<table>
<thead>
<tr>
<th>Date of revision</th>
<th>24/11/2022</th>
</tr>
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<tr>
<td><strong>Update</strong></td>
<td>Changes to contraindications and precautions for mRNA vaccines (p.39)</td>
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<td>Changes to precautions of sub-unit vaccines Nuvaxovid® (p.41)</td>
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<td>Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience. (p.53)</td>
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This guidance is intended for vaccinators administering COVID-19 vaccines. Vaccinators should be trained and competent in immunisation practice.

Vaccinators should have undergone training in the administration of COVID-19 vaccine(s), recognition and management of anaphylaxis, and basic life support and intramuscular injection technique. They should also be familiar with the anaphylaxis protocol outlined in the Immunisation Guidelines for Ireland (see useful links section).

In some circumstances, advice in these guidelines may differ from that in the Summary of Product Characteristics (SmPC) of the vaccines. When this occurs, the recommendations in these guidelines, which are based on current expert advice from the National Immunisation Advisory Committee should be followed.

1. Introduction

The objective of the vaccination programme for SARS CoV-2 is to ensure equitable access to a safe and effective vaccine with the goals of limiting mortality and morbidity from COVID-19, protecting healthcare capacity and enabling social and economic activity.

Purpose of the document

This document has been prepared as a means of providing clinical guidance to all clinicians implementing the COVID-19 vaccination programme.

Indemnity for vaccinators

Claims management in relation to claims and litigation initiated in connection with COVID-19 vaccination is to be delegated to the State Claims Agency by means of Government Order.

Registered medical practitioners (including GPs), nurses, pharmacists, physiotherapists, dentists, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the Health Service Executive (HSE) will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. Vaccinators working in GP surgeries and retail pharmacies however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.
2. Vaccine recommendations

Recommendations for primary and booster vaccination are summarized in the table below.

Table 1: NIAC recommendations for COVID-19 vaccines by age and immune status July 2022

<table>
<thead>
<tr>
<th>Group</th>
<th>Primary course*</th>
<th>Additional dose</th>
<th>1st booster</th>
<th>2nd booster</th>
<th>3rd booster</th>
</tr>
</thead>
<tbody>
<tr>
<td>65 years and older</td>
<td>√√</td>
<td></td>
<td>√</td>
<td>√</td>
<td>√</td>
</tr>
<tr>
<td>50-64 years</td>
<td>√√</td>
<td></td>
<td>√</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>12-49 years</td>
<td><strong>Underlying medical conditions</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Residents of long term care facilities</td>
<td>√√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Healthcare workers</td>
<td>√√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Others</td>
<td>√√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td>√√</td>
<td></td>
<td>√</td>
<td></td>
<td><strong>√</strong></td>
</tr>
<tr>
<td>5-11 years</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12 years and older</td>
<td><strong>Immunocompromise associated with a sub optimal response to vaccines</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5-11 years</td>
<td>√√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*two dose primary course (one dose if COVID-19 vaccine Janssen)
**at 16 weeks gestation or later if not already boosted in this pregnancy

Medical conditions at very high risk and high-risk of severe COVID-19 disease

Conditions at high risk or very high risk of severe COVID-19 disease are detailed in the table on page 10.

Those with conditions in the blue shaded areas are immunocompromising conditions that may be associated with a suboptimal response to vaccines. People with these conditions at the time of vaccination require an additional dose of vaccine for their primary vaccination course (see Section 7.8) as well as a number of booster vaccine doses as outlined in Table 1.
<table>
<thead>
<tr>
<th>Medical condition</th>
<th>Very high risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</td>
<td>Receiving or within 6 weeks of receiving systemic cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies</td>
<td>Receiving treatment or pending treatment for a haematological cancer</td>
</tr>
<tr>
<td></td>
<td>Undergoing or within 6 weeks of surgery or radical radiotherapy for lung or head and neck cancer</td>
<td>Advanced/metastatic cancer</td>
</tr>
<tr>
<td></td>
<td>Advanced/metastatic cancer</td>
<td>All other cancers being treated (excluding hormonal treatment)</td>
</tr>
<tr>
<td>Chronic heart (and vascular) disease</td>
<td>e.g. heart failure, hypertensive cardiac disease</td>
<td></td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>On dialysis, or eGFR &lt;15 ml/min</td>
<td>With eGFR &lt;30 ml/min</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>e.g. cirrhosis or fibrosis</td>
<td></td>
</tr>
<tr>
<td>Chronic neurological disease</td>
<td>With evolving ventilatory failure (requiring non-invasive ventilation) e.g. motor neuron disease, spinal muscular atrophy</td>
<td>Significantly compromising respiratory function and/or the ability to clear secretions e.g. Parkinson’s disease, cerebral palsy</td>
</tr>
<tr>
<td>Chronic respiratory disease</td>
<td>Severe e.g. severe cystic fibrosis, severe COPD, severe pulmonary fibrosis</td>
<td>Other e.g. stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD</td>
</tr>
<tr>
<td>Diabetes</td>
<td>HbA1c ≥58 mmol/mol</td>
<td>All other diabetes (Type 1 and 2)</td>
</tr>
<tr>
<td>Immunocompromise due to disease or treatment</td>
<td>Severe e.g. Transplantation:</td>
<td>Other e.g.</td>
</tr>
<tr>
<td></td>
<td>- Listed for solid organ or haematopoietic stem cell transplant (HSCT)</td>
<td>High dose systemic steroids³</td>
</tr>
<tr>
<td></td>
<td>- Post solid organ transplant at any time</td>
<td>HIV, not on treatment or CD4 count &lt;200 x10⁹L for adults</td>
</tr>
<tr>
<td></td>
<td>- Post HSCT within 12 months</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Genetic diseases:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- APECED²</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Inborn errors in the interferon pathway</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Treatment:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- included but not limited to Cyclophosphamid, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months</td>
<td></td>
</tr>
<tr>
<td>Inherited metabolic diseases³</td>
<td>Disorders of intermediary metabolism/at risk of acute decompensation e.g. Maple Syrup Urine Disease</td>
<td>Disorders of intermediary metabolism not fulfilling criteria for very high risk</td>
</tr>
<tr>
<td>Intellectual disability³</td>
<td>Down syndrome</td>
<td>Intellectual disability excluding Down syndrome</td>
</tr>
<tr>
<td>Obesity</td>
<td>BMI &gt;40 kg/m²</td>
<td>BMI &gt;35 kg/m²</td>
</tr>
<tr>
<td>Severe mental illness³</td>
<td>e.g. Schizophrenia, bipolar disorder, severe depression</td>
<td></td>
</tr>
<tr>
<td>Sickle cell disease</td>
<td>Sickle cell disease</td>
<td></td>
</tr>
</tbody>
</table>

1. Includes e.g., leukaemia, lymphomas, blood dyscrasias or other malignant neoplasms affecting the bone marrow or lymphatic systems
2. APECED - autoimmune polyendocrinopathy candidiasis ecto-dermal dystrophy
3. The following doses of prednisolone (or equivalent dose of other glucocorticoid) are likely to be immunosuppressive:
   - Adults and children 10kg: >40mg/day for more than 1 week, or ≥20mg/day for 2 weeks or longer
   - Children <10 kg: 2mg/kg/day for 2 weeks or longer
### 3. COVID-19 Vaccines

Table 2 shows the vaccines that are recommended by the National Immunisation Advisory (NIAC) following approval by the European Medicines Agency (EMA) that are used in the COVID-19 immunisation program in Ireland.

#### Table 2: vaccines used in the COVID-19 immunisation program

<table>
<thead>
<tr>
<th>mRNA VACCINES</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty® 30mcg</td>
<td>Pfizer/BioNTech</td>
<td>Vaccination of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Comirnaty Ready to Use 30mcg</td>
<td>Pfizer/BioNTech</td>
<td>Vaccination of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Comirnaty® 10mcg</td>
<td>Pfizer/BioNTech</td>
<td>Vaccination of children aged 5-11 years</td>
</tr>
<tr>
<td>Spikevax®</td>
<td>Moderna</td>
<td>Vaccination of individuals aged 30 years and older</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADAPTED mRNA VACCINES</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty® Original/Omicron BA.1</td>
<td>Pfizer/BioNTech</td>
<td>Booster vaccination only of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Comirnaty® Original/Omicron BA.4</td>
<td>Pfizer/BioNTech</td>
<td>Booster vaccination only of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Spikevax® Original/Omicron BA.1</td>
<td>Moderna</td>
<td>Booster vaccination only individuals aged 30 years and older</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROTEIN SUB-UNIT VACCINES</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nuvaxovid®</td>
<td>Novavax</td>
<td>Vaccination of individuals aged 12 years and older who cannot receive an mRNA vaccine (because of a contraindication or clinical precaution) or have chosen not to receive an mRNA vaccine</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>VIRAL VECTOR VACCINES</th>
<th>Manufacturer</th>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>JCovden®</td>
<td>Janssen</td>
<td>Vaccination of individuals aged 18 years and older who cannot receive an mRNA vaccine or Nuvaxovid® (because of a contraindication or clinical precaution)</td>
</tr>
</tbody>
</table>

Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PIL) for the public), is available via the EMA website [www.ema.europa.eu](http://www.ema.europa.eu).

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1 Approved by European Medicines Agency from age 12
4. Infection Prevention and Control for the administration of COVID-19 Vaccines

Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:

- Before vaccine preparation
- Before drawing up and administering the vaccine
- Before and after each recipient contact

Check Health Protection Surveillance Centre (HPSC) website for latest guidance on infection prevention and control for healthcare workers: [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/)

Personal Protective Equipment (PPE) should be worn as per Antimicrobial Resistance in Intensive Care (AMRIC)/HPSC guidance for healthcare staff.

It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for ≥30 seconds, to ensure the alcohol has evaporated.

There is no need to routinely check temperature either at registration or before vaccination. Follow HPSC standard precautions (sharps management, healthcare waste management etc.) [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/)
5. Vaccine details, storage and instructions for preparation and administration

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer.

SmPCs usually state: "The vaccine should be inspected visually for particulate matter and discolouration prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed." When a vaccinator is concerned regarding a vial the following steps should be followed:

- The vaccinator should contact another healthcare professional (HCP) who has experience in using this product and ask for a second opinion
- The affected vial should be returned to the fridge and kept there in Quarantine (between +2°C and +8°C)
- The vial in quarantine should be placed in a clearly marked area in the fridge "Quarantine - do not use"
- The vaccinator and senior experienced HCP should check the other vials in this batch in their fridge by removing one vial at a time and ensuring that the duration out of the fridge is kept to a minimum
- If more vials are considered defective, they should calculate the impact of placing vials into quarantine and arrange for additional deliveries if required.
- The Health Products Regulatory Authority (HPRA), manufacturer and HSE National Immunisation Office (NIO) should be emailed with details of the issue and with a photograph of vial identifying the defect (if possible).
- The NIO will follow up and contact other locations where this batch has been delivered if necessary.

Please ensure vaccines are stored between +2°C and +8°C.

Should vaccines be exposed to temperatures outside of these parameters please contact the NIO immediately.

Contacts for NIO Pharmacist includes: Cliona Kiersey: mobile 087 9915452
Achal Gupta: mobile 087 4064810 Email the immunisation inbox

Pre-drawn syringes of COVID-19 vaccines from multi-dose vials that are prepared within designated vaccine preparation areas may be available within the HSE centralised vaccination clinics (CVCs). National clinical guidance specific to CVC settings on this matter should be adhered to.
6. mRNA COVID-19 Vaccines
Comirnaty® 30 micrograms (Pfizer BioNTech) for those aged 12 years and older

mRNA vaccines are fragile vaccines. Correct storage is essential to ensure the stability of the vaccine. Store vials upright. DO NOT store on their side.

