Q. Should the vaccine be given to a female student who is or thinks she may be pregnant?

It is safe for women who are pregnant to receive the Pfizer vaccine at any stage of the pregnancy. On the day of the clinic, the vaccination nurse will ask female students if they are or could be pregnant. If a student answers yes to this question, she will be vaccinated and will be urged to immediately discuss the issue with her parent/guardian and to seek medical help. She will also be provided with contact details for a health referral service that will provide advice, support and guidance.

Q. What can I do if my child missed out on the vaccine because of illness or absence on the day of the nurses' visit?

Every effort will be made to vaccinate your child at school. Where this is not possible, you should use the Australian Government Vaccine Clinic Finder to identify opportunities for your child to get vaccinated.

Q. Can I get a record of the vaccinations?

The information you provide on the consent form and details about the vaccinations will be entered into a NSW Health immunisation register and then uploaded to the Australian Immunisation Register (AIR) so it can be linked to your child's existing immunisation history.

Parents can request a copy of their child's AIR Immunisation History Statement at any time up to their child being 14 years of age. Students aged 14 years or over can request their own immunisation history statement:

- using their Medicare online account through myGov https://my.gov.au/
- using the Medicare Express Plus App www.humanservices.gov.au/individuals/subjects/express-plus-mobile-apps
- calling the AIR General Enquiries Line on 1800 653 809.

Where can I find more information?

More information is available by visiting health.nsw.gov.au/schoolvaccination or contacting your local public health unit on **1300 066 055**.

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COVID-19 Pfizer (Comirnaty) Vaccine

NSW Health is offering two doses of COVID-19 Pfizer (Comirnaty) vaccine in a school vaccination program at least 21 days apart. Signed parental/guardian consent must be provided.

Your next steps

- Carefully read this information sheet.
- If you would like your child to be vaccinated against COVID-19, complete the Consent Form and give the signed Consent Form to your child to return to school.
- If you do NOT wish your child to be vaccinated against COVID-19, do NOT complete or return the Consent Form.

Q. Why is COVID-19 vaccination important?

COVID-19 is a disease caused by the virus SARS-CoV-2. It can cause severe lung and generalised disease. It has caused over 4.5 million deaths worldwide, with more than 220 million cases reported.

Although the elderly and people with underlying medical conditions are at the highest risk, even healthy young people can get severe COVID-19. In some people, COVID-19 may cause long-term symptoms of fatigue and breathlessness. We are still learning about other long-term complications caused by COVID-19. The virus that causes COVID-19 is easily spread by people with few or no symptoms.

People who are infected may not become unwell with COVID-19, but may pass the virus on to their family and friends without knowing it and they may become very ill. By getting vaccinated, they are protecting themselves and others from severe COVID-19. Once a large proportion of the population is vaccinated, this will decrease the spread of COVID-19 in our community.

Q. What is COVID-19 Pfizer (Comirnaty) vaccine and how does it work?

COVID-19 Pfizer (Comirnaty) vaccine is a COVID-19 mRNA vaccine. This means the vaccine contains the genetic code for an important part of the COVID-19 virus 'spike protein'. After getting the vaccine, the body reads the genetic code and makes copies of the spike protein. The immune system then detects these spike proteins and learns how to recognise and fight COVID-19 if the person is exposed to the virus later. The genetic code is quickly broken down and cleared away by the body.

Q. How effective is the vaccine? How long will the protection from the vaccine last?

In clinical trials COVID-19 vaccines have been shown to provide excellent protection from getting sick with COVID-19. In these trials, after two doses the Comirnaty (Pfizer) vaccine was about 95% effective against symptomatic infection. In an Israeli study, the Pfizer vaccine was 87% effective against COVID-19 requiring hospitalisations from 7 days after two doses.

The Comirnaty (Pfizer) vaccine was found to be around 91% effective against symptomatic COVID-19 up to 6 months after the second dose. More information on the duration of protection of COVID-19 vaccines will be available over the coming months.

Q. Is the vaccine effective against new variants of the virus?

Some recent variants of SARS-CoV-2 are more easily spread and have been associated with increased numbers of cases in some countries.

Current evidence from observational and post-licensure trials indicates that the antibodies that the body produces after COVID-19 vaccination are likely to provide protection against several variants and minor changes in the virus.

A recent study from the UK found the COVID-19 Pfizer (Comirnaty) vaccine is 96% effective against hospitalisation for the Delta variant after the second dose of vaccine.

Q. Can children and adolescents have the COVID-19 vaccine?

The Pfizer vaccine is registered for use in people aged 12 years and older and is currently the preferred COVID-19 vaccine brand for use in people under 60 years of age.

On 23 July 2021, the Therapeutics Goods Administration (TGA) provisionally approved the use of the Pfizer vaccine in people aged 12 years and older. Previously, the Pfizer vaccine was provisionally approved for use in people aged 16 years and older.

In the US, as of 25 July 2021, 28% of the children aged 12–15 years were fully vaccinated and 37% had received at least one dose. On 31 March 2021, Pfizer announced the results of a study in adolescents aged 12–15 years vaccinated with the Pfizer vaccine. The study showed that the vaccine was 100% effective, was safe and was well-tolerated with mild to moderate reactogenicity.

Q. Who can receive COVID-19 Pfizer (Comirnaty) vaccine?

People aged 12 years and older can receive COVID-19 Pfizer (Comirnaty) vaccine.

