

COVID-19 vaccinations for children aged 5-11 years

31 December 2021

OFFICIAL

Introduction

Purpose

This document provides guidance for administering COVID-19 vaccines to children aged 5-11 years in Victoria.

Overview

Vaccination may have benefits for children both for direct protection as well as transmission to vulnerable family members and reduction in cases in schools. International data suggest that the Delta variant has a similar profile to ancestral strains, including those children, adolescents, and young adults with underlying medical conditions who have an increased risk of developing severe disease and complications when infected with SARS-CoV-2 COVID-19¹. Vaccines are likely to offer protection against severe disease at all ages. The approach to vaccinating children aged 5-11 years will be guided by the Australian Technical Advisory Group on Immunisation (ATAGI).

Current vaccine policy for children

On 5 December 2021, the Therapeutic Goods Administration (TGA) provisionally approved the Pfizer Australia Pty Ltd COVID-19 vaccine, Comirnaty, for use in individuals 5 years and older.

In making this regulatory decision, the TGA carefully considered data from clinical trials conducted in the United States, Finland, Poland and Spain which included participants 5 -11 years of age. The study demonstrated effectiveness by showing that the immune response to the vaccine in children was similar to that seen in older age groups.

On 9 December 2021 ATAGI recommended the paediatric Pfizer dose be administered to all children 5-11 years old. The recommended schedule for vaccination in this age group is 2 doses, 8 weeks apart. The interval can be shortened in special circumstances to a minimum of 3 weeks, such as in an outbreak response, prior to the initiation of significant immunosuppression or international travel. It is important to ensure preparedness for the specific considerations that children aged 5-11 years will require to be safely vaccinated. There are approximately 578,499 children between the ages of 5-11 years old in Victoria.

Clinical Governance

All clinical governance around vaccination remains the responsibility of the vaccination provider as outlined in the Victorian COVID-19 Vaccination Guidelines and the Victorian COVID-19 Vaccination Program Service Specifications.

¹ Graff K, Smith C, Silveira L, et al. Risk factors for severe COVID-19 in children. *Pediatr Infect Dis J* 2021; 40: e137–e145.

Models of Service

Children will have different support needs based on their previous experiences and medical history, however, there is a minimum support requirement for all children being vaccinated. The different models of service that are recommended to be available for this age group, based on the level of care needed and possible patient cohorts, can be seen below (Figure 1 and Table 2), as well as a guide to decision making about what level of care a child may need (Figure 2). These models of service are applicable across vaccination delivery models (e.g., drive through, pop-up, in-home vaccination), however they may need to be adapted depending on the setting and resources available e.g., alternative distraction techniques may be required for a drive-through model.

