

COVID Vaccine: Pfizer/BioNTech mRNA-CV (10 mcg) Paediatric and mRNA-CV (30 mcg) Adult for 12 years and older.

# Adult and Paediatric pre-vaccination screening and guidance

SCREENING QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your/ your child's full name and date of birth.	Check you have the correct patient records on the CIR. <b>Confirm child's age verbally. Those aged 5-11 will need mRNA-CV (10 mcg). Those who turn 12 after the first dose should also have mRNA-CV (10 mcg) for their 2nd vaccine.</b> Those aged 12+ years will need mRNA-CV (30mcg). See page 2 re consent for those under 16. Booster doses are only approved for those aged 18 and over.
Are you/your child feeling well today?	Postpone vaccine if: fever >38°C or acute systemic illness. Anyone directed to self-isolate or waiting for test should not attend vaccination appointment. See ops guidelines for the screening questions. For very frail or elderly with comorbid condition, ensure they are stable or as well as possible before vaccination and advise carer on need for post vaccination observation and hydration.
Have you/your child had a serious allergic reaction to anything including previous Pfizer vaccine?	<b>Contraindications: A history of anaphylaxis to previous dose of the mRNA-CV vaccine or to any component of the vaccine. Anaphylaxis to reagent polyethylene glycol (PEG)</b> (vaccine may still be given under specialist guidance). <b>Precaution: A definite history of anaphylaxis-type reaction to any other product.</b> A slightly increased risk of anaphylaxis has been noted in individuals who have had a previous anaphylaxis-type reaction to any other product. These individuals can still receive mRNA-CV. They should be well observed for at least 30 minutes and be given clear post vaccination advice. It is important that the observation staff are specifically alerted to this history by the vaccinator. This must be a verbal handover as the CIR automates a 15-minute wait timer. <b>All vaccination sites are set up to manage anaphylaxis for those with precautions.</b>
Is this your/your child's first COVID vaccination?	Check for any cardiac symptoms (particularly chest pain, palpitations, dizziness ) post the previous vaccine, and refer for further advice if there were any potential concerns not previously considered. Check spacing between vaccines: at least 3 weeks between doses for those aged 12+. For those aged 5-11 years, 8 week spacing is recommended (see comment on back page). Day 0 is the vaccination day. No maximum spacing.
For second vaccines: Did you/ your child have any problems after your last vaccines?	<b>Precaution:</b> A person who has developed myocarditis or pericarditis after their mRNA-CV vaccine <b>should not have any further doses of mRNA-CV without specialist review and advice.</b> If they are 18 or older, they can be offered AstraZeneca as an alternative vaccination.
Do you/your child have a bleeding problem or blood disorders?	Vaccines can be administered to people on anticoagulants. <b>For patients with haemophilia, vaccinations should be given as soon as possible after receiving clotting factor replacement or similar medicine.</b> It is recommended that the platelet count is kept $\geq 30 \times 10^9/L$ . Specialist advice is recommended. After vaccination, apply firm pressure over the injection site, without rubbing, for 10 minutes to reduce the risk of bruising.
Do you have any other questions? See responses to medical concerns.	<b>Cardiac concerns:</b> People with a history of myocarditis ad pericarditis unrelated to COVID-19 may receive mRNA-CV vaccine after the episode of myocarditis or pericarditis has completely resolved (ie, no symptoms and no evidence of ongoing heart inflammation). Those with heart disease or cardiac abnormalities are recommended to receive the vaccine. <b>Immunosuppression:</b> The antibody response to the vaccine may be reduced and protection may be suboptimal, but it is still likely to be adequate to protect against severe disease and there are no safety concerns. Patients may have been advised on specific timing of vaccinations to fit into other treatment regimens. Where possible accommodate this. <b>Bilateral lymph clearance:</b> Vaccine can be given in the vastus Lateralis. Seek help from experienced vaccinator or call 0800 if unsure.
Other vaccines in the last 7 days	Any National Schedule vaccines can be given at the same time as mRNA-CV with any interval spacing. The only exception to this is for older people receiving Zostavax (shingles vaccine). Ideally it is recommended to allow 7 days between Zostavax and either dose of mRNA-CV.

