipur need to be repeated

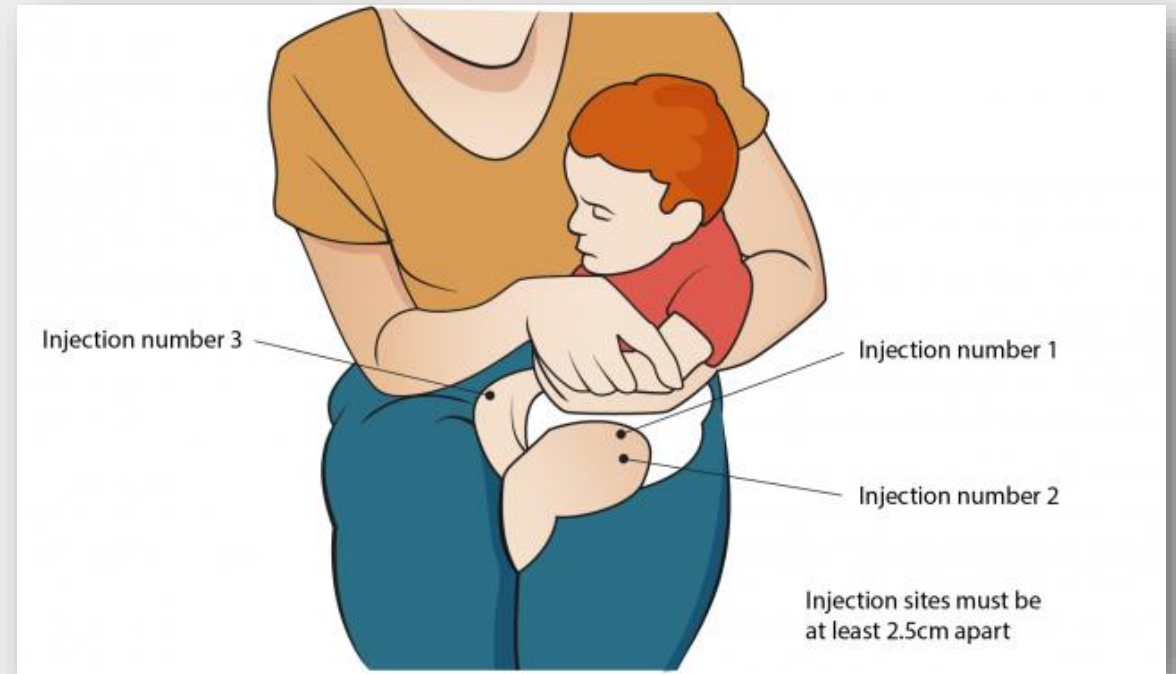




- Positioning SO important!!
- Prepare the parent/patient
- Prepare yourself



- 18m old female
- All 3 scheduled vaccines given in same deltoid
- ISR - unable to distinguish which vaccine was causative (IM vs SC)
- Follow recommendations in AIH about appropriate site of vaccination according to age
- Thigh can be used as an alternative site to deltoid in children >12m and adults if the deltoid is not large enough or is unavailable



Giving 2 vaccines into the deltoid muscle



- ▶ Leave 2.5 cm between injection sites.

Rashes

- 12 month old female
- 6 days post MMR, PCV13 & MenACWY developed fever and generalised rash
- Well prior to vaccination but developed malaise 5 days post vaccination



Rashes cont...

- Systemic reaction - result of non-specific activation of the immune system
- Delayed onset of rash (non-infectious) & fever is consistent with the live-attenuated MMR vaccine - can occur between 5-12 days post vaccination
- Systemic reactions to inactivated vaccines usually occur within the first few days post vaccination
- No further investigation required
- Subsequent doses can be given as this is not a hypersensitivity reaction - no risk of allergic reaction/anaphylaxis
- Less chance of AEFI post dose 2 MMR or MMRV



Rashes cont...

- 6 month old, healthy, male
- 10 mins post influenza vaccine developed generalised urticarial
- Nil other symptoms
- Resolved following day with antihistamine administration



Rashes cont...

- Hypersensitivity reaction
- Generally occur within minutes to an hour of exposure - delayed reactions occur rarely
- Can be caused by any of the vaccine components e.g. antigen, preservatives, stabilisers etc.
- Observe for developing symptoms of anaphylaxis i.e. breathing difficulty
- Refer to specialist immunisation service for assessment for subsequent doses



Rashes cont...

- Description is very important
- Take a photo if it occurs in your clinic
- Encourage parents/patients to take a photo - everyone has a phone!!



ADJECTIVES USED TO DESCRIBE A RASH:
A GUIDE FOR MED STUDENTS

COLOR:

PINK RED MORE RED PURPLY MULTICOLORED

MORPHOLOGY:

BUMPY LESS BUMPY FLUID FILLED PUS FILLED ALL OOZING AND GROSS

SIZE:

SMALL MEDIUM LARGE REALLY LARGE FRIGGIN' HUGE

CAN YOU DESCRIBE THE PATIENT'S RASH?