Figure 1 – Models of service for COVID-19 vaccination for children aged 5-11

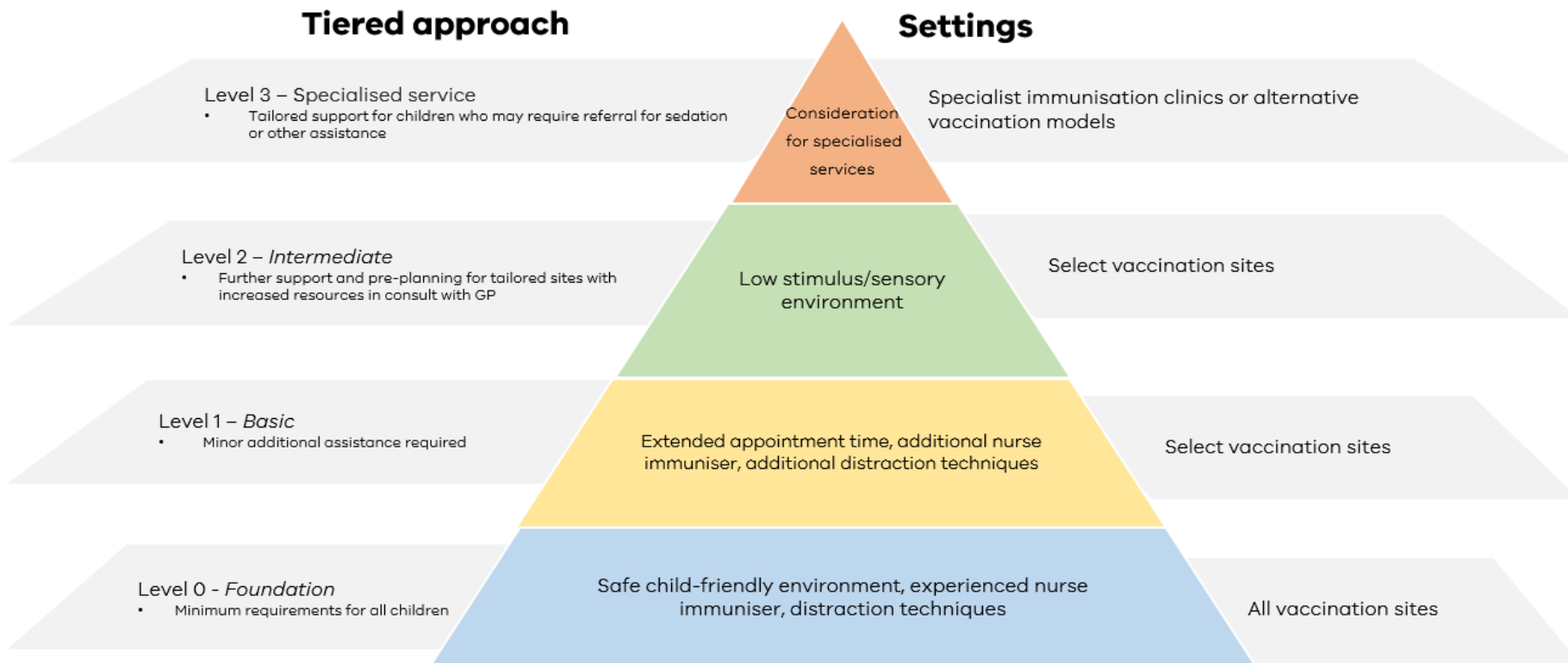


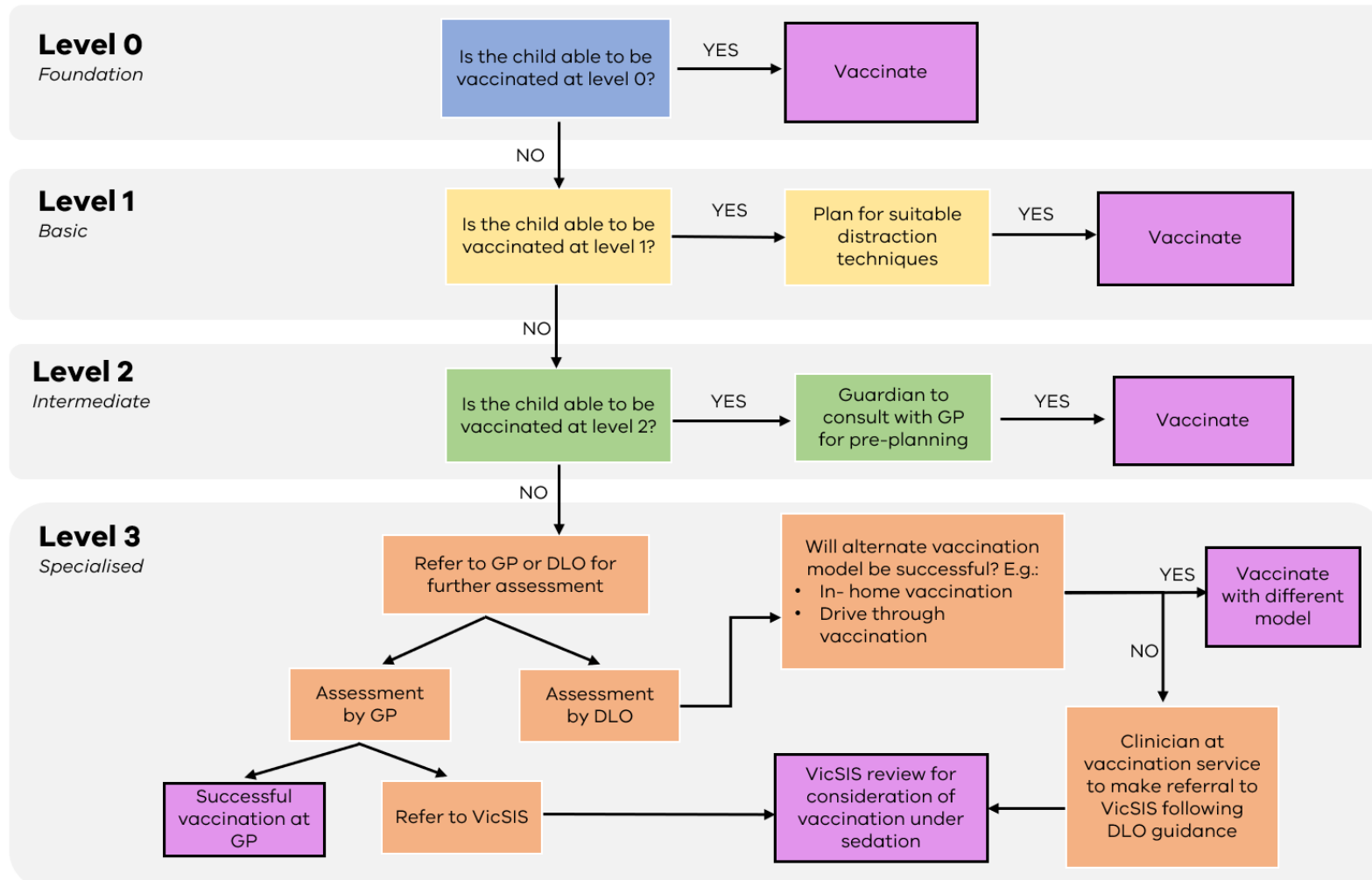
Table 1 – Care pathway for COVID-19 vaccination for children aged 5-11