Table 3: Details of Comirnaty® (Pfizer BioNTech) for those aged 12 years and older

<table>
<thead>
<tr>
<th>Indication</th>
<th>Vaccination of individuals aged 12 years and older.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
</tbody>
</table>
| Constituents | Polyethylene glycol/macrogol (PEG) as part of ALC-0159.  
ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl) bis (2-hexyldecanoate),  
ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide  
1,2-Distearoyl-sn-glycero-3-phosphocholine  
Cholesterol  
Potassium chloride  
Potassium dihydrogen phosphate  
Sodium chloride  
Disodium hydrogen phosphate dihydrate  
Sucrose  
Water for injections |
| Presentation | Concentrated solution of vaccine is contained in a multidose clear glass vial. |
| Number of doses in each vial | Post dilution 6 doses.  
If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose.  
No more than 7 valid doses are available. |
| Dilution | Yes with 1.8 mls of 0.9% Sodium Chloride (supplied separately) |
| Latex | The vial stopper does not contain latex. |
| Dosage | 0.3ml (30 mcg) |
| Number of doses and recommended interval for primary vaccination | 2 doses intramuscularly. Recommended interval between doses is 21 to 28 days |
| Interval between doses | |

2 Comirnaty may be used for booster vaccination, however adapted mRNA vaccines (Comirnaty BA.1 and Comirnaty BA.4-5 are preferred)
Comirnaty® (Pfizer BioNTech) storage

The vaccine is delivered from the manufacturer to the HSE National Cold Chain Service (NCCS) at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ultra-cold temperature (ULT) freezer at -90°C to -60°C.

The vaccine is supplied by the HSE NCCS to sites/clinics at +2 to +8°C.

The shelf life is written on the box supplied by the National NCCS. This is the “USE BEFORE” date. The “USE BEFORE” date must be adhered to and not the expiry date as the expiry date refers to vaccines stored at -90°C to -60°C.

Table 4: Definitions of terms for expiry date and usage times of Comirnaty® (Pfizer BioNTech)

<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry date</td>
<td>The date the vaccine expires when stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. Do not record the expiry date in the person’s record.</td>
</tr>
<tr>
<td>“Use before” date and time Maximum time from removal from the ULT freezer to expiry, when stored at +2°C to +8°C</td>
<td>USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the Use before date and time. Record the USE BEFORE date in the person’s record.</td>
</tr>
<tr>
<td>Maximum time allowed from removal from storage at +2°C to+8°C fridge to Dilution</td>
<td>Once the vaccine is removed from the fridge it must be diluted within 2 hours. It must be discarded, if not diluted within 2 hours.</td>
</tr>
<tr>
<td>“Discard” date and time Maximum time allowed from dilution to expiry</td>
<td>When the vaccine is diluted it must be used within 6 hours. The “discard” date and time i.e. 6 hours after dilution must be written on the vial using a 24-hour format. e.g. Vial is diluted 01/01/2022 at 10.00. Discard time is 01/01/2022 at 16.00. This is the date and time that should be written on the vial. Any unused or partially unused diluted vials must be discarded when this time has been reached.</td>
</tr>
<tr>
<td>Transportation time</td>
<td>Undiluted vial: Within the USE BEFORE shelf life at 2°C to 8°C, up to 48 hours may be used for transportation. The total transportation time from NCCS to the delivery location is written on the box. Diluted vial: maximum of 6 hours from the time of dilution (this is in addition to the maximum transportation time of 48 hours for the undiluted vial). Please note that all doses of the vaccine must be given within 6 hours of dilution.</td>
</tr>
</tbody>
</table>

For General Practice (GP) and Pharmacies, please return any unused and unusable vials to the NCCS for destruction. Please give these to the NCCS van driver at your next vaccine delivery. See http://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/gpvaccretreturn.pdf
Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PIL) for the public), is available via the EMA website www.ema.europa.eu

Primary Vaccination Course for those aged 12 years and older: Comirnaty® (Pfizer BioNTech): dosage, scheduling and site of vaccination

Two doses of 0.3mls Comirnaty® administered intramuscularly with an interval of 21 days between doses (the NIAC recommends an interval of 21 to 28 days). The day the first dose is given is day 0.

Dilution of Comirnaty® (Pfizer BioNTech) for those aged 12 years and older

Requirements for diluting the vaccine

- One Comirnaty® (Pfizer BioNTech) multidose vial
- One 10ml ampoule of Sodium Chloride 0.9% solution for injection (Stored at room temperature/should not be kept in a fridge)
- Two 70% alcohol swabs
- One 21 gauge green needle
- A 2.5ml, 3ml or 5ml syringe

STEP 1. PREPARING FOR DILUTION

- Check the “use before” date and time on the box containing the vials with a colleague
- Remove the vial from the box in the fridge/cool box
- Gently invert vial 10 times prior to dilution. Do not shake
- Inspect the liquid in the vial prior to dilution
- Should be an off-white solution. It may contain white to off-white amorphous particles.
- Remove cap
- Clean with 70% alcohol swab and allow it to air dry fully
**STEP 2. DILUTION**

- Twist to separate one ampoule of sodium chloride from other ampoules if attached
- Check product and expiry date with colleague
- Clean with a 70% alcohol swab
- Open the ampoule by twisting the cap using standard aseptic technique
- Connect syringe tightly to sodium chloride ampoule
- Withdraw 1.8ml of Sodium Chloride 0.9% Solution for Injection
- Cross check correct amount withdrawn with colleague
- Discard the ampoule and any remaining diluent in it into waste bin
- Using a 21 gauge green needle attached to the syringe,
  - Insert diluent slowly into the vaccine vial. You may feel some pressure in the vial as you add the diluent.
  - Do not remove the needle from the vial. Keeping the needle above the level of the liquid, slowly withdraw 1.8 ml of air into the empty diluent syringe to equalise the pressure.
  - Remove needle and syringe from vial.
  - Dispose of the needle and syringe in a sharps bin.
  - Gently invert the diluted solution 10 times. Do not shake.
  - Diluted vaccine should be an off-white solution with no visible particles. Discard if particles present.
  - Discard the diluted vaccine if particulates or discolouration are present

**STEP 3. LABELLING THE VIAL**

- Label the diluted vial with the date and “discard time” (6 hours after time of dilution) using a 24-hour format.
- Do not use the diluted vaccine after this date and time.
- e.g. vial diluted at 10.00 01/01/2021. Discard time is 16.00 01/01/2021
- After dilution, the vial contains 6 doses* of 0.3 ml
- Diluted vaccines can be stored at room temperature between +2°C and +30°C but must be used within 6 hours following dilution.
- Bring the vial to your vaccination table/site for vaccine preparation and administration

*If a seventh 0.3ml dose can be safely and accurately withdrawn from a diluted vial, then it can be used as valid doses
If it is not possible to withdraw more than six 0.3mls doses from the vial, the remaining vaccine solution should be discarded.

**There should be no pooling of vaccine solution from different vials.**

**Administration of Comirnaty® (Pfizer BioNTech)**

- Vaccine dose preparation and administration should be carried out at the point of administration i.e. within the clinic area.
- All six doses should be drawn up from the vial and a seventh if possible.
- The vial should be inspected for any remaining solution.
- Each syringe should be re-checked if the remaining volume in the vial appears to be more than 0.15ml.
- The same needle and syringe should be used to draw up and administer the vaccine.
- Each dose should be drawn up and immediately administered to the patient.
- Vials should not routinely be diluted in advance as per best practice and the manufacturer’s instructions that diluted vials should be used immediately.
- There should be no pooling of vaccine solution from different vials.

**Requirements for administration of up to 7 doses of vaccine**

- One diluted Comirnaty® (Pfizer BioNTech) multidose vial (up to 7 doses)
- x 70% alcohol swabs
- x 23 gauge blue needles

One Comirnaty® vial (0.45 mL) contains up to 7 doses of 0.3 mL after dilution with NaCl (1.8 ml).

Sites must ensure that proper procedures are in place before administration so that a maximum of 7 doses are obtainable from a vial.

Should 8 doses be obtained from a vial the following steps should be considered:

- Identify stage of the process where the error happened e.g. dilution, dose draw up
- Add extra in-process and finished product checking steps
- Retrain personnel involved
- Audit the process regularly

Should 8 doses be administered, in addition to the above steps, the following steps should also be considered:

- Discuss the incident at management level-this is a clinical decision and must be taken locally
- Consider the need for open disclosure
Coring issues with Comirnaty® reconstitution

A number of complaints have been submitted to Pfizer regarding the presence of rubber stopper particles inside the solution. Investigation of the complaint samples at the Pfizer manufacturing site has established that the following factors can cause rubber particles to be removed from the stopper:

- When the needle is not inserted in the centre ring of the top plug;
- When the end of the needle scrapes rubber off the inner wall of the small channel of the stopper due to non-vertical insertion of the needle;
- When the needle is rotated or twisted during piercing of the stopper, resulting in a particle cored out of the stopper. This damage is enlarged when a wider bore needle is used.

The needle used for reconstitution should be 21G or narrower.

The presence of rubber stopper particles inside the solution may be due to incorrect technique used during product administration.

**STEP 1. Preparation and administration of one dose of vaccine**

Check the date and "discard time" has not expired (dilution was within last 6 hours).

Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully Attach 23 gauge blue needle to 1ml syringe Withdraw 0.3ml of diluted product

Make sure correct dose is drawn up as smaller dose may not provide protection

Ensure all air bubbles have been removed before the needle is withdrawn

Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated
Administer vaccine to patient intramuscularly (See Appendix A) Dispose of used needle and syringe in a sharps bin

---

When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn
### Comirnaty 30 micrograms ready to use dispersion for injection

#### Table 5: Details of Comirnaty® ready to use dispersion for those aged 12 years and older

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Name of vaccine and description</td>
<td>Comirnaty® 30 micrograms ready to use dispersion for injection</td>
</tr>
<tr>
<td>Indication</td>
<td>Vaccination of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Constituents</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- ((4-hydroxybutyl)azanediy)bis(hexane-6,1-diyl)bis(2- hexyldecanoate) (ALC-0315)</td>
</tr>
<tr>
<td></td>
<td>- 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)</td>
</tr>
<tr>
<td></td>
<td>- 1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)</td>
</tr>
<tr>
<td></td>
<td>- Cholesterol</td>
</tr>
<tr>
<td></td>
<td>- Trometamol</td>
</tr>
<tr>
<td></td>
<td>- Trometamol hydrochloride</td>
</tr>
<tr>
<td></td>
<td>- Sucrose</td>
</tr>
<tr>
<td></td>
<td>- Water for injections</td>
</tr>
<tr>
<td>Presentation</td>
<td>The vaccine is contained in a multi-dose clear glass vial.</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>6 doses. If a seventh dose of 0.3ml can be safely and accurately withdrawn from a vial, it is a valid dose. No more than 7 valid doses are available.</td>
</tr>
<tr>
<td>Dilution</td>
<td>DO NOT DILUTE</td>
</tr>
<tr>
<td>Latex</td>
<td>The vial stopper does not contain latex.</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.3ml (30 mcg)</td>
</tr>
<tr>
<td>Number of doses required and interval between doses for primary vaccination</td>
<td>2 doses intramuscularly. The recommended interval between doses is 21 to 28 days</td>
</tr>
<tr>
<td>Expiry date</td>
<td>The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.</td>
</tr>
<tr>
<td>“Use before” date and time Maximum time from removal from ULT freezer to expiry, when stored at +2°C to +8°C</td>
<td>USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the Use before date and time. The use before date must be recorded in the person’s record</td>
</tr>
</tbody>
</table>

---

4 Comirnaty ready to use may be used for booster vaccination, however adapted mRNA vaccines (Comirnaty BA.1 and Comirnaty BA.4-5) are preferred if available especially for those at highest risk
<table>
<thead>
<tr>
<th><strong>“Discard” date and time Maximum time allowed from first puncture of vial to expiry</strong></th>
<th>After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) Discard any unused vaccine. e.g. Vial is punctured at 10.00. Discard time is at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transportation time</strong></td>
<td><strong>Unpunctured vial</strong> No limit within the use before date and time, when stored at +2 to +8 °C  <strong>Punctured vial</strong> Up to 6 hours transportation time within the 12 hour discard date and time when stored at +2 °C to +30 °C.</td>
</tr>
</tbody>
</table>

**VIAL VERIFICATION OF COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**

- “Use before” date and time on the vaccine box
- Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty 30 micrograms/dose dispersion for injection.
- Gently mix by inverting vials 10 times prior to use. Do not shake.
- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles.
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present.

**REPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY 30 MICROGRAMS/DOSE DISPERSION FOR INJECTION (12 YEARS AND OLDER)**

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of Comirnaty. Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial.
- If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.
- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial.
- Discard any unused vaccine 12 hours after first puncture.
Table 6: Interval between 2 doses for primary vaccination with Comirnaty® or Comirnaty ready to use formulation for those aged 12 years and older

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd Doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 17 days</td>
<td>This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.</td>
</tr>
<tr>
<td>17 to 21 days</td>
<td>No further action needed (Evidence from trial data is that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 21 days</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>
Spikevax® (COVID-19 Vaccine Moderna)

mRNA vaccines are fragile vaccines. Correct storage is essential to ensure the stability of the vaccine. Store vials upright in their original carton in a fridge at temperature between +2°C and +8°C. DO NOT store on their side.

Table 7: Details of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Indication</td>
<td>Vaccination of individuals aged 30 years and older⁵</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Spikevax® (COVID-19 Vaccine Moderna)</td>
</tr>
<tr>
<td>Constituents</td>
<td>Lipid SM-102 Cholesterol 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)</td>
</tr>
<tr>
<td></td>
<td>1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG)</td>
</tr>
<tr>
<td></td>
<td>Tromethamol Hydrochloride Acetic acid</td>
</tr>
<tr>
<td></td>
<td>Sodium acetate trihydrate Sucrose</td>
</tr>
<tr>
<td></td>
<td>Water for injections</td>
</tr>
<tr>
<td>Presentation</td>
<td>The vaccine is contained in a multidose clear glass vial.</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 10 doses⁶</td>
</tr>
<tr>
<td></td>
<td>If more than 10 (0.5 ml) doses can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vaccine vials As per SmPC the bung must not be punctured more than 20 times.</td>
</tr>
<tr>
<td>Dilution</td>
<td>NOT REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>No. The vial has a synthetic rubber stopper (chlorobutyl rubber) – the vial stopper does not contain latex</td>
</tr>
<tr>
<td>Preservatives</td>
<td>No</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.5ml (PLEASE NOTE THAT IF ADMINISTERING A BOOSTER DOSE, THE DOSE IS 0.25ml⁷⁸)</td>
</tr>
<tr>
<td>Number of doses required and interval between doses for primary vaccination</td>
<td>2 doses intramuscularly. 28 days is the recommended interval between doses 21 days is the minimum interval</td>
</tr>
</tbody>
</table>

⁵ Approved by the EMA from age 12
⁶ Spikevax may be used for booster vaccination at a dose volume of 0.25mls, however adapted Spikevax (Spikevax BA.1) is preferred if available.
Spikevax® (COVID-19 Vaccine Moderna) storage

mRNA vaccines are fragile vaccines. Correct storage is essential to ensure the stability of the vaccine.

Store vials upright. DO NOT store on their side.

The vaccine is transported to vaccination sites/clinics at temperature between +2°C and +8°C. The vaccine is delivered in its thawed state and the USE BEFORE date and time will be printed on the label that has been affixed to the box by the NCCS.

The unopened vial may be stored between +8°C and +25°C up to 24 hours within the USE BEFORE date & time.

Never refreeze thawed vaccine.

DISCARD date and time

Once a vial is punctured to draw up the first dose, a “DISCARD” date and time must be written on the vial. The maximum time after which the vial should be discarded is 19 hours. The “DISCARD” date and time is calculated by adding 19 hours to the time the vial is first punctured. The “DISCARD” date and time must be written on the vial using a 24 hour format e.g. vial is first punctured 29/06/2021 at 11.00. Discard date and time is 30/06/2021 at 06.00.

Table 8: Storage of unopened vials of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator</td>
<td>Between +2°C and +8°C</td>
<td>“use before” date as labelled by NCCS</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +8°C and +25°C</td>
<td>Up to 24 hours</td>
</tr>
</tbody>
</table>

Table 9: Storage of opened (needle punctured) vials of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator or Room Temperature</td>
<td>Between +2°C and +25°C</td>
<td>Up to 19 hours (until discard date and time)</td>
</tr>
</tbody>
</table>
### Table 10: Definitions of terms for expiry date and usage times of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expiry date</strong></td>
<td>The date the vaccine expires when continuously stored frozen at temperatures between -25°C and -15°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.</td>
</tr>
<tr>
<td><strong>Maximum shelf-life when vaccine is thawed</strong></td>
<td>At vaccination sites/clinics the vaccine is stored at a temperature between +2°C and +8°C. The “USE BEFORE” date and time is on the label affixed to the box by NCCS, and is dependent on the vaccine being stored between +2°C and +8°C. The vials must be returned to the NCCS for destruction if they remain unopened when the “USE BEFORE” date and time has been reached.</td>
</tr>
<tr>
<td><strong>“Discard” date and time</strong></td>
<td>After the initial puncture the vial must be used within 19 hours (within the allowed use period of 30 days at +2°C to +8°C and 24 hours at +8°C to +25°C). The “discard” date and time i.e. 19 hours after the initial puncture must be written on the vial using a 24 hour format. e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00 Any doses remaining in the vials must be discarded when this time has been reached, by discarding the vial into a sharps bin.</td>
</tr>
</tbody>
</table>

For GPs and Pharmacies, please return any unopened and unusable vials to the NCCS for destruction. Please give damaged or unusable vaccines to the NCCS van-driver at your next vaccine delivery.


Further regulatory information on COVID-19 vaccines can be found in the approved product information (SmPC) for health care professionals, and Package Leaflet (PL) for the public, is available via the EMA website [https://www.ema.europa.eu/en](https://www.ema.europa.eu/en).
Spikevax® (COVID-19 Vaccine Moderna) dosage, scheduling for the primary vaccination course

In general, a vaccine course started with Spikevax® should be completed with this product. When possible the same vaccine should be used for both doses, unless contraindicated.

Two doses of 0.5mLs of Spikevax® COVID-19 Vaccine Moderna are required with an interval of 28 days between doses. The minimum interval between the first and second dose is 21 days. The day the 1st dose is given is day 0.

Note that Spikevax® is not recommended in people aged <30 years.

The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.

Table 11: Interval between 2 doses for the Primary Vaccination Course

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd Doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 21 days</td>
<td>This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.</td>
</tr>
<tr>
<td>21-27 days</td>
<td>No further action needed (Evidence from trial data that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 28 days</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

---

7 Please refer to section 8 for details of booster doses
8 The 4 day rule does not apply to the 21 days
Preparation of Spikevax® (COVID-19 Vaccine Moderna)

Vials that have not been punctured may be kept at room temperature between +8°C and +25°C for up to 24 hours.

NEVER refreeze thawed vaccine

**STEP 1. PREPARING THE VACCINE**

- Check the “USE BEFORE” date and time on the box containing the vials with a colleague
- Allow vaccine stored at +2°C to +8°C to come to room temperature for 15 minutes
- DO NOT DILUTE THE VIAL
- DO NOT SHAKE THE VIAL
- Gently swirl the vaccine once thawed and before withdrawing subsequent doses.

**STEP 2. LABELLING THE VIAL**

- Label the vial with the “discard” time which is 19 hours after initial puncture using a 24 hour format. Store the vial at temperature between +2°C and +25°C.
- Bring the vial to the vaccination table

**Spikevax® (COVID-19 Vaccine Moderna) dose preparation and administration**

- Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person to be vaccinated
- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not routinely be drawn up in advance as per best practice and the manufacturer's instructions
- Each dose should be drawn up and immediately administered to the patient
- There should be no pooling of vaccine from different vials
- Pierce the stopper preferably at a different site each time.
- Do not puncture the vial more than 20 times
Requirements for administration of vaccine

- One Spikevax® (COVID-19 Vaccine Moderna) multidose vial
- 10 x 70% alcohol swabs
- 10 x 23 gauge blue needles
- 10 x 1ml syringe

### STEP 1. Preparation and administration of one dose of vaccine

**Unpunctured vials**: Check the USE BEFORE date and **NEVER** administer the vaccine after the USE BEFORE date and time

**Punctured vials**: Check the DISCARD time. Never administer the vaccine after the discard time. With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer.

Examine the vaccine. It should be white to off-white in colour and may contain white or translucent coloured particulates. Do not use if discoloured or contains other particulate matter.

Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully. Attach 23 gauge blue needle to 1ml syringe

Withdraw 0.5ml of vaccine\(^9\)

**PLEASE NOTE FOR A BOOSTER DOSE, THE VOLUME REQUIRED IS 0.25mls\(^{10}\)**

Make sure correct dose is drawn up as a smaller dose may not provide protection. Ensure all air bubbles have been removed before the needle is withdrawn.

Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated.

Administer vaccine to the patient intramuscularly (see Appendix A). Dispose of used needle and syringe in a sharps bin.

**Note: Gently swirl the vaccine before withdrawing each dose of vaccine**

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\(^9\) When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn.

\(^{10}\) Spikevax BA.1 should preferentially be used as a booster dose.
7. Protein Sub-Unit Vaccines: Nuvaxovid® (Novavax)

This vaccine is currently used only in people aged 12 years and older who cannot receive a COVID-19 vaccine because of a contraindication or a precaution, or in people who have declined another COVID-19 vaccine.

Table 12: Details of Nuvaxovid® for the primary vaccination course

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Protein sub-unit vaccine</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Nuvaxovid®</td>
</tr>
<tr>
<td>Constituents</td>
<td>One dose (0.5 ml) contains 5 micrograms of the of SARS-CoV-2 spike protein* and is adjuvanted with Matrix-M.</td>
</tr>
<tr>
<td></td>
<td>- Disodium hydrogen phosphate heptahydrate</td>
</tr>
<tr>
<td></td>
<td>- Sodium dihydrogen phosphate monohydrate</td>
</tr>
<tr>
<td></td>
<td>- Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>- Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>- Sodium hydroxide (for adjustment of pH)</td>
</tr>
<tr>
<td></td>
<td>- Hydrochloric acid (for adjustment of pH)</td>
</tr>
<tr>
<td></td>
<td>- Water for injections</td>
</tr>
<tr>
<td>Adjuvant (Matrix-M)</td>
<td>Adjuvant Matrix-M containing per 0.5 ml dose: Fraction-A (42.5 micrograms) and Fraction-C (7.5 micrograms) of Quillaja saponaria Molina extract.</td>
</tr>
<tr>
<td></td>
<td>- Cholesterol</td>
</tr>
<tr>
<td></td>
<td>- Phosphatidylcholine (including all-rac-α-Tocopherol)</td>
</tr>
<tr>
<td></td>
<td>- Potassium dihydrogen phosphate</td>
</tr>
<tr>
<td></td>
<td>- Potassium chloride</td>
</tr>
<tr>
<td></td>
<td>- Disodium hydrogen phosphate dihydrate</td>
</tr>
<tr>
<td></td>
<td>- Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>- Water for injections</td>
</tr>
<tr>
<td>Presentation</td>
<td>Multidose clear glass vial</td>
</tr>
<tr>
<td></td>
<td>The dispersion is colourless to slightly yellow, clear to mildly opalescent</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 10 doses</td>
</tr>
<tr>
<td></td>
<td>If more than 10 doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials</td>
</tr>
<tr>
<td>Dilution</td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>No, the vaccine is latex free</td>
</tr>
<tr>
<td></td>
<td>Each vial has a stopper (bromobutyl rubber) and an aluminium overseal with blue plastic flip-off cap</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.5 mls</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>2</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>21 days</td>
</tr>
</tbody>
</table>

* produced by recombinant DNA technology using a baculovirus expression system in an insect cell line that is derived from Sf9 cells of the Spodoptera frugiperda species.
Evidence shows that protection starts from approximately 7 days after the second vaccine.