IT'S A FRIGGIN' HUGE PURPLY RASH THAT'S ALL OOZING AND GROSS.

A hand-drawn guide for describing rashes. It is organized into three sections: Color, Morphology, and Size. Each section has five hand-drawn examples with corresponding labels. At the bottom, there is a cartoon of a doctor asking a question and a patient responding.

Seizures

- 12 month old, healthy, female
- 9 days post vaccination developed fever to 39°C accompanied by 5-minute generalised tonic-clonic seizure at home
- Reviewed in ED
- Normal examination, no recurrence, no significant medical/familial history
- D/C diagnosis was simple febrile seizure
- At 18 months there had been no further seizures
- Vaccination continued as per schedule

Deng L., Wood N., Danchin M. *“Seizures following vaccination in children: Risks, outcomes and management of subsequent revaccination.”* Australian Journal of General Practice, Vol. 49, No. 10, October, 2020.



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Seizures cont...

- 4 month old, healthy, male
- 15 hours post 4-month vaccinations presented to ED in status epilepticus
- Resolved after 40 mins and 4 doses of midazolam and levetiracetam
- Subsequent seizures occurred unrelated in time to vaccination
- Diagnosed with Dravet syndrome after showing signs of developmental regression and genetic confirmation of *SCN1A* variant
- Vaccination continued through NSWISS

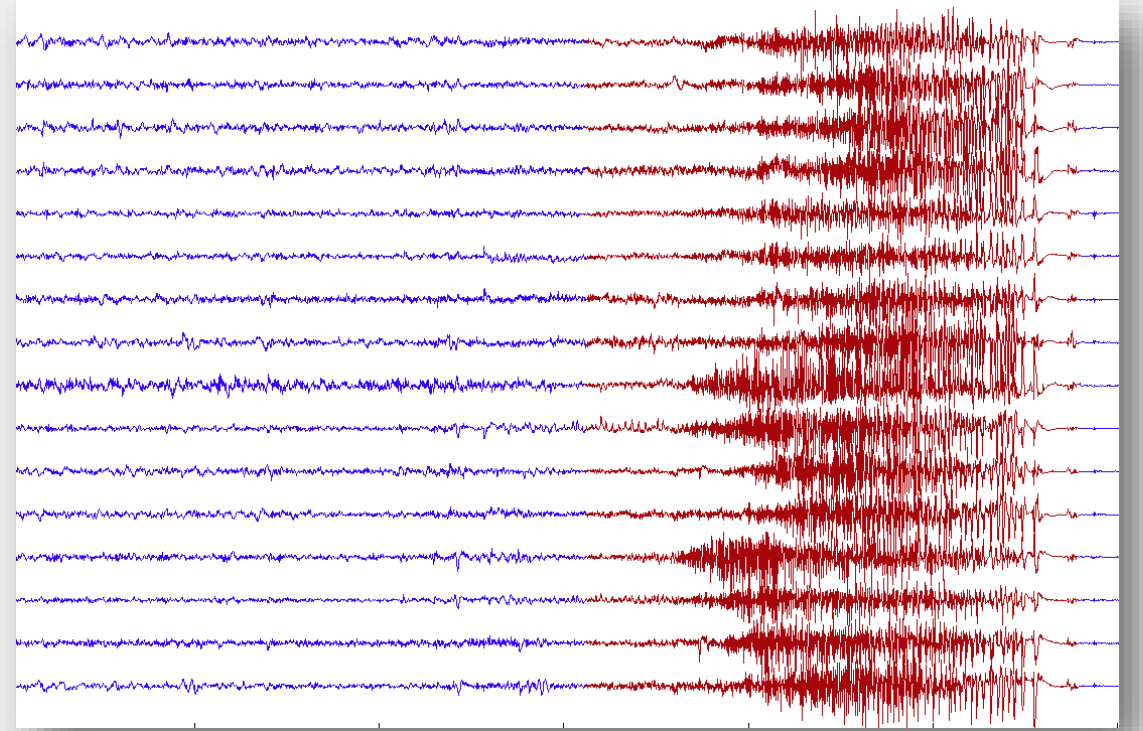
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Seizures cont...

- Sudden surge of electrical activity in the brain - neuronal hyperactivity
- Characterised by:
 - involuntary muscle contractions
 - sensory disturbances
 - autonomic dysfunction
 - behavioural abnormalities
 - impaired or loss of consciousness



Seizures cont...

➤ Things that can look like seizures but aren't:

- rigors
- benign myoclonus / shuddering attacks
- syncope / faint
- sleep related disorders
- movement disorder
- migraine associated disorders



Seizures cont...