| Level | Possible cohorts | Recommended Requirements |
|---|---|--|
| Level 0: Foundation Minimum requirements for all children | Children with no anticipated additional support needs | Safe child-friendly environment (inclusive, healthy, friendly, and protective): <ul style="list-style-type: none"> • Pre assessment to identify care level required • Experienced nurse immuniser with adequate paediatric training • Availability of COVID-safe activities e.g. stickers, play area, digital devices e.g., tablets • Availability of music – white noise apps, parents encouraged to bring devices to play music, speakers • Floor and wall decals for directional signage and observation area • Parents encouraged to bring toys and distraction from home for child • Big screen to display animations and child entertainment material • Parent or guardian to always remain with child • Children’s band aids • Activity pack to be given to child as well as fidget toy and stress ball |
| Level 1: Basic As above plus minor additional assistance required | <ul style="list-style-type: none"> • Minor behavioural issues • Developmental disability or autism normally needing minimal support • Previous negative experience with procedures • Anticipated anxiety | <ul style="list-style-type: none"> • Additional nurse immuniser to provide additional support • Extended appointment time • Availability of distraction methods <ul style="list-style-type: none"> • Buzzy bee (a bee-shaped distraction device) • Cool sense • Viewer devices • Virtual Reality headsets (Smiley Scope) |
| Level 2: Intermediate As above plus further support for tailored sites with increased resources (e.g., Children with special needs) | If the vaccination team is unable to vaccinate the child using the previous techniques or: <ul style="list-style-type: none"> • History of autism with sensory issues • Easily overwhelmed in crowded spaces • Moderate anxiety or needle phobia • Intellectual disability, developmental disorders or significant physical disability (e.g., cerebral palsy GMFCS V) | <ul style="list-style-type: none"> • Additional pre-planning of the vaccination consult • Low stimulus “quiet” environment • Low volume hubs OR sessions • Appropriate holding techniques must be used <p>Do not have more than 2 unsuccessful attempts at vaccinating this cohort before aborting and referring to the patient’s GP or a DLO (see decision tree).</p> |
| Level 3: Specialist service As above plus tailored support for children who have high needs or may require referral for sedation | If the vaccination team is unable to vaccinate the child using the previous techniques or: <ul style="list-style-type: none"> • severe needle phobia • developmental disorders with high needs | Alternate models: <ul style="list-style-type: none"> • In-home vaccination • Drive through vaccination <p>Specialist services: Referral to the Victorian Specialist Immunisation Services (VicSiS) should be considered for possible sedation</p> |

Resources:

- [Needle phobia and sedation guidelines](#) and [Safe immunisation holding practices for children with disabilities](#)

Figure 2 – Decision tree for COVID-19 vaccination for children aged 5-11



Vaccinating children with neurodevelopmental conditions

Below is a list of important adjustments, supports and strategies that vaccine providers can make to ensure children with a disability and/or autism, as well as their families/carers, can have positive experiences and outcomes when attending the vaccination site.