**Nuvaxovid® storage**

The vaccine will be delivered by the NCCS at +2°C to +8°C.

**Unopened (unpunctured) multidose vial** should be stored in a pharmaceutical grade refrigerator (+2°C to +8°C) until expiry. Vials must be stored upright in outer carton in order to protect from light. Unopened Nuvaxovid® vaccine has been shown to be stable up to 12 hours at +25°C.

**Opened multi-dose vial**

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than 6 hours at +2°C to +25°C. The “discard” date and time i.e. 6 hours after the vial is first punctured must be written on the vial using a 24 hour format.

**Table 13: Definitions of terms for expiry date and usage times of Nuvaxovid® (Novavax)**

<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry date</td>
<td>This is date after which the vial must not be punctured. It is printed on the vaccine vial and original box</td>
</tr>
<tr>
<td>“Discard” date and time</td>
<td>When the vaccine is first punctured it must be used within 6 hours The “discard” date and time i.e. 6 hours from first puncture of the vial, should be written on the vial using a 24 hour format. E.g. Vial is first punctured on 20/02/2022 at 10.00. Discard date and time is 20/02/2022 at16.00. This is the date and time that should be written on the vial</td>
</tr>
<tr>
<td>Maximum time allowed from first puncture to vaccine administration</td>
<td>Any unused or partially used vials must be discarded when this time has been reached</td>
</tr>
</tbody>
</table>

**Preparation and administration of Nuvaxovid®**

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person being vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not be drawn up in advance as per the manufacturer’s instructions
- Each dose should be drawn up and immediately administered to the patient
- There should be no pooling of vaccine from different vials
Requirements for administration of vaccine

- One Nuvaxovid® multidose vial
- 70% alcohol swabs
- 23 gauge blue needles or 25 gauge orange needles
- 10 x 1ml syringes

Preparation and administration of one dose of vaccine

Preparation for use:

- The vaccine comes ready to use.
- Unopened vaccine should be stored at +2°C to +8°C and kept within the outer carton to protect from light.
- Immediately prior to use, remove the vaccine vial from the carton in the refrigerator.
- Record the date and time of discard on the vial label. Use within 6 hours after first puncture.

Inspect the vial:

- Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.
- Each multidose vial contains a colourless to slightly yellow, clear to mildly opalescent dispersion free from visible particles.
- Visually inspect the contents of the vial for visible particulate matter and/or discolouration prior to administration.
- Do not administer the vaccine if either is present.

Administer the vaccine:

- Each 0.5 mL dose is withdrawn into a sterile needle and sterile syringe to be administered by intramuscular injection, preferably in the deltoid muscle of the upper arm.
- Do not mix the vaccine in the same syringe with any other vaccines or medicinal products.
- Do not pool excess vaccine from multiple vials.

Storage after first needle puncture:

- Nuvaxovid does not contain a preservative.

Store the opened vial between +2°C to +25°C for up to 6 hours after first puncture

Discard:

- Discard this vaccine if not used within 6 hours after first puncture of the vial
- Any unused medicinal product or waste material should be disposed of

Email immunisation@hse.ie if you require a session report form/vial traceability form
Nuvaxovid® (Novavax) dosage, scheduling and site of vaccination

Two doses of 0.5mls should be administered intramuscularly with an interval of 21 days between doses. The preferred site of administration is the deltoid muscle. The day the first dose is given is day 0.

The minimum interval between the first and second dose is 17 days. The minimum interval should only be used in exceptional circumstances (e.g. commencing chemotherapy).

A vaccine course started with Nuvaxovid should, if possible be completed with this product.

Table 14: Interval between 2 doses

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd Doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 17 days</td>
<td>This is not considered a valid vaccine. Revaccination is not recommended at this time as there is no evidence as to the safety and efficacy of an additional dose in these circumstances</td>
</tr>
<tr>
<td>17 to 21 days</td>
<td>No further action needed This is a valid vaccine.</td>
</tr>
<tr>
<td>Longer than 21 days</td>
<td>Give the second dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>
8. **Viral Vector Vaccines: Jcovden®**

This vaccine is currently used only in people aged 18 years and older who cannot receive an mRNA vaccine or Nuvaxovid® because of a contraindication or a special precaution.

**Table 15: Details of Jcovden (COVID-19 Vaccine Janssen®) for the primary vaccination course**

<table>
<thead>
<tr>
<th>Title</th>
<th>Jcovden</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of vaccine</strong></td>
<td>Adenovirus vector vaccine*</td>
</tr>
<tr>
<td><strong>Name of vaccine</strong></td>
<td>Jcovden Ad26.COV2.S</td>
</tr>
<tr>
<td><strong>Constituents</strong></td>
<td>One dose (0.5 ml) contains: recombinant, replication-incompetent adenovirus type 26 expressing the SARS-CoV-2 spike protein, citric acid monohydrate, trisodium citrate dehydrate ethanol, 2-hydroxypropyl-β-cyclodextrin (HBCD), polysorbate 80, sodium chloride, sodium hydroxide, hydrochloric acid</td>
</tr>
<tr>
<td><strong>Presentation</strong></td>
<td>Multidose clear glass vial</td>
</tr>
<tr>
<td></td>
<td>The vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection</td>
</tr>
<tr>
<td><strong>Number of doses in each vial</strong></td>
<td>Up to 5 doses</td>
</tr>
<tr>
<td></td>
<td>If more than 5 doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials</td>
</tr>
<tr>
<td><strong>Dilution</strong></td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td><strong>Latex</strong></td>
<td>No, the vaccine is latex free</td>
</tr>
<tr>
<td><strong>Dosage</strong></td>
<td>0.5 mls</td>
</tr>
<tr>
<td><strong>Number of doses required for primary vaccination</strong></td>
<td>1. Single dose schedule</td>
</tr>
</tbody>
</table>

Evidence shows that protection starts from approximately 14 days after the vaccine.

**Jcovden® storage**

The vaccine will be delivered by the NCCS at +2°C to +8°C.

**Unopened (unpunctured) multidose vial** should be stored in a pharmaceutical grade refrigerator (+2°C to +8°C) until the Use Before Date.
Vials must be stored in outer carton in order to protect from light. Vials may be stored between 9°C to 25°C for up to 12 hours.

**Opened multidose vial**

After first opening, chemical and physical in-use stability has been demonstrated from the time of vial puncture to administration for no more than **3 hours at room temperature**. The “discard” date and time i.e. 3 hours after the vial is first punctured must be written on the vial using a 24 hour format. E.g. vial is first punctured 20/01/2021 at 10:00. Discard date and time is 20/01/2021 at 13:00.

<table>
<thead>
<tr>
<th>Table 16: Definitions of terms for expiry date and usage times of Jcovden®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use before date</strong></td>
</tr>
<tr>
<td><strong>“Discard” date and time Maximum time allowed from first puncture to expiry</strong></td>
</tr>
</tbody>
</table>

**Jcovden dosage, scheduling and site of vaccination for the primary vaccination course**

A single dose of vaccine is 0.5 ml. The vaccine is a single dose schedule.

**Preparation and administration of Jcovden®**

Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person being vaccinated.

- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not be drawn up in advance as per the manufacturer’s instructions
- Each dose should be drawn up and immediately administered to the patient.
- There should be no pooling of vaccine from different vials.

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¹¹ The SmPC states that after the first puncture of the vial, the vaccine can be held at +2°C to +8°C for up to 6 hours. However, the stability data for opened vials in a refrigerator at (+2°C to +8°C) applies ONLY if the vial remains at this temperature throughout i.e. is punctured and doses withdrawn while in a walk-in refrigerator

**BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 3 HOURS OF FIRST PUNCTURE**
Requirements for administration of vaccine

- One Jcovden multidose vial (up to 6 doses)
- x 70% alcohol swabs
- x 23 gauge blue needles or 25 gauge orange needles
- 6 x 1ml syringes

**STEP 1. Preparation and administration of one dose**

**Check the box**
Check the “use before” date on the box containing the vials with a colleague

**Punctured vials**: Check the discard time. Never use vaccine after the discard time. With the vial upright, gently swirl the vaccine for 10 seconds. Do NOT shake.

**Examine the vaccine.**
It should be a colorless to slightly yellow, clear to very opalescent.
The vaccine should be inspected visually prior to administration. Discard the vial if the suspension is discoloured or visible particles are observed.

**Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully**

**Attach 23 gauge blue or 25 gauge orange needle to a 1ml syringe**
Withdraw 0.5ml of vaccine
Make sure the correct dose is drawn up as a smaller dose may not provide protection Ensure all air bubbles have been removed before the needle is withdrawn.

**Withdraw the needle from the vial.**
Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated.

**Administer vaccine to the patient intramuscularly (see Appendix A) Dispose of used needle and syringe in a sharps bin**

**Repeat for each dose**

Email immunisation@hse.ie if you require a session report form/vial traceability form.

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12 When vaccination is carried out in settings where this is practicable and feasible, best practice is for the volume of each dose to be checked by a colleague to ensure the correct volume has been withdrawn
9. Adapted Booster COVID-19 mRNA Vaccines

The following vaccines are recommended for Booster vaccination. Please refer to Section 8 for further details:

- Comirnaty® BA.1
- Comirnaty® BA.4-5
- Spikevax® BA.1

### Comirnaty® BA.1 and Comirnaty® BA.4-5

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Name of vaccines and</td>
<td>• Comirnaty® Original/Omicron BA.1</td>
</tr>
<tr>
<td>description</td>
<td>• Comirnaty Original/Omicron BA.4-5</td>
</tr>
<tr>
<td>Indication</td>
<td>Booster vaccination of individuals aged 12 years and older</td>
</tr>
<tr>
<td>Constituents</td>
<td>• (4-hydroxybutyl)azanediyl)bis(hexane-6,1-diylibis(2-hexyldecanoate) (ALC-0315)</td>
</tr>
<tr>
<td></td>
<td>• 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide (ALC-0159)</td>
</tr>
<tr>
<td></td>
<td>• 1,2-Distearyl-sn-glycero-3-phosphocholine (DSPC) Cholesterol</td>
</tr>
<tr>
<td></td>
<td>• Trometamol</td>
</tr>
<tr>
<td></td>
<td>• Trometamol hydrochloride</td>
</tr>
<tr>
<td></td>
<td>• Sucrose</td>
</tr>
<tr>
<td></td>
<td>• Water for injections</td>
</tr>
<tr>
<td>Presentation</td>
<td>The vaccines are contained in a multi-dose clear glass vial.</td>
</tr>
<tr>
<td>Number of doses in each</td>
<td>6 doses.</td>
</tr>
<tr>
<td>vial</td>
<td>If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose. No more than 7 valid doses are available.</td>
</tr>
<tr>
<td>Dilution</td>
<td>DO NOT DILUTE</td>
</tr>
<tr>
<td>Latex</td>
<td>The vial stopper does not contain latex.</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.3ml (30 mcg) intramuscularly</td>
</tr>
</tbody>
</table>

#### VIAL VERIFICATION OF COMIRNATY® BA.1 OR COMIRNATY® BA.4-5

- Check “Use before” date and time on the vaccine box
- Verify that the vial has a grey plastic cap and a grey border around the label and the product name is Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for Injection or Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for Injection
**Gently mix by inverting vials 10 times prior to use. Do not shake**

- Prior to mixing, the thawed dispersion may contain white to off-white opaque amorphous particles
- After mixing, the vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the vaccine if particulates or discolouration are present

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**REPARATION OF INDIVIDUAL 0.3 mL DOSES OF COMIRNATY® BA.1 or COMIRNATY® BA 4-5**

- Using aseptic technique, cleanse the vial stopper with a single-use antiseptic swab.
- Withdraw 0.3 mL of vaccine.