Contraindications (reasons why your child may not be able to have the Pfizer vaccine):

- anaphylaxis after a previous dose of an mRNA COVID-19 vaccine (Comirnaty or Spikevax)
- anaphylaxis to any component of the vaccine, including anaphylaxis to polyethylene glycol (PEG)
- other serious adverse events attributed to a prior dose of an mRNA COVID-19 vaccine

Precautions:

People with the conditions below should be assessed for suitability for vaccination, and if necessary, specialist opinion should be sought:

- an allergic reaction to a previous dose or ingredient of COVID-19 Pfizer (Comirnaty) vaccine
- anaphylaxis to other vaccines or to other medicines where there are common ingredients with the COVID-19 vaccine
- Mastocytosis with recurrent anaphylaxis that requires treatment
- bleeding disorder or blood thinning medication
- immunocompromising conditions
- pregnancy
- history of confirmed COVID-19 infection
- current illness
- a recent history of inflammatory cardiac illness within the past 6 months, e.g., myocarditis, pericarditis, endocarditis; acute rheumatic fever (i.e., with active myocardial inflammation) or acute rheumatic heart disease; or acute decompensated heart failure.

Q. What additives are in the vaccine?

The vaccine contains a number of additives in very small amounts to either assist the vaccine to work or to act as a preservative. These include ((4-hydroxybutyl)azanediyl) bis (hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315); 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159); distearoylphosphatidylcholine (DSPC); cholesterol; potassium chloride; monobasic potassium phosphate; sodium chloride; dibasic sodium phosphate dihydrate; and sucrose.

Q. Is the vaccine safe?

The Therapeutic Goods Administration (TGA) has approved COVID-19 Pfizer (Comirnaty) vaccine for use in people aged 12 years and over. The vaccine has been shown to be safe in large clinical studies of tens of thousands of people and has also been monitored for safety issues after being given to tens of millions of people around the world. The only serious safety concern that has been identified is a risk of anaphylaxis.

Anaphylaxis is a type of severe allergic reaction that may occur quite quickly after vaccination, but it is rare, and was reported to occur in 1 in 200,000 vaccine doses given in the USA. Students will be monitored for at least 15 minutes after vaccination for any side effects and school immunisation nurses are fully trained in the treatment of anaphylaxis. The TGA will continue to monitor the longer-term safety and effectiveness of the COVID-19 Pfizer (Comirnaty) vaccine.

Q. What side effects might occur after vaccination?

Common side effects after the COVID-19 Pfizer (Comirnaty) vaccine include:

- pain or swelling at the injection site
- tiredness
- headache
- muscle pain
- fever and chills
- joint pain.

Less common side effects include:

- redness at the injection site
- nausea
- enlarged lymph nodes
- feeling unwell
- pain in limb
- insomnia
- itching at the injection site.

Rare side effects that have been reported after vaccination are:

- severe allergic reaction (anaphylaxis)
- inflammation of the heart muscle, called myocarditis and pericarditis.

Q. What about myocarditis and pericarditis? Does the COVID-19 Pfizer (Comirnaty) vaccine cause these conditions?

Myocarditis is inflammation of the heart muscle. Pericarditis is inflammation of the outer lining of the heart. Myopericarditis is where these two conditions occur together. There are many conditions that can cause myocarditis and pericarditis, and these include autoimmune conditions, viruses and bacteria, certain cancers and certain medications. People who get sick with COVID-19 can develop myocarditis and pericarditis.

Myocarditis and pericarditis have been seen in people who have had some COVID-19 vaccines overseas, including COVID-19 Pfizer (COMIRNATY) vaccine. Cases have been reported more commonly in males less than 30 years of age, mostly after the second dose of vaccine and typically within the first few days after COVID-19 vaccination.

The exact rate is not yet known but it is rare. Most cases have been mild and respond to simple measures such as pain relief. The benefits of COVID-19 vaccine strongly outweigh the risk of myocarditis or pericarditis.

Cases of myocarditis and pericarditis after vaccination have also been reported in Australia and the TGA is monitoring these cases. Both these conditions occur relatively commonly in the general population, and not all cases that are reported after vaccination will be caused by the vaccine (that is, some may occur coincidentally).

Q. What are the symptoms of myocarditis or pericarditis and when should I seek help?

Symptoms of pericarditis and myocarditis typically occur within 1 to 5 days (and up to 10 days) of vaccination and include:

- chest pain (often sharp in nature but can also be stabbing or aching)
- feelings of having a fast-beating, fluttering, or pounding heart
- fainting
- shortness of breath.

If your child develops any of these symptoms, please seek medical attention and let your health care provider know about their recent vaccination history.

Q. How are side effects reported?

Suspected side effects can be reported to the vaccinating nurse or other healthcare professional. They will then make a formal report on your behalf.

If you would prefer to report it yourself, please visit health.nsw.gov.au/schoolvaccination and follow the links to the TGA website.

Q. What if my child has asthma and takes cortisone or prednisone by a “puffer”?

The vaccine can be safely given to someone who has asthma regardless of which medications they are taking.

Q. Who can consent to vaccination and can consent be withdrawn?

Only parents/guardians can consent to vaccination for students less than 18 years of age. Students aged 18 years and over may consent to their own vaccination and should complete and sign the Consent Form where ‘Parent/Guardian’ is indicated. Consent can be withdrawn at any time by providing the school with written notification of the withdrawal of consent or telephoning the school to withdraw consent.