- Dedicated “quiet” and low stimulus sessions at vaccination centres to cater for children with a disability
- Sites should be disability accessible
- Clearly mark priority queue or entrance for children with disability
- Involving staff trained in disability support e.g., [Disability Liaison Officers \(DLOs\)](#) and immunisers who have experience vaccinating this specific cohort.
- An extended appointment time and single additional nurse immuniser should be provided, as too many people assisting with the procedure may increase anxiety. Minimising the number of staff in the room to only those necessary is important.
- Appropriate holding techniques can be considered to provide comfort and stability to the child. Forceful holding should never be used. These [Murdoch Children’s Research Institute \(MCRI\) guidelines](#) provide useful advice in relation to holding techniques and outlines when they are appropriate and when they are not permissible.
- If immunisation attempts are unsuccessful or the child is flagged as high risk, a referral for to an immunisation specialist may be considered. Refer to [MVEC website for further information](#) on options such as sedation and specialist needle phobia clinics.
- Several [resources specific to COVID-19 vaccination for people with autism](#) are available through Amaze. This includes training tools, checklists and social scripts that explain the COVID-19 vaccination process.
- **It is important to recognise when the vaccination shouldn’t go ahead. Such indicators include:**
 - If the child attempts to leave the room
 - If a child is unable to be settled using the child’s usual comfort measures
 - If the child requires holding that requires more than one person or any degree of force
 - If the resources required to complete safe vaccination are unable to be provided
 - If the parent/guardian requests to abandon attempt
- Vaccination should be aborted after two unsuccessful attempts and the individual should be [referred to a DLO](#) for consideration of alternate vaccination models or [referral to the Victorian Specialist Immunisation Services \(VicSIS\)](#).

Workforce and Regulations

Workforce Requirements

- Vaccination sites must ensure that an experienced authorised immuniser is present on-site, who has completed all required COVID-19 vaccination training and has completed anaphylaxis training within the past twelve months.
- Vaccination site leads should consider the competence and experience of their workforce to determine their suitability to vaccinate children.
- Experienced emergency authorised vaccination staff may be considered suitable to administer the COVID-19 vaccine to children aged 5-11. These staff should demonstrate competency in administering the vaccine to this age group. A competency assessment will be provided by the department for all emergency authorised immunisers.
- It is recommended that a health professional who has qualifications in basic paediatric life support be present in any setting where children aged 5-11 are being vaccinated.
- For the purposes of working in the COVID-19 vaccination program, a Working with Children Check (WWCC) is recommended regardless of role. Some organisations may have their own policies that require workers to have a WWCC and it may also be a requirement in some settings, for example schools. Employers are responsible for ensuring that workers (including volunteers) have a WWCC where required.

Training for immunisation staff

Melbourne Vaccine Education Centre (MVEC)

- Melbourne Vaccine Education Centre (MVEC) have been engaged to provide training to staff working at state clinics.
- Sites will nominate nurse immunisers to act as 'hub champions.' The hub champions can contribute to the training of other vaccination staff without experience in vaccinating children.
- There are two training elements: an online 'Immunising children and infants' webinar, and practical training sessions at council immunisation clinics.
- The webinar is accessible through MVEC's Education Portal: <https://education-mvec.mcri.edu.au/>
- The webinar is a mandatory requirement for all staff working with 5–11-year-olds at state-run vaccination sites.
- The practical training sessions will only be completed by hub champions.
- The training requirements for hub champions and existing vaccination staff is outlined in [Table 2](#) – MVEC training workplan.
- Sites are responsible for identifying staff who they assess to have the relevant skills and experience to vaccinate 5–11-year-olds without further practical training. For example, nurse immunisers that have previously worked in council or paediatric immunisation settings may not require any additional practical training.
- The MVEC practical training will provide a standardised training package for hub champions. Staff undertaking this training can then support further training at sites to expand workforce capacity.
- Deciding who needs further practical training at each site will be up to the respective sites.
- To give flexibility, on-site training at vaccination services will not be limited to delivery by hub champions, and sites may use suitably skilled staff with paediatric immunisation experience to train others.