Low dead-volume syringes and/or needles should be used in order to extract 6 doses from a single vial. If standard syringes and needles are used, there may not be sufficient volume to extract a sixth dose from a single vial.

- Each dose must contain 0.3 mL of vaccine.
- If the amount of vaccine remaining in the vial cannot provide a full dose of 0.3 mL, discard the vial and any excess volume.
- Record the appropriate date/time on the vial. Discard any unused vaccine 12 hours after first puncture.
<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expiry date</strong></td>
<td>The date the vaccine expires when continuously stored in an ULT freezer at -90°C to -60°C. The batch number on the side of each vial is recorded in the patient record. This is linked to the expiry date.</td>
</tr>
<tr>
<td><strong>“Use before” date and time Maximum time from removal from ultra-low temperature (ULT) freezer to expiry, when stored at +2°C to +8°C</strong></td>
<td>USE BEFORE date and time. This time and date will be labelled on the box by NCCS. The vials must be used before the use before date and time. The use before date must be recorded in the person’s record.</td>
</tr>
<tr>
<td><strong>“Discard” date and time Maximum time allowed from first puncture of vial to expiry</strong></td>
<td>After first puncture, the vaccine must be used within 12 hours (when stored at +2 °C to +30 °C) e.g. Vial is punctured 01/01/2022 at 10.00. Discard time is 01/01/2022 at 22.00. This is the date and time that should be written on the vial. Any unused or partially unused vials must be discarded when this time has been reached.</td>
</tr>
<tr>
<td></td>
<td>From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user</td>
</tr>
<tr>
<td><strong>Transportation time</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Unpunctured vial.</strong></td>
<td>No limit within the use before date and time, when stored at +2 to +8 °C</td>
</tr>
<tr>
<td><strong>Punctured vial</strong></td>
<td>Up to 6 hours transportation time within the 12 hour discard date and time when stored at +2 °C to +30 °C.</td>
</tr>
</tbody>
</table>
### Spikevax® BA.1

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturing process</td>
<td>mRNA</td>
</tr>
<tr>
<td>Indication</td>
<td>Booster vaccination of individuals aged 30 years and older&lt;sup&gt;13&lt;/sup&gt;</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Spikevax® Original/Omicron BA.1</td>
</tr>
</tbody>
</table>
| Constituents            | SM-102 (heptadecan-9-yl 8-[(2-hydroxyethyl)[6-oxo-6-(undecyloxy)hexyl]amino]octanoate)  
                          | Cholesterol 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC)               
                          | 1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000-DMG)  
                          | Trometamol                                                               
                          | Trometamol                                                               
                          | hydrochloride Acetic acid                                                
                          | Sodium acetate                                                           
                          | trihydrate Sucrose                                                       
                          | Water for injection                                                      |
| Presentation            | The vaccine is contained in a multidose clear glass vial.                   |
| Number of doses in each vial | Up to 5 doses  
                          | If more than 5 (0.5 ml) doses can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vaccine vials |
| Dilution                | NOT REQUIRED                                                               |
| Latex                   | No. The vial has a synthetic rubber stopper (chlorobutyl rubber) – the vial stopper does not contain latex. |
| Preservatives           | No                                                                          |
| Dosage                  | **0.5ml**                                                                   |

<sup>13</sup> Approved by the EMA from age 12
### Shelf life and transportation

<table>
<thead>
<tr>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expiration date</strong></td>
</tr>
<tr>
<td><strong>“Use before” date and time</strong></td>
</tr>
<tr>
<td><strong>“Discard” date and time</strong></td>
</tr>
<tr>
<td><strong>Transportation time</strong></td>
</tr>
</tbody>
</table>

### Preparation and administration of one dose of Spikevax BA.1

**Unpunctured vials:** Check the USE BEFORE date and Never administer the vaccine after the USE BEFORE date and time.

**Punctured vials:** Check the DISCARD time. Never administer the vaccine after the discard time. With the vial upright, gently swirl the vaccine. **Do NOT shake.** If the vial is shaken, contact the manufacturer. Examine the vaccine. It should be white to off-white in colour and may contain white or translucent coloured particulates. Do not use if discoloured or contains other particulate matter. Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully. Attach 23 gauge blue needle to 1ml syringe. Withdraw 0.5ml of vaccine. Make sure correct dose is drawn up as a smaller dose may not provide protection. Ensure all air bubbles have been removed before the needle is withdrawn. Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated. Administer vaccine to the patient intramuscularly (see Appendix A). Dispose of used needle and syringe in a sharps bin. **Note:** Gently swirl the vaccine before withdrawing each dose of vaccine.

Comirnaty® 30mcg, Comirnaty® Ready to Use 30mcg and Spikevax® may also be used for booster vaccination if adapted booster vaccines are unavailable. Please refer to relevant sections for details.

**Note that the booster dose volume for Spikevax® is 0.25mls**
10. Contraindications and precautions to COVID-19 vaccines

mRNA Vaccines

Contraindications to mRNA vaccines

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG).
- Comirnaty RTU, Comirnaty BA.1, Comirnaty BA.4-5, Spikevax and Spikevax BA.1 contain *Trometamol
- Anaphylaxis following another mRNA vaccine.

Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine.

Consideration may be given to a non-mRNA vaccine. Nuvaxovid® may be considered for anyone 12 and older including pregnant women. This should be given after an interval of at least 28 days after the first COVID-19 vaccine. In individuals who cannot receive an mRNA vaccine or Nuvaxovid® because of a contraindication or special precaution, COVID-19 vaccine Jcovden® (Janssen)® is licensed from the age of 18 years and may be considered.

Precautions:

- Acute severe febrile illness; defer until recovery. Routine physical examination and temperature measurement of persons who appear to be healthy are not necessary prior to vaccination.
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine - seek specialist advice before vaccination.
- There should be an interval of four weeks between monkeypox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.
- Individuals aged <30 years should receive Comirnaty®
- Consider a non-mRNA vaccine (Nuvaxovid)® for those aged 12 years and older, including pregnant women, with:
  - Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy)
  - Anaphylaxis after a vaccine, or a medicine which contained PEG
  - Unexplained anaphylaxis (may indicate PEG allergy)

*Trometamol has been implicated in one report of contrast medium anaphylaxis relating to gadolinium-based contrast agents (GBCAs) used in MRI radiological studies.

Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the individual’s risk and provide advice based on the person’s immune response and likely immune response to vaccination.
Viral vector vaccines Jcovden® (Janssen)

Contraindications to Jcovden® (Janssen) (See Table 18)

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80).
- Anaphylaxis following another viral vector vaccine.
- Thrombosis with Thrombocytopenia Syndrome (TTS) after the first dose of another viral vector COVID-19 vaccine
- Previous history of capillary leak syndrome.

Precautions to Jcovden® (Janssen) (See Table 18)

- Acute severe febrile illness; defer until recovery.

- Advice from a relevant specialist should be sought for a person with a history of an immediate severe allergic reaction to:
  - multiple drug classes with no identified allergen
  - any other vaccine, injected antibody preparation or medicine likely to contain polysorbate 80
  - unexplained anaphylaxis (may indicate polysorbate 80 allergy)
  - age < 50 years

If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as Immune thrombocytopenia (ITP) as a very rare side effect to Jcovden® (Janssen) should be considered before vaccination. Therefore platelet monitoring is recommended after Jcovden® (Janssen) vaccination in an individual who has a past history of ITP.

Please refer to the NIAC guidelines Table 5a.5 for details of contraindications and precautions to an adenoviral vector COVID-19 vaccine
Protein sub-unit vaccines Nuvaxovid®

Contraindications
Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents including polysorbate 80. 

Precautions
Acute severe febrile illness; defer until recovery.

Previous history of myocarditis or pericarditis after any COVID-19 vaccine, seek specialist advice.

There should be an interval of four weeks between monkeypox/smallpox vaccine and a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.

Advice from a relevant specialist should be sought for a person with:
- a history of an immediate severe allergic reaction to multiple drug classes with no identified allergen,
- any other vaccine injected antibody preparation or medicine likely to contain polysorbate 80 or
- idiopathic anaphylaxis

The risks should be weighed against the benefits of vaccination. Please refer to the NIAC Immunisation Guidelines for details.

Vaccination after COVID-19 (primary vaccination course)
Those who are unvaccinated and develop laboratory confirmed COVID-19 infection/antigen positive infection with symptoms, should complete a primary vaccination course. The first dose should be given at least four weeks after diagnosis or onset of symptoms.

Those who are partially vaccinated and develop laboratory confirmed COVID-19 infection/antigen positive infection with symptoms, should complete their primary vaccination course. Their next dose should be given at least four weeks after diagnosis or onset of symptoms.

Vaccination is not contraindicated for people with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration.
11. **Clinical considerations for COVID-19 vaccines**

**Pregnancy**

Pregnant women should be offered mRNA COVID-19 vaccines (Comirnaty® (Pfizer BioNTech) or COVID-19 Vaccine Moderna®) at any stage of pregnancy this includes the additional mRNA vaccine dose recommended for immunocompromised individuals and the 1st booster dose. For details of timing of a second booster dose please read below.

Pregnant women are at similar risk of COVID-19 infection to non-pregnant women of the same age.

However, if pregnant women become infected with SARS-COV2 they are at increased risk of hospitalisation, premature delivery if symptomatic in the third trimester and of stillbirth, and at significantly higher risk of ICU admission.

There is now a growing body of evidence on the safety and effectiveness of mRNA COVID-19 vaccination - clearly indicating that that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Long term follow-up is on-going. Please note that women aged less than 30 years should receive Comirnaty®, rather than Spikevax ® as a second, booster or additional dose.

Vaccination is the best way to protect both mother and baby from serious harm and mRNA vaccines should be available to pregnant women at all stages of pregnancy. Emerging data indicates that the maternal COVID-19 antibodies can cross the placenta, which may offer neonatal protection.

NIAC and the Institute of Obstetricians and Gynaecologists have developed materials to support healthcare workers and pregnant women in decision making about COVID-19 vaccination. Visit www.rcpi.ie

Please refer to Section 13.0 for details of booster vaccinations.

**Vaccination in pregnancy with Nuvaxovid®**

There is limited experience with use of the vaccine in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, delivery or post-natal development.

Administration may be considered when the benefits outweigh the potential risks to the mother or the fetus and when mRNA vaccines are contraindicated or declined. The pregnant women and a relevant health professional should engage in shared decision-making in advance of vaccination. Counselling should balance the available data on vaccine safety, risks to pregnant women from COVID-19 infection, and a woman’s individual risk for infection and severe disease. The two doses should be given 21 days apart at any stage in pregnancy.
Breastfeeding
There is no known reason to avoid breastfeeding.
All COVID-19 vaccines can be given to women who are breastfeeding.

