

mRNA COVID-19 vaccine Pfizer/BioNTech [mRNA-CV]
Screening and guidance form for health professional use

COVID-19 Vaccinator guidelines

Preparation of vaccines

It is best practice for vaccinators to prepare their own vaccines for administration. However, for COVID-19 vaccination clinics it may be more practical for another appropriately skilled person to prepare vaccine doses. If this occurs, we recommend:

- Recording details of the person preparing the vaccines.
- Each group of vaccines is given to each vaccinator with a sticker stating vaccine batch number and date and time of dilution. **This is the information that you will need to enter onto the CIR.**
- A second checker is recommended to oversee vaccine preparation.

Gaining informed consent

Most people attending for vaccination will already have received an information letter, may also have watched the general information video and may have seen **The Immunisation Event Form** information on possible side effects.

1. Confirm what information they have had about the vaccine, both benefits and risks.
2. Check if they need any further information or have any questions.

Refer 'COVID-19 vaccines: frequently asked questions' available at <https://www.immune.org.nz/>

3. Complete pre-vaccination screening as below.
4. Confirm if informed consent is given and record this either directly into the CIR or tick on the immunisation event form

For further information on informed consent, including information around those who lack capacity, see the *Immunisation Handbook 2020* [section 2.1.2].

The immunisation consent form alone does not indicate informed consent. It is important the steps listed above are also taken and that any extra patient-specific guidance given is recorded. A written consent form is not essential if all steps have been undertaken.

Pre vaccination screening, guidance for vaccinators

SCREENING QUESTIONS	RATIONALE
Are you currently unwell?	Postpone vaccination when: <ul style="list-style-type: none"> • fever >38°C • acute systemic illness
Have you had a serious allergic reaction to anything including previous mRNA-CV vaccine? Note: Those without any history of anaphylaxis, now only need to wait for 20 minutes.	Contraindications: A history of anaphylaxis to previous dose of the mRNA-CV vaccine or to any component. Precaution: A history of anaphylaxis-type reaction to any other product. A slightly increased risk of an anaphylactic response has been noted with the mRNA-CV in an individual who has had a previous anaphylaxis-type reaction, most commonly to a medication. This risk needs to be discussed and balanced against the risk of SARS-CoV-2 exposure and severe COVID-19. These individuals can still receive mRNA-CV and should be well observed for 30 minutes and be given clear post vaccination advice on symptoms to be alert to and how to call for help, prior to leaving. It is important that the observation staff are specifically alerted to this history by the person giving the vaccine. The 20 minute wait can be extended at vaccinators discretion.
Have you had a previous COVID-19 vaccine?	Check days since previous dose to ensure a minimum of 21 days between doses. Check for previous severe reactions.

SCREENING QUESTIONS	RATIONALE
<p>Have you had any other vaccinations in past four weeks?</p> <p>Note: updated guidance for clinicians. Where planning non urgent vaccinations we still recommend spacing vaccines.</p>	<p>The guidance re 2 weeks between COVID and other vaccines and 4 weeks post live vaccines is precautionary, due to no current data on the effectiveness of vaccines given concomitantly with mRNA vaccines and to ensure it is easier to establish if a side effect is related to a specific vaccine. There is not expected to be any significant safety or immune response concern if vaccines are given closer than these intervals, so if it is not feasible to separate out vaccines it is more important not to miss out on giving vaccines for disease protection.</p>
<p>Are you pregnant or trying to get pregnant, or breastfeeding?</p>	<p>COVID-19 infection during pregnancy can increase the risk of severe disease and adverse fetal outcomes. See the IMAC factsheet on COVID vaccines and pregnancy for more information.</p> <p>Pregnancy is a precaution for use of mRNA-CV. Based on how mRNA vaccines work, they are not expected to pose a specific risk if given in pregnancy. To date, clinical studies have not investigated this vaccine in pregnancy, however accumulating international post-licensure data shows no safety concerns to date.</p> <ul style="list-style-type: none"> • It is recommended to delay vaccination until after birth if at low risk of exposure, but for those at high risk of exposure to COVID-19, mRNA-CV can be offered with informed consent. • Routine testing for pregnancy before COVID-19 vaccination is not recommended. • Women who are trying to become pregnant do not need to avoid pregnancy after receiving mRNA-CV. • While breastfeeding women were not included in phase III studies, as with all Schedule vaccines there are no safety concerns about giving mRNA-CV to breast feeding women.
<p>Do you have a bleeding problems or blood disorders?</p>	<ul style="list-style-type: none"> • Vaccines can be administered to people on anticoagulants, aspirin, dabigatran (Pradaxa), enoxaparin (Clexane), heparin, ticagrelor (Brilinta) Rivaroxaban and warfarin. <ul style="list-style-type: none"> - After vaccination, apply firm pressure over the injection site without rubbing for 10 minutes to reduce the risk of bruising. • For patients with haemophilia receiving clotting factor replacement or a similar therapy, vaccinations should be given as soon as possible after receiving the medicine. Specialist advice is recommended. Apply pressure after vaccines as mentioned above.
<p>Not a specific question, but those being vaccinated may seek reassurance about immunosuppression due to disease or treatment.</p> <p>Note: No longer a need to ask about Checkpoint inhibitors although consent forms will still mention this initially.</p>	<p>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. Vaccinees may have been given advice by specialist or GP re optimal timing for vaccinations, where practical please accommodate these requests when making appointments.</p> <p>The decision on the management of Checkpoint inhibitors has been reviewed. It is no longer necessary to ask patients to seek Specialist advice.</p> <p>Patients on nivolumab (Opdivo), pembrolizumab (Keytruda), atezolizumab (Tecentriq) or ipilimumab (Yervoy) can receive this vaccine.</p> <p>There will be a delay in updating the consent form to reflect this change.</p>

Post vaccination advice must include a reminder:

- to stay for at least 20 minutes for observation.
 - Anyone with higher risk of anaphylaxis needs close observation and clear post vaccination advice.
- of possible side effects and the option to use paracetamol or other analgesia for pain or discomfort.
- the second appointment, and no other non-urgent vaccines to be received until after second dose.
- of how to ask for further advice or call for help, 111 and Healthline.
- recommending a wait of 2 weeks after second dose before having any non-urgent vaccines.

If you do need to record an AEFI in CIR for CARM: Please include details of patient's GP and contact number for patient, for any follow up that may be needed.

CALL 0800 IMMUNE (466 863) FOR ANY CLINICAL ADVICE