- MVEC practical training will be complemented by guidance materials which will be made available to the hub champions to consolidate their learning.
- Further training to other suitable staff and any associated 'accreditation' or competency assessment is the responsibility of the relevant LPHUs / sites. A competency assessment will be provided by the department for emergency authorised immunisers and may also be used at the discretion of sites for nurse immunisers.

Murdoch Children's Research Institute (MCRI) Vaccine Uptake Group

- Delivery of 20 training sessions over the first few months by Murdoch Children's Research Institute focussed on CALD, disability and Aboriginal and Torres Strait Islander populations run in partnership with Victorian Multicultural Commission and Victorian Aboriginal Community Controlled Health Organisations. Supported with resources, the training is designed to upskill people working in healthcare, education and with priority children on COVID-19 vaccination and its benefits including having conversations with vaccine hesitant parents, guardians, and carers in addition to having conversations about vaccination with children.

Table 2 – MVEC training workplan

| <p style="text-align: center;">Hub Champion Senior nurse immuniser (2 per site)</p> | <p style="text-align: center;">Other Vaccination Staff Has completed existing training and has experience in Victorian COVID-19 Vaccination Program</p> |
|--|--|
| <p style="text-align: center;">Commonwealth COVID-19 vaccine course incorporating additional modules specific to paediatric vaccine</p> | <p style="text-align: center;">Commonwealth COVID-19 vaccine course incorporating additional modules specific to paediatric vaccine</p> |
| <p style="text-align: center;">MVEC immunising children and infants webinar <i>(from week of 13 December)</i></p> | <p style="text-align: center;">MVEC immunising children and infants webinar <i>(from week of 13 December)</i></p> |
| <p style="text-align: center;">Orientation session (Zoom) with MVEC <i>(from week of 13 December)</i></p> | <p style="text-align: center;"><i>Optional:</i> <i>MVEC Vaccination Procedures learning package</i></p> |
| <p style="text-align: center;">Council session (practical) facilitated by MVEC <i>(from week beginning 13 December 2021 and throughout January 2022)</i></p> | <p style="text-align: center;">Practical training, competency assessment and supervision by Hub Champions</p> |

Note: practical training requirements for existing and new workforce members can be determined on a case-by-case basis depending on prior experience, training and individual assessment. Emergency authorised immunisers are required to undertake a competency assessment.

Eligibility confirmation

Before administering the vaccine, an immuniser must verify the minimum eligible age (5 years and above) with identification (ID) or any proof of age document, such as a birth certificate, passport or school card. Cross-referencing Medicare card details with the Australian Immunisation Register or a letter from the child's general practitioner or school is also acceptable if there is no other 'proof of age' documents available at the relevant time. A statutory declaration from the child's parent or guardian is not recommended as proof of age but can be used on discretion of the health provider

The child should be clinically assessed, and their details confirmed before administering the vaccine.

- Review consent forms
- Undertake pre-vaccination assessment
- Provide an opportunity for the child and parent/guardian to raise any questions
- Complete consent and pre-immunisation assessment checklists.
- Instruct the child and parent/guardian to wait for at least 15 minutes, as a safety requirement, while they are observed for signs of adverse reaction. Provide information on post-vaccination self-care and direct the parent/guardian to read this (Available in a range of community languages if applicable).

Informed consent

- A parent or guardian will be required to provide consent to vaccinate a child (aged 5-11), as the child will not be competent to consent for themselves as per the [Medical Treatment Planning and Decisions Act 2016 \(Vic\) \(MTPD Act\)](#).
- A medical treatment decision-maker for a child will be the child's parent, guardian, or other person with parental responsibility for the child who is available and willing to provide informed consent for the child's COVID-19 vaccination.
- Appropriate reading level English and culturally and linguistically diverse (CALD) resources should also be provided to the children and carers – if resources permit.
- The health professional administering the vaccination is responsible for obtaining and recording consent for the child to be vaccinated against COVID-19. Other staff including administrative staff, teachers and/or support workers can help to coordinate this process (by contacting the decision maker) but cannot record consent. Schools, disability services and in-reach programs should have systems in place to support this process, if required.
- For more information refer to the additional resources on consent [Appendix 24: Consent for COVID-19 vaccination administration in children and adolescents under the age of 18 years](#).