Fertility
There is no evidence that any COVID-19 vaccine affects fertility or the fetus. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy. There is no biologically plausible reason why any of the COVID-19 vaccines would have any effect of fertility. There is no evidence that any of the COVID-19 vaccines have any effect on fertility.

Individuals with a bleeding disorder
Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the recipient about this risk.

For those with thrombocytoopenia (platelet count <50 x 10^3/ml) consult the supervising consultant.

People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at http://www.stjames.ie/services/hope/nationalcoagulationcentre

Those with inherited coagulopathies receiving factor replacement therapy should receive the treatment on the day of vaccination, prior to the IM vaccination.

If there is uncertainty about the need for cover, contact the patient’s Comprehensive Care Centre.

If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as Immune Thrombocytopenia (ITP) should be considered before vaccination with virus vector Jcovden® (Janssen), and platelet monitoring is recommended after vaccination with in an individual who has a history of ITP.
Individuals taking anticoagulants

Those receiving long term anticoagulation with either warfarin or heparin are not considered to be at higher risk of bleeding complications following immunisation. There is no reason to expect that there is a greater risk of bleeding complications with the newer types of anticoagulants, such as antiplatelet agents, than with other anticoagulants.

People on Warfarin® should follow their usual schedule for international normalised ratio (INR) testing and can be vaccinated if it is less than 4.0. If the INR is 4.0 or more, follow the advice of the clinic/practice managing Warfarin® and wait until the INR is less than 4.0 to be vaccinated.

Technique for IM injections in persons with bleeding disorders or on anticoagulants

- Use a 23 or 25 gauge needle to reduce the pressure gradient and cause less trauma to the tissue.
- The vaccine should be injected slowly (≥ 5 seconds) to reduce the risk of tissue damage.
- Firm pressure should be applied to the site for 5 to 10 minutes after injection.
- Stabilisation of the limb will reduce the risk of a haematoma.
- The site should not be rubbed or massaged.
- Instruct the patient/caregiver to monitor the injected limb and to report any concerns to their supervising consultant.

Co-administration of COVID-19 vaccines with other inactivated or live vaccines for those aged over 12 years:

Other vaccines including influenza vaccines may be administered with COVID-19 vaccines at the same time or at any interval before or after a COVID-19 vaccine. This applies to all COVID-19 vaccines including mRNA vaccines, Nuvaxovid® and JCovden® and adapted COVID-19 vaccines. If other vaccines are being given at the same time as COVID-19 vaccines, it is preferable to give them in separate limbs.

The only exception to this is if someone has received a monkeypox/smallpox vaccine. In this case there should be a 4 week interval before a subsequent COVID-19 vaccine because of the unknown risk of myocarditis.
Immunosuppression due to disease or treatment

Individuals with immunosuppression due to disease or treatment should be vaccinated if they have no contraindications.

Patients with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used.

Specialists should consider the individual’s risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of the patient’s immune status and likely immune response to vaccination.

Extended primary course for those with immunosuppression due to disease or treatment: mRNA vaccines

Data indicates that those with severe immunocompromise at the time of primary vaccination do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional mRNA vaccine dose, representing an extension of the primary vaccination series.

An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination who have completed their primary course.

People less 30 years of age should receive Comirnaty® and not Spikevax®.

The additional vaccine should be given after a minimum interval of four months following the last dose of an authorised COVID-19 vaccine. In exceptional circumstances a 3 month interval may be used. If the vaccine is given before the minimum interval, there is no evidence of the safety and efficacy of administering a further additional dose of vaccine, and therefore a further additional vaccine dose should not be administered.

See Table 5a.2 for conditions that may be associated with a suboptimal response to vaccines (shaded in blue in the table)

Vaccination with the additional dose after breakthrough infection

For those who have had laboratory or antigen-positive confirmed COVID-19 breakthrough infection since primary vaccination with an authorized COVID-19 vaccine, the additional dose should be deferred until at least 4 months from diagnosis. If it is not possible to establish if an individual had breakthrough infection during that timeframe, they may be vaccinated. A minimum 3 month interval may be used in exceptional circumstances.

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14 The EMA has concluded that an extra dose of the COVID-19 vaccines Comirnaty® (Pfizer BioNTech) COVID-19 mRNA Vaccine and SpikeVax® (COVID-19 Vaccine Moderna) may be given to people with severely weakened immune systems, at least 28 days after their second dose. However, in Ireland we follow the interval recommended by the NIAC as described above.
Contraindication to mRNA vaccines

A non-mRNA vaccine may be considered as an additional dose in those with a contraindication to an mRNA vaccine. For those aged 12 years and older Nuvaxovid may be considered. For individuals who cannot receive Nuvaxovid, COVID-19 vaccine Janssen is licensed from the age of 18 years.

Please refer to section 11.1 for details of vaccination in pregnancy.

People being treated with chemotherapy for cancer

Chemotherapy is not a contraindication to COVID-19 vaccination. People taking chemotherapy should be vaccinated according to their priority group (provided there are no contraindications).

Vaccination for children aged 5-11 years is discussed in a separate chapter within this guidance document.

Heterologous vaccination

The same vaccine should preferably be used for both doses of a primary vaccination course. NIAC advise that those who have partially completed a COVID-19 vaccine course with a vaccine authorised by the FDA, MHRA or recommended by WHO, should be offered an EMA authorized COVID-19 vaccine to complete the series, and then should be considered fully vaccinated.

The recommended minimum interval between a 1st and 2nd dose in a heterologous primary course is 28 days.
12. **Protection from COVID-19 vaccines after a primary vaccination course**

Following a primary vaccination course vaccine recipients may not be protected until:

- 7 days after the second dose of Comirnaty® (Pfizer BioNTech)
- 14 days after second dose of Spikevax® (Moderna).
- 15 days after the second dose of Vaxzevria® (AstraZeneca) (vaccine no longer available in Ireland)
- 14 days after COVID-19 Jcovden® (Janssen)
- 7 days after the second dose of Nuvaxovid® (Novavax)

For those who received a 1\textsuperscript{st} dose of Vaxzevria® and an mRNA vaccine as a 2\textsuperscript{nd} dose, protection is assumed from

- 7 days after the dose of Comirnaty® (Pfizer BioNTech)
- 14 days after the dose of Spikevax® (Moderna).

Clinical trial follow-up is on-going to determine the duration of protection from COVID-19 vaccines. Duration of protection after a 1\textsuperscript{st} or 2\textsuperscript{nd} booster COVID-19 vaccination has not yet been determined.

**Vaccinated persons should be informed that they should continue to follow all current public health guidance to protect themselves and others.**
13. **Booster COVID-19 Vaccines**

Booster doses of an mRNA vaccine are recommended for everyone aged 12 years and older including pregnant women and those with immunocompromise associated with a suboptimal response to vaccines who have completed an extended primary course.

All approved mRNA vaccines may be used as booster doses\(^\text{15}\), however adapted mRNA COVID-19 vaccines should preferentially be used when available.

Adapted mRNA vaccines are bivalent. They contain mRNA based on the spike protein of the ancestral virus (like the original vaccine) as well as mRNA based on the spike protein of Omicron strains, either Omicron BA.1 or Omicron BA.4-5. Current evidence indicates that these adapted vaccines will offer similar or better protection as the original vaccines and it is expected that additional protection against variant disease may be gained.

The following adapted vaccines are recommended:

**People aged 12-29**
- Comirnaty® BA.1 or Comirnaty® BA.4-5 (adapted Vaccines)
- NOTE - Spikevax® and Spikevax® BA.1 should **not** be administered to this cohort.

**People aged 30 years and older:**
- Comirnaty BA.1 or Comirnaty BA.4-59
- Spikevax® BA.1

Note that these vaccines are not licensed or recommended for primary vaccination.

If adapted vaccines are not available, Comirnaty® 30 mcg/dose (purple cap) 0.3ml or Comirnaty® Ready to Use 30mcg (grey cap) 0.3mls may be administered as a booster dose to those aged 12 years and older.

Spikevax® 0.25mls may be administered only to those **aged 30 years and older**.

**Recommended intervals:**
- At least 4 months (4-6 months) after the last dose of a COVID-19 vaccine. In exceptional circumstances a 3-month interval may be used. If a booster dose was given in error before the minimum 3-month interval, this is not considered a valid vaccine. However revaccination is not recommended.
Vaccination after COVID-19 breakthrough infection

For those who have had laboratory confirmed/antigen positive with symptoms COVID-19 breakthrough infection since full vaccination, the booster dose should be deferred until 4 months after diagnosis. In exceptional circumstances a 3-month interval may be used.

Safety of booster doses of mRNA vaccines

- First and second booster doses of mRNA vaccines have not shown any unexpected safety concerns. Myocarditis and pericarditis are very rare risks of mRNA vaccination, predominantly in males aged under 30 years after the second dose of the primary vaccination course and the risk appears to be comparatively lower following a first booster dose.
- Data on second booster doses is more limited but experience has not revealed any new safety concerns.
- As the adapted vaccines are adaptations of the original COVID-19 vaccine for which the safety profile is well established, it is expected that their safety profile will be similar.
- Limited clinical data on BA.1 adapted vaccines shows local and systemic reactogenicity profiles similar to that of the original vaccines. Long-term follow up data is not available.
- In authorising the BA.405 bivalent vaccine, the EMA based their recommendations on safety of the bivalent BA.1 mRNA COVID-19 vaccine and long term data on previous mRNA vaccines.

Table 17. Adapted Booster Vaccine Summary

<table>
<thead>
<tr>
<th>Description</th>
<th>Comirnaty® BA.1</th>
<th>Comirnaty® BA.4-5</th>
<th>Spikevax® BA.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial/cap colour and label</td>
<td>Grey Original/Omicron BA.1 Booster only</td>
<td>Grey Original/Omicron BA.4 BA.5 Booster only</td>
<td>Blue BA.1 only</td>
</tr>
<tr>
<td>Indication for booster vaccination</td>
<td>Aged 12 years and older USE FOR BOOSTER ONLY NOT FOR PRIMARY OR ADDITIONAL DOSES</td>
<td>Aged 12 years and older USE FOR BOOSTER ONLY NOT FOR PRIMARY OR ADDITIONAL DOSES</td>
<td>Aged 30 years and older USE FOR BOOSTER ONLY NOT FOR PRIMARY OR ADDITIONAL DOSE</td>
</tr>
<tr>
<td>Dose volume (dose)</td>
<td>0.3ml (30mcg)</td>
<td>0.3ml (30mcg)</td>
<td>0.5ml (50mcg)</td>
</tr>
<tr>
<td>Dilution</td>
<td>READY TO USE DO NOT DILUTE</td>
<td>READY TO USE DO NOT DILUTE</td>
<td>READY TO USE DO NOT DILUTE</td>
</tr>
<tr>
<td>Doses per vial</td>
<td>6</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>Interval since last dose of COVID-19 vaccine</td>
<td>At least 4 months (3 months in exceptional circumstances)</td>
<td>At least 4 months (3 months in exceptional circumstances)</td>
<td>At least 4 months (3 months in exceptional circumstances)</td>
</tr>
</tbody>
</table>
Please refer to section 5 for details of preparation, transport and storage of vaccine

**Vaccination in pregnancy**

Pregnant women should already have received a primary vaccination course and a booster dose, in line with recommendations for the general population. Pregnant women are also recommended to receive a second booster dose in pregnancy. The timing of this second booster vaccine is recommended to be at 16 weeks gestation or later. This timing is to enhance protection to the infant and the mother.

Pregnant women who have had COVID-19 infection during the same pregnancy should receive the 2nd booster dose at least 4 months after diagnosis (and at 16 weeks or more gestation).

If a woman has already received a 1st booster vaccination in the current pregnancy, there is no requirement for a 2nd booster dose in this pregnancy.