➤ Vaccine proximate febrile seizure risk

Vaccine type	Vaccines	Risk interval (days after vaccination)	Febrile seizure risk
Live-attenuated	MMR	5-14	One febrile seizure per 1,150-3,000 vaccinations ^{9,10}
	MMRV	5-14	One additional febrile seizure per 2,600 MMRV vaccinations when compared with MMR+V ^{6,11} No increased risk if administered as dose two ¹²
Inactivated	DTPa	0-2	No increased risk ^{4,13,14}
	TIV	0-2	One febrile seizure per 70,000 vaccinations (2003-04) ¹⁶ One febrile seizure per 300 vaccinations (2010) ¹⁵ No increased risk with current formulation ¹⁸

➤ Small increased risk of fever and febrile convulsions when children receive TIV and PCV13 concurrently

- AIH recommend can be given together but parents need to be advised of the risk
- Can be given on separate days - interval of 3 days in between

Seizures cont...

➤ 2 types of seizures following vaccination

- vaccine proximate febrile seizures (VP-FS)
- vaccine proximate status epilepticus (VP-SE)

➤ VP-FS

- Most common type of childhood seizure - generally occurring in association with a febrile illness
- Occur in 2-5% of children aged 6m - 3yrs
- Fever following vaccination generally occurs within 48 hours post inactivated vaccines and 5-14 days post live-attenuated vaccines
- Severity and neurodevelopmental outcome no different to febrile seizures from other causes
- Further vaccinations can proceed in the usual setting



Seizures cont...

➤ VP-SE

- Children presenting with status epilepticus or afebrile seizure post vaccination should be referred for specialist neurological review
- Important to distinguish Dravet syndrome from epilepsy
- Subsequent vaccination should only proceed under medical supervision
- Children diagnosed with Dravet syndrome are ideally vaccinated in an in-patient setting



Anaphylaxis

- 12 year old, healthy, female
- Within 5 minutes post HPV and dTpa vaccines developed generalised erythema, chest tightness with wheeze and dizziness
- Given dose of IM adrenaline with good effect
- ED via ambulance - nil further treatment required
- Referred to NSWISS for investigation



Anaphylaxis cont...

- Severe allergic reactions and anaphylaxis are rare BUT important
- Anaphylaxis - sudden onset, rapid progression & simultaneous involvement of ≥ 2 organ systems
- Generally occur within 1 hour of vaccination
- Distinguish between vaso-vagal and anaphylaxis
- Be prepared to give adrenaline and commence BLS
- ALWAYS transfer to ED for observation



Table 2. Clinical features that may help differentiate between a vasovagal episode and anaphylaxis⁷

Clinical features	Vasovagal episode	Anaphylaxis
Onset	Immediate, usually within minutes of, or during, vaccine administration	Usually within 15 minutes of vaccine administration, but can occur within hours
Respiratory symptoms or signs	Normal breathing; may be shallow, but not laboured	<ul style="list-style-type: none">• Cough• Wheeze• Hoarseness• Stridor• Signs of respiratory distress, such as abnormally rapid breathing (tachypnoea), cyanosis or rib recession• Upper airway swelling (eg lip, tongue, throat, uvula, larynx)
Cardiovascular symptoms or signs	<ul style="list-style-type: none">• Bradycardia• Weak/absent peripheral pulse• Strong carotid pulse• Hypotension — usually transient and corrects in supine position• Loss of consciousness — improves once in supine or head-down position	<ul style="list-style-type: none">• Tachycardia• Weak/absent carotid pulse• Hypotension — sustained and no improvement without specific treatment (note: in infants and young children, limpness and pallor are signs of hypotension)• Loss of consciousness — no improvement once in supine or head-down position
Skin symptoms or signs	<ul style="list-style-type: none">• Generalised pallor• Cool, clammy skin	<ul style="list-style-type: none">• Pruritus (skin itchiness)• Generalised skin erythema (redness)• Urticaria (weals)• Angioedema (localised or general swelling of the deeper layers of the skin or subcutaneous tissues)
Gastrointestinal symptoms or signs	Nausea or vomiting	<ul style="list-style-type: none">• Abdominal cramps• Diarrhoea• Nausea or vomiting
Neurological symptoms or signs	Person feels faint or light-headed	Person has a sense of severe anxiety and distress

Zostavax

- July 2020 - death reported to TGA
- 3 weeks post vaccination developed fatal chickenpox infection related to the shingles vaccine
- Patient was taking low-dose prednisolone and hydroxychloroquine at the time of vaccination
- Review found that Zostavax was given *within existing recommendations*
- **ALERT**: Zostavax should NOT be used in people with compromised immune function
- Follow the recommendations in the AIH
- “If in doubt - leave it out!!”



NSW Immunisation Specialist Service (NSWISS)

Assists clinicians and families by providing the following services:

- Immunisation Advice Line 1800NSWISS (1800 679 477)
- Drop-in Immunisation Clinic at The Children's Hospital at Westmead
- Specialist Immunisation Clinic including Telehealth Consultations
- Children and adolescents who are difficult to vaccinate

NSW Immunisation Specialist Service at The Children's Hospital at Westmead



Take home messages...

- Vaccines are safe - tried and tested
- Severe reactions are uncommon
- Reporting is **IMPORTANT**
- Communication is key
- PHU Contact: 1300 066 055



Thanks for Listening