Operational planning and preparedness

Creating a child-friendly and safe vaccination site

The design and layout of sites must ensure that vaccination spaces are child-friendly and welcoming. Site planning should also be informed by [existing guidance](#) on delivering culturally safe vaccination services. Key considerations should include easy to read information in multiple languages, rapid and on-site access to interpreter services and workforce diversity to support delivery of culturally appropriate care. Consultation with parents of children with disability and from Culturally and Linguistically Diverse communities informed these recommendations.

Pre-immunisation preparation

- Where possible, parents should be provided with an **immunisation plan** (<https://www.coronavirus.vic.gov.au/vaccination-information-children-and-teenagers>) to guide the immunisation experience for the child. This can be completed ahead of time to provide the child with a level of control over the process, in terms of selecting who will accompany them, time of day, toys, music or other distractions that the parent/carer brings to the appointment. The parent can record any previous negative immunisation experiences or anticipated anxiety and select the most appropriate immunisation pathway that may suit their child (see Figure 2). The plan will help to reduce anxiety and needle distress.
- A child-friendly concierge to greet people at vaccination centres and direct to priority queues for children with disability or special needs, as well as active queue management to recognise signs of distress in children, is required to ensure a positive experience.
- Awareness of Disability Liaison Officer (DLO) services prior to and at the point of booking aims to provide the most appropriate immunisation experience first time for children with disability, special needs, needle phobia and/or anxiety.

Site design

- Create a child friendly environment using colour and collateral to make them feel safe. This will include the use of pictorial decal (for example, images of small feet or bricks) as a wayfinding device to the vaccination booths.
- Place posters and directions at children's height to allow them to read (note: Department of Health will supply a base themed pack).
- Availability of COVID-safe activities (e.g., stickers, storybooks, toys, and play therapy, outdoor play area, if possible, will ensure adequate distraction for children both waiting in line and during vaccination procedure, particularly children with special needs. Please see Diagram 1 under models of service and [CDC Paediatric Planning Guide](#) for further guidance.
- All COVID-safe activities and distraction techniques should be single use or wipeable in line with IPC advice, refer to [vaccine guidelines](#) for further information on environmental cleaning
- Availability of music is recommended, either through encouraging parents to bring their own devices or through speakers at select vaccination sites that are intended for children with special requirements.
- Availability of Wi-Fi for families (either hospital Wi-Fi or portable Wi-Fi) could be considered to assist with streaming music or videos to distract children.
- Noise should be minimised where possible by ensuring empty bays between children to ensure a calming environment and reduce the levels of anxiety and needle distress. If resources allow, consider music to distract from distressing ambient noise for example white noise apps with calming sounds such as the ocean. (see Table 1 under Models of Service).
- Children under distress can trigger stress response in other children who are in the vicinity, and so it is recommended to have a designated partition (preferably with a door to minimize sound transmission) that ensures privacy for children that experience acute stress episodes for their recovery.
- Offer dedicated "quiet" sessions at vaccination centres to cater for children living with a disability, which include smaller enclosed spaces, low lighting/sensory surroundings and staff trained in disability support
- Where possible, minimise harsh lighting.

Site layout and flow

- There should be dedicated lanes and observation areas reserved for children aged 5-11 and their parent/guardian. The parent/guardian should always remain with the child. Consider changes to the layout of the waiting area to allow for small groups of families to be together and distraction opportunities for children (e.g., colouring books).
- A large clock can be helpful to allow children to track time and as a learning opportunity.
- Consideration could be given to separate waiting lines and check-in areas from adults to reduce children’s anxiety and wait times.
- Active queue management to identify children with special needs or in distress and an express queue to accommodate such needs. Ample “easy read” clear signage should be available to help parents and children with disabilities identify this express lane.
- All staff should wear a name badge with their name and photo to make them appear more approachable when wearing PPE
- Consider extended appointment times and increased intervals between appointments to reduce risks of over-crowding
- Preference for after school and evenings as well as longer hours of operation on weekends in addition to regular hours.
- Additional time should be allocated for discussion of parents’ questions and concerns and to ensure valid consent
- Consideration could be given to specific days or half days dedicated to vaccinating only in this cohort