**Our message is 'don't delay'. Before turning anyone away, please consult with your clinical lead or IMAC on 0800 IMMUNE [0800 466 863]. 8 am – 8pm 7 days a week**



### Gaining informed consent

- Confirm person has received adequate information about the vaccine, including the benefits, the common side effects and the rare but serious adverse events, including anaphylaxis and myocarditis. Offer them opportunity for questions and remind them of the need to wait 15 min.
- **Consent from Parent or legal guardian is required for children under 12 years. It is acceptable to gain verbal consent from parent and guardian via phone if child attends with a different family member.**
- Those aged 12-15 years would usually attend with parent. If they attend on their own and assessed as competent by an appropriately trained health professional, they can self-consent. Record any discussion regarding competency, higher risk of anaphylaxis or other significant issues.
- For further information on informed consent, including information around those who do not have the capacity to consent, refer to the Immunisation Handbook (section 2.1.2). Also see [Informed Consent for Young People Aged 12-15 Years Policy Statement](https://www.tinyurl.com/zkhrhvf3) ([tinyurl.com/zkhrhvf3](https://www.tinyurl.com/zkhrhvf3)).

### Preparation of vaccines

- Staff preparing and administering vaccines should have completed the online COVID-19 education course. Additional online education is required for vaccine for 5-11 year olds.
- Ensure Paediatric vaccine and 12+ vaccines are only prepared in separated dedicated spaces. It is essential that every dose of vaccine is clearly labeled and that the vaccine preparation guidance is followed including record keeping. For more detailed instructions please see IMAC adult and paediatric multi-dose vial preparation and administration guidance documents.
- DO NOT interrupt the vaccine preparation process

### Third doses of mRNA-CV

Third primary vaccine dose is recommended for those who are severely immunocompromised aged 12 and over. Administer from 8 weeks after 2nd dose. For details of who is eligible see the Immunisation Handbook.

A third primary vaccines may also be required, following clinical advice, in situations where an invalid dose of vaccine has been administered.

Third primary doses are off label so will require a prescription and a written consent form.

### Booster dose

Booster doses are approved from 18 years; given 4 months from 2nd dose. The vaccine used is mRNA-CV (30 mcg), the same vaccine as for their previous doses. Boosters are not currently approved for anyone under 18.

### Pregnancy vaccines

mRNA-CV vaccine (30mcg) is recommended at all stages of pregnancy. Booster doses can be given from 4 months after the second dose of the primary course. Booster doses are particularly recommended for individuals most at high risk of exposure to SARS-CoV-2 or with significant medical issues that increase their risk for severe COVID-19.

### Paediatric vaccine spacing

The recommended spacing is 8 weeks for 2nd dose for 5-11 year olds of mRNA-CV (10mcg) for an optimal immune response. This can be reduced to 21 days in situations where an earlier interval is important for quicker protection, eg, significant medical issues such as immunosuppression.

### Post Vaccination advice to be given by Vaccinator

It is important that every consumer is given clear post vaccination advice **verbally and in writing**. This advice is needed for each dose of vaccine and for all ages and must include the following information:

- Discussion of potential minor side effects as well as the rare but serious ones. The advice should include expected side effect and how to manage them with the use of paracetamol or other analgesia for pain, or discomfort, and if unwell rest, drinking fluids and avoid vigorous activities, such as going to the gym.
- Awareness that anaphylaxis, although very unlikely, could occur within a few hours of vaccination and should they have any breathing difficulties, they should dial 111.
- Cardiac problems are extremely rare but can be serious, so ensure they understand the importance of seeking medical advice early for any out of character symptoms such as: Chest pain, heavy feeling in chest, discomfort, sensation of heart fluttering, racing or skipping beats, difficulty breathing, dizziness and fainting. These symptoms should not be ignored. It is important that they seek advice from a doctor or Healthline.
- For those who are insulin dependent diabetics, discuss the need to closely monitor blood sugars for next few days, as high or low sugars can. occasionally be a side effect of the vaccine.
- Supply information on how and when to make a second appointment.

### Incident management

- It is the site clinical and quality lead's responsibility to record, report and investigate vaccine administration incidents.
- IMAC will continue to offer support and guidance in the event of such incidents.
- **Please contact 0800 IMMUNE (466 863) or your IMAC Regional Immunisation Advisor.**

**CALL 0800 IMMUNE (466 863) FOR CLINICAL ADVICE, 8AM - 8PM, 7 DAYS PER WEEK**