**Nuvaxovid®**

Nuvaxovid® may be considered as a booster dose in those aged 12 years and older with a contraindication or precaution to an mRNA vaccine, or in individuals who have declined vaccination with other COVID-19 vaccines. A 4-month interval is recommended, in exceptional circumstances a 3 month interval may be used.

If there is a contraindication or precaution other than myocarditis or pericarditis to a booster dose of an mRNA vaccine, or a person has chosen not to receive an mRNA COVID-19 booster, consideration can be given to a booster of Nuvaxovid following an individual benefit-risk assessment. The booster dose should be given after a minimum interval of four months.

If pregnant women are receiving Nuvaxovid® as a booster dose, they should have a discussion with a healthcare professional (e.g. clinical lead vaccinator) on their individual risks and benefits of receiving the vaccine. Please refer to section 11.1.

**JCovden®**

JCovden may be considered as a booster dose in individuals aged 18 years and older who cannot receive Nuvaxovid® or an mRNA vaccine because of a contraindication or special precaution to COVID-19 vaccine. Risks and benefits of vaccination for the individual should be considered.
14. **Post Vaccination**

**Recording vaccination**

The individual should be given a record of vaccination and HSE advice leaflet for after vaccination. Vaccine administration should be recorded in the IT system.

Record the “USE BEFORE date and the batch number in the vaccination record (written on the vaccine box by the NCCS). The batch number of the Sodium Chloride diluent should also be recorded if Comirnaty has been administered.

**Observation period**

Cases of anaphylaxis have been reported following administration of COVID-19 vaccines.

Please note that NIAC recommends a 15 minute observation period following administration of a homologous or heterologous booster COVID-19 mRNA vaccine.

**Recommended observation period following vaccination (includes booster vaccination):**

- All vaccine recipients (see exceptions below): 15 minutes of observation
- Those with a history of mastocytosis: 30 minutes
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Vaccine recipients should be advised to seek urgent medical attention if they have symptoms suggestive of an allergic reaction such as difficulty breathing, feeling faint, rapid heartbeat or a skin rash.
15. **Adverse Reactions**

Adverse reactions of COVID-19 vaccines

Please refer to the relevant Summary of Product Characteristics for details.

The adverse events are listed below in Table 17 according to the following frequency: Very common (≥ 1/10), Common (≥ 1/100 to < 1/10), Uncommon (≥ 1/1,000 to < 1/100), Rare (≥ 1/10,000 to <1/1,000), Very rare (< 1/10,000).

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**Table 18: Adverse reactions of COVID-19 vaccines from clinical trials and post authorisation experience**

<table>
<thead>
<tr>
<th>Type of Reaction</th>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>Spikevax® (Moderna)</th>
<th>Jcovden® (Janssen)</th>
<th>Nuvaxovid® (Novavax)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Very Common (≥ 1/10)</strong></td>
<td>Local: injection site swelling and erythema</td>
<td>Local: injection site pain, injection site swelling, lymphadenopathy (axillary swelling and tenderness of the vaccination arm)</td>
<td>Local: injection site pain</td>
<td>Local: Injection site Tenderness, Injection site pain</td>
</tr>
<tr>
<td></td>
<td>General: arthralgia, fatigue, fever, chills, headache, myalgia, Diarrhea</td>
<td>General: fatigue, headache, myalgia, arthralgia, fever, chills, nausea and vomiting</td>
<td>General: headache, nausea, myalgia, fatigue</td>
<td>General: headache, nausea or vomiting, myalgia, arthralgia, fatigue, malaise</td>
</tr>
<tr>
<td><strong>Common (≥ 1/100 to &lt; 1/10)</strong></td>
<td>Local: injection site erythema, injection site urticarial, injection site Rash</td>
<td>Local: injection site swelling,</td>
<td>Local: Injection site erythema, injection site swelling</td>
<td>Local: Injection site redness, Injection site swelling</td>
</tr>
<tr>
<td></td>
<td>General: nausea, vomiting</td>
<td>General: rash</td>
<td>General: cough, fever, chills, joint pain,</td>
<td>General: pyrexia, chills, pain in extremity</td>
</tr>
<tr>
<td><strong>Uncommon (≥ 1/1,000 to &lt; 1/100)</strong></td>
<td>Local: injection site pruritus</td>
<td>Local: injection site Pruritus</td>
<td>Local: Injection site pruritus</td>
<td></td>
</tr>
<tr>
<td></td>
<td>General: insomnia, lymphadenopathy, extremity pain (refer to the vaccinated arm), hyperhidrosis (night sweats), decreased</td>
<td></td>
<td>General: Tremor, sneezing, oropharyngeal pain, rash, hyperhidrosis, muscle pain, pain in extremities, back pain,</td>
<td>General: Rash, Erythema Pruritus, Urticaria, Hypertension*, **, Lymphadenop</td>
</tr>
<tr>
<td>Appetite, asthenia and lethargy</td>
<td>Hypersensitivity reactions (e.g. rash, pruritus, urticaria, angioedema)</td>
<td>Asthenia, malaise, diarrhea, paresthesia</td>
<td>Athy</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td><strong>Rare</strong> (≥1/10,000 to &lt;1/1,000)</td>
<td>General: acute peripheral facial paralysis</td>
<td>General: Hypersensitivity, urticarial, urticaria, lymphadenopathy, vomiting and tinnitus</td>
<td>General: Venous Thromboembolism</td>
<td></td>
</tr>
<tr>
<td><strong>Very rare</strong> (&lt;1/10,000)</td>
<td>Myocarditis and pericarditis</td>
<td>Thrombosis in combination with thrombocytopenia **</td>
<td>**Capillary leak syndrome, Guillain-Barré syndrome</td>
<td></td>
</tr>
<tr>
<td><strong>Not known (cannot be estimated from the available Data)</strong></td>
<td>Anaphylaxis Facial swelling in those who have had dermatological fillers</td>
<td>Erythema Multiforme</td>
<td>Anaphylaxis Transverse Myelitis Immune thrombocytopenia</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extensive swelling of the vaccinated limb Myocarditis and pericarditis Erythema Multiforme Paraesthesia and hypoesthesia</td>
<td></td>
<td>Cutaneous small vessel vasculitis*</td>
<td></td>
</tr>
</tbody>
</table>

*Low platelet counts were noted in some participants who underwent blood tests as part of clinical trials, these were asymptomatic, mild and were not associated with clotting events.

** Severe and very rare cases of thrombosis in combination with thrombocytopenia have been reported post-marketing. These included venous thrombosis such as cerebral venous sinus thrombosis, splanchnic vein thrombosis, as well as arterial thrombosis.

***Throughout the clinical trials, an increased incidence of hypertension following vaccination with Nuvaxovid (n=46, 1.0%) as compared to placebo (n=22, 0.6%) was observed in older adults during the 3 days following vaccination.

*Product information will be updated
Events of anaphylaxis have been reported after COVID-19 vaccines. Appropriate medical treatment and supervision should always be readily available in case of an anaphylactic reaction following the administration of the vaccine.

Very rare events of neuroinflammatory disorders have been reported following vaccination with COVID-19 vaccines. A causal relationship has not been established.

Based on a review of small number of cases, a warning will be added to the product information regarding a few cases of capillary leak syndrome (CLS) flare-ups have been reported in the first days after vaccination with Spikevax. Healthcare professionals should be aware of signs and symptoms of CLS to promptly recognise and treat the condition. In individuals with a medical history of CLS, planning of vaccination should be made in collaboration with appropriate medical experts. Note also that PRAC did not agree that there should be a contraindication to vaccination. There are also some literature reports of COVID-19 infection causing severe flare ups of CLS.

A higher rate of pyrexia (after Comirnaty®) and local and systemic adverse events (after Spikevax® (COVID-19 Vaccine Moderna) were seen after the second dose.

A higher rate of injection site reactions (redness, swelling, tenderness or pain), nausea or vomiting, myalgia, arthralgia, fatigue and malaise, and pyrexia were seen after the second dose of Nuvaxovid® (Novavax).

If required, symptomatic treatment with analgesic and/or anti-pyretic medicinal products (e.g. paracetamol containing products or ibuprofen) may be used. Note: Ibuprofen is not recommended for pregnant women.

Adverse events following Comirnaty® (Pfizer/BioNTech) and Spikevax® (Moderna) and very rare cases of Myocarditis and Pericarditis

There has been an increase of very rare cases of myocarditis and pericarditis following vaccination with both Comirnaty and Spikevax.

The cases occurred particularly in males aged under 30 years, and following the second dose of Spikevax.

Reporting rates for vaccine-associated myocarditis were highest among males aged 12–29 years. In Israel, the estimated incidence 2 per 100,000 persons who had received at least one dose of Comirnaty. The highest incidence of myocarditis was 10.7 per 100,000 in males aged 16-29 years. Most cases of myocarditis were mild or moderate in severity.

Studies have shown that after the second dose of Comirnaty there were about 2.6 extra cases of myocarditis per 100,000 males aged 12 - 29 years after seven days and 5.7 extra cases of myocarditis per 100,000 males aged 16 - 24 years after 28 days. The rates for Spikevax were three to five times higher.
Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. They should tell people receiving these vaccines to seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. These include:

- breathlessness,
- palpitations and
- chest pain.

Healthcare professionals should consult applicable guidance and/or consult specialists (e.g. cardiologists) to diagnose and treat these conditions.

**Adverse events following Nuvaxovid® (Novavax) and unknown frequency of cases of Myocarditis and Pericarditis**

There is an increased risk of myocarditis and pericarditis following vaccination with Nuvaxovid®.

These conditions can develop within a few days after vaccination and have primarily occurred within 14 days.

The EMA concluded that the overall benefit risk remains favourable.

Available data suggest that the course of myocarditis or pericarditis following vaccination is not different from myocarditis or pericarditis in general.

The frequency of myocarditis and pericarditis after Nuvaxovid® cannot be estimated from the available data.

Myocarditis and pericarditis may present with chest pain, shortness of breath, palpitations and fatigue. Most patients respond well to standard treatment, and the prognosis is good. However, it can occasionally progress to dilated cardiomyopathy and chronic heart failure.

Healthcare professionals should be aware of the signs and symptoms of myocarditis and pericarditis.

Vaccine recipients should be advised to promptly seek medical attention if they develop acute and persisting chest pain, palpitations or shortness of breath in the days after vaccination.

Healthcare professionals should consult applicable guidance and/or consult a cardiologist for advice on management.
Adverse events following Jcovden® (Janssen) and very rare cases of Thrombosis and Thrombocytopenia Syndrome (TTS)

The NIAC has issued recommendations in relation to Jcovden® (Janssen) following the reports of the EMA of rare thromboembolic events associated with thrombocytopenia after vaccination called Thrombosis and Thrombocytopenia Syndrome (TTS) and review of data from the US, and the EMA in relation to Jcovden®.

Based on recent data from the United States, the estimated risk of TTS after vaccination with Jcovden® is 1 in 312,000. The risk of this rare condition is higher in younger people.

These are the groups where risk of severe COVID-19 outcome is less, although the age-related risk of long-COVID is unknown.

As the risk/benefit of these vaccines is different in different age groups NIAC recommends that Jcovden® (Janssen) should be given to people aged 50 years and older, and that younger people should be offered an mRNA vaccine. In Ireland, Jcovden® (Janssen) is offered to individuals from the age of 18 who cannot receive an mRNA vaccine or Nuvaxovid® due to a contraindication or precaution.

Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia.