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Vaccine logistics

Paediatric dosage of COVID-19 vaccine



On 5 December 2021, the Therapeutic Goods Administration (TGA) provisionally approved the Pfizer Australia Pty Ltd COVID-19 vaccine, Comirnaty, for use in individuals 5 years and older. As for other age groups, this vaccine should be given in a two doses regimen for children aged 5-11 years. The interval period in the ATAGI guidance of 9th Dec 2021 is that doses be 8 weeks apart. The interval can be shortened in special circumstances to a minimum of 3 weeks, such as in an outbreak response, prior to the initiation of significant immunosuppression or international travel. A lower dose (10 micrograms or 0.2 ml) will be given to children aged 5-11 years, compared to that used for individuals 12 years and older (30 micrograms). A child should be vaccinated with the recommended dose based on their age at time of vaccination (e.g., if they turn 12 between dose 1 and 2 they would be vaccinated with an adult dose for dose 2).

To deliver the smaller dose, an orange-capped vial will be used to vaccinate children. It will be clearly differentiated from the vial currently used to vaccinate those 12 years and older (purple top). Expected differences in dosing, storage and preparation for adult and paediatric Pfizer vaccine can be seen in Table 3.

To reduce the risk of vaccine errors the following should be considered:

- A paediatric vial can only be used for children 5-11 years old.
- Where practicable, paediatric and adult Pfizer vials should be stored separately in vaccine fridges/freezers. Paediatric and adult Pfizer doses should not be drawn up together or the filled syringes stored together.
- Paediatric and adult doses should be clearly labelled to reduce the risk of errors.
- AstraZeneca and Moderna vaccines should not be stored with the paediatric Pfizer vaccine.
- Implementation should ensure that the risk of vaccine errors are minimised by specific awareness and training around multi-dose vials for this age group i.e., orange caps

Table 3 – Differences between adult and paediatric dosage and preparation (Source: US CDC, 2021²)

| Description | Current Adult/Adolescent Formulation (1170 and 450 packs) | Future Pediatric Formulation |
|------------------------------------|---|---|
| | <i>Dilute Prior to Use</i> | <i>Dilute Prior to Use</i> |
| Age Group | 12 years and older | 5 to <12 years** |
| Vial Cap Color | PURPLE  | ORANGE  |
| Dose | 30 mcg | 10 mcg |
| Injection Volume | 0.3 mL | 0.2 mL |
| Fill Volume (before dilution) | 0.45 mL | 1.3 mL |
| Amount of Diluent* Needed per Vial | 1.8 mL | 1.3 mL |
| Doses per Vial | 6 doses per vial (after dilution) | 10 doses per vial (after dilution) |
| Storage Conditions | | |
| ULT Freezer (-90°C to -60°C) | 9 months | 6 months |
| Freezer (-25°C to -15°C) | 2 weeks | N/A |
| Refrigerator (2°C to 8°C) | 1 month | 10 weeks |

Further guidance on paediatric storage, preparation, and dosage of COVID-19 vaccine to be provided by TGA and ATAGI.

² <https://www.cdc.gov/vaccines/covid-19/downloads/Pfizer-Pediatric-Reference-Planning.pdf>

Preparing for vaccination

Equipment

Access to emergency medical equipment such as Automated External Defibrillator (AED) with paediatric pad/key option, portable emergency oxygen kits, first aid kit, and anaphylaxis response kit should be available on site. Equipment should be regularly checked and maintained in line with the organisation's policy on resuscitation equipment use.

Please note that a defibrillator is rarely required in children. Most paediatric life support initially focuses on airway and respiratory management.

Recommended injection site and needle length

Needle length and injection site are the same for this cohort as adults. Refer to [Australian Immunisation Handbook](#) for more information. The solo sitting position is recommended for this age group; however, the cuddle or straddle position may also be considered.

The anterolateral thigh and ventrogluteal area can be used as alternative sites if the deltoid muscle is difficult to access due to distress or injury. Immunisation providers should be familiar with the landmarks used to identify these injection sites and only administer to these sites if they have been suitably trained.

Refer to the links below to see the alternative injection sites:

- [Anatomical markers used to identify the vastus lateralis injection site on the anterolateral thigh.](#)
- [Anatomical markers used to identify the ventrogluteal injection site](#)

Preparing an anaphylaxis response kit

Before each vaccination session, ensure that protocols, equipment, and medicine to manage [anaphylaxis](#) are available by keeping an anaphylaxis response kit handy. Ensure that a printed table with [age-based adrenaline dosing](#) is readily available.

