The Immunisation Advisory Centre

COVID-19 EDUCATION

mRNA COVID-19 vaccine Pfizer/BioNTech [mRNA-CV]

Screening and guidance form

Pre vaccination screening, guidance for regulated vaccinators

SCREENING QUESTIONS	RATIONALE FOR QUESTIONS AND ADVICE ON ACTIONS REQUIRED
Please tell me your full name and date of birth.	To check you have the correct patient records on the CIR. **Check '12 years or older'**. If any doubt, ask them their age. See back page re consent for those under 16.
Are you 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. 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 vaccines observation and hydration.
Have you had a serious allergic reaction to anything including previous Pfizer vaccine?	**Contraindications: A history of anaphylaxis to previous dose of the mRNA-CV vaccine or to any component of the vaccine.** **Precaution: Anaphylaxis to reagent polyethylene glycol (PEG)** (under specialist guidance). **A definite history of anaphylaxis-type reaction to any other product.** 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. **All vaccination sites are set up to manage anaphylaxis for those with precautions.** **Those who have been diagnosed with myocarditis following first COVID-19 vaccine dose** should have had cardiac review and guidance from IMAC on future doses of vaccine.
Is this your first COVID-19 vaccination?	Check spacing between vaccines: **at least 6 weeks between doses is now recommended.** For those who need urgent protection, in particular border and MiQ workers and those soon to be immunosuppressed, 21 days is minimum allowed spacing. Day 0 is the vaccination day. Vaccination at less than 21 days is off-label use (ie unapproved by Medsafe). No Max spacing.
Do you have a bleeding problem or blood disorders?	Vaccines can be administered to people on anticoagulants. **For patients with haemophilia**, receiving clotting factor replacement or similar, vaccinations should be given as soon as possible after receiving the medicine. It is recommended that the platelet count is kept ≥30x109/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.	Immunosuppression: 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. Cardiac patients with heart disease or cardiac abnormalities should be vaccinated. If patients have had bilateral lymph clearance, vaccine can be given in the vastus Lateralis, seek help from experienced vaccinator or 0800 if unsure. **Other concerns, if you are unsure how to respond, call IMAC for support.**
Other vaccines within last 2 weeks	It is safe to vaccinate people who have had vaccines in the last 14 days. Spacing when planning vaccinations is still recommended. However, if they are at the vaccination centre please vaccinate.

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

IMAC09/2021

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Gaining informed consent

1. Confirm person has received accurate information about the vaccine, both benefits and risks, knowledge of side effects, post vaccine 15 min wait, and has had an opportunity for questions.
2. Those aged 12-15 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.
3. 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). See new online learning for supported decision making; further training on confirming competency for those under 16 is due soon.

Preparation of vaccines *includes new guidance on dilution of vials*

- Minimum of two appropriately trained people need to be involved in this process, independently checking: diluent; volumes of diluent drawn up; vaccine appearance [before and after dilution]; and volume, appearance of each dose of vaccine, number of doses per vial and expiry date and time. This information should be recorded and saved.
- Diluent should be used immediately as it is preservative free.
- Syringes and needles should not be prepared in advance and packets should be opened by unpeeling, not pressing the needle or syringe out through packaging.
- It is expected that you may obtain 6 or 7 doses per vial with LDS needles, 5 or 6 with non-LDS. Draw up all doses from a vial at once so you can check you have expected number of doses.
- **Do not interrupt the vaccine preparation process until all vaccine is in the syringes and appropriately labelled. Never dilute a vial that has already had the top removed by someone else. To prevent errors, discard vaccine and start preparing with a sealed vial. Finish this process before handover to the next shift.**
- Once the vial has been drawn up it must be defaced and **immediately removed** from the vaccine preparation area.
- Reconciliation needs to be documented and to occur regularly. Vials should be numbered when taken out of the fridge and listed on a vaccine dilution/ temp monitoring/ reconciliation record.
- Syringes should be given to the vaccinator with a sticker/ label stating vaccine and diluent batch numbers and expiry date (date from vaccine box, not from vial), the time of expiry (6 hours post dilution), and initials of who drew up and who checked.
- For more detailed instructions please see related document: *Instructions for multi-dose vial Pfizer/BioNTech vaccine: preparation and administration*.

Post vaccination advice must include:

- Reminder of need to stay for at least 15 minutes for observation.
  - Anyone with a history of anaphylaxis to any product, will still need close observation, a 30-minute wait and given clear post vaccination advice.
- Discussion of possible expected side effects and advise use of paracetamol or other analgesia for pain, fever, or discomfort and how and where to seek help including Healthline and use of GP, 111.
- Seek medical advice for any unexpected concerns including chest pain, shortness of breath, or palpitations.
- 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.

Reminder

- It is important that the name of the person administering the vaccine is logged in the CIR.
- If you do need to record an AEFI in CIR for CARM please include patient's GP contact phone number.
- Expiry date record in CIR is the sub-batch number from the box NOT the vial.

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

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