

COVID-19 Vaccinator guidelines: mRNA COVID-19 vaccine Pfizer/BioNTech [mRNA-CV]

Preparation of vaccines

It is best practice for vaccinators to prepare their own vaccines for administration. In the setting of 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 and that each group of vaccines is given to each vaccinator with a sticker stating vaccine batch number and date and time of dilution. 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 will have seen **The Immunisation Event Form** information on possible side effects.

- Confirm what information they have had about the vaccine, both benefits and risks.
- Check if they need any further information or have any questions. See 'COVID-19 vaccines: frequently asked questions' available at <https://www.immune.org.nz/covid-19-vaccines>
- Complete screening as below
- 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 record.

Pre vaccination screening, guidance for Vaccinators:

Screening questions	Rationale
Are you currently unwell?	Postpone vaccine when: <ul style="list-style-type: none"> • fever >38°C • acute systemic illness
Have you had a serious allergic reaction (to anything)? Including previous Pfizer/BioNTech mRNA COVID-19 vaccine (Comirnaty)	<p>Contraindications: A history of anaphylaxis to previous dose of the mRNA-CV vaccine or to <u>any component</u> including, polysorbate or polyethylene glycol (PEG)</p> <p>Precaution: A definite history of immediate allergic reaction to any other product. A slightly increased risk of a severe allergic response has been noted with the Pfizer 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.</p> <p>These individuals can still receive mRNA-CV and should be observed for 30 minutes as normal. It is important that the observation staff are specifically alerted the to this history by the person giving the vaccine.</p>
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.

<p>Have you had any other vaccinations in past four weeks?</p>	<p>2-week gap recommended between mRNA-CV and influenza vaccines. 4-week gap recommended between mRNA-CV and any other vaccines. Defer vaccination if necessary, or take further clinical advice</p>
<p>Are you are currently receiving the cancer drugs Keytruda, Opdivo, Yervoy, or Tecentriq or have done so in the past six months?</p>	<p>Specialist advice should be sought before administering any vaccinations to individuals who are currently being treated with nivolumab (Opdivo), pembrolizumab (Keytruda), atezolizimab (Tecentriq) or ipilimumab (Yervoy), or if these drugs have been given or discontinued in the past six months. These are prescribed by a cancer specialist (oncologist) See the Immunisation Handbook 2020 [section 4.3.2]</p>
<p>Are you pregnant or trying to get pregnant, or breastfeeding?</p>	<p><i>An increased risk of severe COVID-19 disease in pregnancy and adverse fetal outcomes have been documented.²⁶ See the IMAC factsheet on COVID vaccines and pregnancy for more information.</i></p> <p>Pregnancy is a precaution for mRNA-CV. Based on how mRNA vaccines work, they are unlikely to pose a specific risk when given in pregnancy. To date, clinical studies have not investigated this vaccine in pregnancy.</p> <ul style="list-style-type: none"> • It is recommended to delay vaccination until after delivery 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, dabigatran (Pradaxa), enoxaparin (Clexane), heparin, ticagrelor (Brilinta) 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
<p>Not a specific question, but those being vaccinated may seek reassurance about immunosuppression due to disease or treatment [other than drugs mentioned above]</p>	<p>The antibody response to the vaccine may be reduced and protection may be suboptimal but, it is likely to be adequate to protect against severe disease and there are no safety concerns</p>

Post vaccination advice to include:

- Reminder to stay for 30 minutes for observation.
- Reminder re possible side effects and option to use paracetamol for pain or discomfort.
- Reminder re second appointment, and no other vaccines to be received until after second dose.
- How to ask for further advice or call for help, 111 and helpline.
- After second dose wait at least 2 weeks before flu vaccine and 4 weeks before other vaccines.