See [Preparing an anaphylaxis response kit](#) and [Australian Society of Clinical Immunology and Allergy \(ASCI\) Anaphylaxis e-Learning for Health Professionals.](#)

Vaccine safety considerations

Adverse Events Following Immunisation (AEFI)

Information on possible adverse events after receiving a COVID-19 vaccine should be provided to the child (depending on age and maturity) and parent/guardian. They should be made aware of how to manage of common, minor, expected adverse events, such as the use of simple analgesics for injection site pain, fever, headaches, or body aches, and advised to seek further medical attention if more serious adverse events are experienced.

Fainting and syncopal seizures

There may be variations in the frequency and type of adverse events following immunisation for children aged 5 years compared to children aged 11 years.

Anxiety/pain related reactions to any vaccine is likely to be higher for children and adolescents than adults. An Australian study³ showed the occurrence of syncope and seizures following vaccination administering is higher in children and adolescents compared to adults.

While most cases of fainting and syncopal seizures are not serious, some children may sustain injury from high impact falls, so it is important to have a safe vaccinating environment and an awareness of the clinical signs of a faint/syncope.

Allergic reactions

Allergic reactions to COVID-19 vaccines are rare but need to be closely monitored for. The signs/symptoms of mild to moderate allergic reaction include:

- rapid onset swelling to face, lips and/or eyes
- tingling of the mouth
- hives (urticaria) or welts
- abdominal pain/vomiting.

A mild to moderate allergic reaction may sometimes progress to a severe allergic reaction, such as anaphylaxis. Signs/symptoms of anaphylaxis may include difficult or noisy breathing, swelling of the tongue or throat tightness, wheeze or persistent cough, hoarse voice, pallor, and floppiness (in a young child), or collapse.

All immediate (within 4 hours) and generalised symptoms of a possible allergic reaction to a previous dose of COVID-19 vaccine should be reported to [SAEFVIC](#) and the vaccinee referred to a [VicSIS clinic](#). See [ASCIA Guide: Allergy and COVID-19 Vaccination](#) for more information.

Myocarditis and pericarditis

- Myocarditis and/or pericarditis occur very rarely in younger people, including adolescents and children.
- Myocarditis and pericarditis typically occur within 10 days of mRNA vaccines.
- The classic symptoms of myocarditis or pericarditis can include chest pain, pressure, or discomfort palpitations (irregular heartbeat, skipped beats or 'fluttering'), syncope (fainting), shortness of breath, pain with breathing. Younger individuals with myocarditis and pericarditis may present with symptoms that are more non-specific.
- Most myocarditis and pericarditis cases linked to mRNA vaccination have been mild and patients have recovered quickly. Longer-term follow-up of these cases is ongoing.
- The risk of myocarditis appears highest in the 12-29 years age group. There is not yet sufficient data to predict rates of myocarditis and pericarditis in the 5-11 years age group⁴.

For further information refer to the ATAGI's [Guidance on Myocarditis and Pericarditis after mRNA COVID-19 Vaccines](#).

³ [Syncope and seizures following human papillomavirus vaccination: a retrospective case series | The Medical Journal of Australia \(mja.com.au\)](#)

⁴ Daniels CJ, Rajpal S, Greenshields JT, et al. Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2 Infection: Results From the Big Ten COVID-19 Cardiac Registry. JAMA Cardiol. Published online May 27, 2021. doi:10.1001/jamacardio.2021.2065

Reporting of AEFI

For further information refer to [SAEFVIC](#) vaccine safety information and reporting.

**An AEFI is considered significant if it is life-threatening, requires in-patient hospitalisation or prolongation of existing hospitalisation, deemed clinically significant, results in persistent or significant disability/incapacity or requires intervention to prevent permanent impairment or death.*

Serious adverse events requiring urgent reporting

AEFI that result in:

- Transfer to hospital care
- CPR
- Defibrillator use
- Life-threatening incidents
- Death

Vaccine administration errors

1. Manage the AEFI by usual clinical pathways

2. Immediately notify via phone:

→ Business hours (Mon – Fri, 9AM – 5PM)

Call SAEFVIC **1300 882 924** (Option 1)

→ Out of Hours

Call Victorian Vaccine Control Centre (VVCC)

1800 675 398 (Options 3-1-2)

3. Submit an AEFI report online to [SAEFVIC](#)