Government of **Western Australia**
Department of **Health**

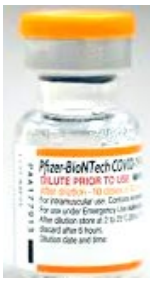
Clinician alert #76 – all clinicians

Effective from 10 January 2022

Paediatric formulation Pfizer (Comirnaty) COVID-19 Vaccine for 5-11 year-olds

- Following approval by the Therapeutic Goods Administration (TGA) and a recommendation by the Australian Technical Advisory Group on Immunisation (ATAGI), the paediatric formulation of the Pfizer COVID-19 vaccine may be administered to children aged 5-11 years.
- ATAGI recommends vaccination of this cohort based on the direct benefits to the child in preventing illness and the indirect benefits for the child, their family and the broader community. The paediatric COVID-19 vaccination program will commence on 10 January 2022.

There are important differences between the paediatric formulation of the Pfizer COVID-19 vaccine and that used for people aged 12 years and over:



- The paediatric formulation is not identical to the adult formulation, and is distinguished by having an **orange cap** on the vaccine vial, instead of purple.
- The paediatric vaccine **dose is 10µg** (0.2mL after dilution); this is one-third the dose given to people aged ≥12 years (i.e. 30µg).
- The recommended **paediatric schedule is different: 2 doses given 8 weeks apart.** The 8- week 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 for international travel.
- The **paediatric vaccine vial requires dilution with 1.3mL of normal saline, which is different to the purple cap vaccine** used for those aged 12 years and older.

Co-administration with other vaccines

The paediatric Pfizer COVID-19 vaccine can be co-administered with other vaccines. Parents and guardians should be aware this may be associated with an increase in mild-moderate adverse events.

Safety and side-effects

The paediatric Pfizer COVID-19 vaccine has been demonstrated in clinical trials to be well tolerated, with **most adverse events being mild and transient**. Real world evidence on the safety of paediatric Pfizer COVID-19 vaccine is rapidly accumulating; as of 19 December 2021, >8.6 million children aged 5-11 years in the United States had received at least one dose. Under active surveillance, local and systemic adverse events in the 5-11 year age group were slightly less frequent than in the 12-15 year age group. Pain at the injection site is the most common adverse event reported, followed by fatigue, headache, myalgia and chills.

Myocarditis and pericarditis have been associated with the use of mRNA COVID-19 vaccines. The people at highest risk of these adverse events are adolescent and young adult males, with no other risk factors currently identified. The risk in children aged 5-11 is not yet established but appears to be very low based on preliminary data from US Vaccine Safety Datalink (VSD); as of 25 December 2021, 431,485 doses of Pfizer COVID-19 vaccine have been administered in this age group under the VSD and no increased risk of myocarditis, or other serious safety signal, has been identified.
Most pre-existing cardiac conditions are **NOT** regarded as contraindications to vaccination.

Pfizer (Comirnaty) **CAN** be given without specific precautions to children with a history of chronic cardiovascular conditions including congenital heart disease, prior history of rheumatic heart disease, Kawasaki disease, cardiomyopathy, stable heart failure and arrhythmias.

Advice regarding additional precautions and best timing of vaccination should be sought in children with a history of:

- Recent (i.e. in the past 3 months) or current inflammatory cardiac illness e.g. myocarditis, pericarditis
- Acute rheumatic fever or acute rheumatic heart disease
- Acute decompensated heart failure

Children should not receive the Pfizer COVID-19 vaccine if they have had:

- Anaphylaxis to a previous dose of the Pfizer COVID-19 vaccine
- Anaphylaxis after exposure to any component of the vaccine, including polyethylene glycol (PEG)
- Any other serious adverse event that an experienced immunisation provider or medical specialist has confirmed was caused by a previous dose of the Pfizer COVID-19 vaccine, without another cause identified.

More detailed information on contraindications and precautions is available in the ATAGI & Cardiac Society of Australia and New Zealand (CSANZ) Guidance on Myocarditis and Pericarditis after mRNA Covid-19 Vaccines and the ATAGI recommendations on the use of the paediatric Pfizer Covid-19 vaccine in children aged 5 to 11 years in Australia

Vaccine administration

- Consent from a parent or guardian is required for vaccination of children under 12 years of age. Providers may use a combined information and consent document developed by the Australian Government available on-line.
- Topical anaesthetics, such as EMLA® cream, are not recommended for routine use, but could be considered in a child with excessive fear or dislike of needles. Children with **severe** needle phobia that cannot be managed in a GP setting may be referred to the PCH Specialist Immunisation Clinic.
- ATAGI recommends against use of the adolescent/adult Pfizer COVID-19 vaccine formulation in children aged 5-11 years.
- Children who turn 12 years of age after their first dose may receive the adolescent/adult formation of the Pfizer COVID-19 vaccine to complete their primary vaccine course.
- Any vaccine administration error is required to be reported as a Vaccine Administration Error to the WA Vaccine Safety Surveillance System (online at https://www.safevac.org.au/Home/Info/WA) and to the Vaccine Operations Centre (VOC) on 1800 318 208.

Healthcare providers can access further information through the links above or by telephoning Metropolitan Communicable Disease Control (MCDC) on 9222 8588.

Thank you for efforts to protect West Australians from COVID-19.

Dr Paul Effler, MD, MPH

SENIOR MEDICAL ADVISOR, COVID-19 VACCINATION PROGRAM