Recipients of Jcovden® should be advised to seek immediate medical attention if they develop the following symptoms in the weeks after vaccination:

- shortness of breath
- chest pain
- leg swelling
- persistent abdominal pain
- severe or persistent headaches (particularly 3 or more days after vaccination)
- blurred vision
- confusion (or mental status change)
- seizures
- petechiae or ecchymoses beyond the site of vaccination

Healthcare professionals should seek early expert advice from the National Coagulation Centre about the specialised testing and treatment options for patients presenting with thromboembolic events that are associated with thrombocytopenia, (including Disseminated Intravascular Coagulation (DIC) or Cerebral venous sinus thrombosis (CVST)) occurring within weeks following vaccination with Jcovden® (Janssen). Furthermore, the EMA has recommended that healthcare professionals who diagnose thrombocytopenia post vaccination should check for any thrombosis and vice versa (i.e. if they have a diagnosed thrombosis to check for thrombocytopenia).
Adverse events following Jcovden® (Janssen) and Rare cases of Venous Thromboembolism (VTE)

VTE (which is different from TTS or Thrombosis with Thrombocytopenia syndrome) was added a rare (frequency >1/10,000 to <1/1,000) side effect of Jcovden® (Janssen) based on data from clinical trials and post marketing surveillance. Healthcare professionals and individual receiving the vaccine should be aware of this risk, especially in those who may have an increased risk of VTE.

Adverse events following Jcovden® (Janssen) and very rare cases of Capillary Leak Syndrome (CLS)

Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with Jcovden® (Janssen), with an estimated reporting rate of one case per approximately 6 million doses. A history of CLS has been reported in at least one of the cases.

Capillary leak syndrome is a very rare, serious condition that causes fluid/plasma leakage from capillaries resulting in swelling mainly in the arms and legs, low blood pressure, thickening of the blood and low blood levels of albumin.

The EMA concluded that people who have previously had CLS syndrome, must not be vaccinated with Jcovden® (Janssen).

(Refer to Section 6 for contraindications and precautions to Jcovden® (Janssen))

Jcovden® (Janssen) and very rare cases of Guillain-Barre Syndrome

Information for vaccinated people

Guillain-Barre syndrome (GBS) has occurred very rarely in people who have had Jcovden® (Janssen). GBS is a rare neurological disorder in which the body's immune system mistakenly attacks nerves located outside the brain and spinal cord. Symptoms of GBS range from mild weakness to more severe paralysis. Most people eventually fully recover even from the most severe symptoms, while some may continue to have some degree of weakness.

People receiving Jcovden® (Janssen) should seek immediate medical attention if they develop the following:
- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking
- tingling sensations in the hands and feet
- weakness in the limbs, chest or face
- problems with bladder control and bowel function
Healthcare professionals should be alert to signs and symptoms of GBS to ensure correct diagnosis, to initiate adequate supportive care and treatment and to rule out other causes.

Transverse myelitis (TM) have been reported very rarely following vaccination with Jcovden® (Janssen). Healthcare professionals should be alert to TM signs and symptoms to ensure correct diagnosis, in order to initiate adequate supportive care and treatment and to rule out other causes.

**Immune Thrombocytopenia (ITP) with Jcovden® (Janssen)**

ITP is a condition in which the immune system mistakenly targets blood cells called platelets that are needed for normal blood clotting. It can cause bleeding and can sometimes be fatal. Very few cases of ITP have occurred after Jcovden® (Janssen). It has usually occurred within 4 weeks of vaccination and will be added as a side effect for both vaccines (frequency unknown).

If an individual has a history of thrombocytopenic disorder, the risk of developing low platelet levels such as ITP should be considered before vaccination, and platelet monitoring is recommended after vaccination with either of these vaccines in an individual who has a history of ITP.

**Reporting adverse reactions**

The HPRA is responsible for managing the national pharmacovigilance system. The HPRA reports nationally occurring adverse reactions to the EMA.

Adverse reaction reporting is an important part of the EMA intensive monitoring plan for COVID-19 vaccines, so that any changes in benefit risk balance can be promptly detected and acted upon.

This enables the EMA to continue to safeguard public health safety.

COVID-19 vaccines are subject to additional monitoring. This will allow quick identification of new safety information.

Healthcare professionals and members of the public are encouraged to report any suspected adverse reactions to the HPRA following the instructions available on the HPRA website [www.hpra.ie](http://www.hpra.ie). As much information as is known should be provided, and where possible, the vaccine batch number should be included.
Reporting of incidents during the vaccination session to HSE

In the case of medication errors that directly involve the vaccine recipient, i.e. wrong medication/dose/route being administered or another medication error, the vaccinator must remain with the person and closely monitor them for any adverse reactions.

The incident must be reported to the relevant line manager/person in charge as soon as possible. The incident and all actions taken must be recorded and the relevant National Incident Management Report Form (NIRF) completed as soon as practicable after the event occurs and within one working day. (National Incident Report Form (NIRF 01 – V11)) (2020) available at: https://www.hse.ie/eng/about/qavd/incident-management/

The vaccine recipient and/or significant others should be informed of the incident. An incident report form must be completed by the vaccinator and forwarded to local or regional Risk Manager as per local policy.

Any suspected adverse reactions associated with medication errors should be reported to the HPRA as outlined above.

16. Guidance for vaccination of those who are contacts of a case of COVID-19

If a person is required to restrict their movements, they must not attend for vaccination until the period of restricted movements has been completed. See https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/contacttracingguidance/

Where vaccination is being carried out in Residential Care Facilities (residents and staff) the following advice applies:

Primary vaccination: asymptomatic close contacts of cases of COVID-19 may receive COVID-19 vaccine.

Asymptomatic individuals who have undergone testing for COVID-19 and who are residents in a long-term care facility should also proceed with vaccination while awaiting the results of their tests. Healthcare staff in LTCFs should follow all public health and occupational health guidance. www.hpsc.ie

Vaccination is a low contact clinical activity. Hand hygiene, PPE and infection prevention and control guidance should be followed. See www.hpsc.ie for details
17. Vaccination of children aged 5-11 years

For children aged 5 to 11 years, the recommended COVID-19 vaccine is Comirnaty® (Comirnaty® Children 5-11 years).

Comirnaty® 10 micrograms is licensed for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus in children aged 5-11 years.

The dose and schedule of Comirnaty® for this age group is 10 micrograms, two doses given 21 days apart.

NIAC recommendation
Following approval of Comirnaty® formulation for children by the EMA in November 2021, the NIAC has made the following recommendations:

- COVID-19 vaccination is strongly recommended for those aged 5 to 11 years:
  - With underlying conditions
  - Living with a younger child with complex medical needs
  - Living with a person who is immunocompromised
- COVID-19 vaccination should be offered to all other children aged 5 to 11 years
  - This is because of the favourable benefit risk profile of the vaccine, to protect them from severe disease and from the consequences that can follow infection e.g., multisystem inflammatory syndrome in children (MISC), long COVID as well as psychosocial and developmental impacts
- Children aged 5 to 11 years who are severely immunocompromised should be given a third dose of Comirnaty® at least 28 days after the second dose to complete the primary series

Before vaccination, parents or guardians should be informed of the known benefits, risks and uncertainties of COVID-19 vaccination.

Booster doses
A first mRNA COVID-19 booster vaccine is now recommended for those aged 5 – 11 years with immunocompromise associated with a sub optimal response to vaccines at the time of their primary or additional vaccination (See Table 5a.1 areas shaded in blue) (4 doses in total)

In children who have become immunocompromised since their primary vaccination course, a booster dose is recommended. In this case they are expected to have mounted an adequate response to their primary vaccination and so they do not require an additional dose. (3 doses in total)

The decision to accept, defer or refuse vaccination for a child should be respected.
Clinical Guidance for COVID-19 Vaccination | HSE National Immunisation Office

Vaccine storage

The vaccine is delivered from the manufacturer to the HSE NCCS at -90°C to -60°C and this storage condition is continued as the vaccine is stored in an ULT freezer at -90°C to -60°C. The vaccine is supplied to sitesclinics by the HSE NCCS at +2 to +8°C with a shelf life of 10 weeks. This new “use before” time and date is labelled by NCCS once vials are removed from ULT. The vaccine in each multi-dose vial requires dilution with 1.3ml of 0.9% sodium chloride.

0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.

Undiluted vials of Comirnaty® (Pfizer/BioNTech) have a shelf life of 10 weeks when stored at +2 to +8°C (labelled “use before” time and date) and up to 12 hours at up to +30°C.

After dilution, the vaccine must be kept at +2°C to +30°C and used within 12 hours after which the vial must be discarded.

Summary of Comirnaty 10 micrograms/dose

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of vaccine</td>
<td>Comirnaty 10 micrograms/dose concentrate for dispersion for injection COVID-19 mRNA Vaccine (nucleoside modified)</td>
</tr>
<tr>
<td>Constituents</td>
<td>(4-hydroxybutyl)azanediy)(hexane-6,1-diyl)bis(2-hexyldecanoate) (ALC-0315)</td>
</tr>
<tr>
<td></td>
<td>2-[[polyethylene glycol]-2000]-N,N-ditetradecylacetamide (ALC-0159)</td>
</tr>
<tr>
<td></td>
<td>1,2-Distearoyl-sn-glycero-3-phosphocholine (DSPC)</td>
</tr>
<tr>
<td></td>
<td>Cholesterol</td>
</tr>
<tr>
<td></td>
<td>Trometamol</td>
</tr>
<tr>
<td></td>
<td>Trometamol hydrochloride</td>
</tr>
<tr>
<td></td>
<td>Sucrose</td>
</tr>
<tr>
<td></td>
<td>Water for injections</td>
</tr>
<tr>
<td>Number of doses in</td>
<td>Post dilution 10 doses.</td>
</tr>
<tr>
<td>each vial</td>
<td>If more than 10 doses can be accurately withdrawn from a diluted vial, it is a valid dose. No more than 12 valid doses are available.</td>
</tr>
<tr>
<td>Dilution</td>
<td>Yes dilute with 0.9% Sodium Chloride (supplied separately)</td>
</tr>
<tr>
<td>Latex</td>
<td>No. The vial has a synthetic rubber (bromobutyl) stopper– the vial stopper does not contain latex.</td>
</tr>
<tr>
<td>Preservatives</td>
<td>No</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.2ml</td>
</tr>
<tr>
<td>Number of doses</td>
<td>2</td>
</tr>
<tr>
<td>required</td>
<td></td>
</tr>
<tr>
<td>Interval between doses</td>
<td>The recommended interval between doses is 21 days</td>
</tr>
<tr>
<td></td>
<td>The minimum interval between doses is 19 days.</td>
</tr>
<tr>
<td></td>
<td>(the day of the first vaccine dose is day 0)</td>
</tr>
</tbody>
</table>
Vaccine dose

The vaccine for children is a different vaccine formulation, it contains a lower dose of antigen (10 micrograms per dose). The dose of the diluted vaccine is 0.2mls. Two doses of Comirnaty® for children aged 5-11 years are required for full protection.

The dose of Comirnaty® depends on the age at the time of vaccination i.e., an 11-year-old child who receives the first dose of 10 micrograms Comirnaty® and who is 12 years of age at the time of their second dose, should receive the 30 microgram dose of Comirnaty® as a second dose.

This is a different dose compared to the dose for those aged ≥12 years.

This image shows the children's formulation

Interval between doses

The recommended interval between doses is 21 days\(^{16}\). If the interval between doses is longer than 21 days, the second dose should be given as soon as possible. The course does not need to be restarted. The minimum interval is 19 days. This is a different minimum interval compared to the minimum interval for those aged ≥12 years. The date of administration of the first dose is to be calculated as Day 0. If the second dose is given between 19 and 20 days after the first dose, it is a valid dose. If the second dose is given before 19 days, this is not considered a valid dose. A third dose should be given 21 days after the second (invalid) dose.

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd Doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 19 days</td>
<td>This is not considered a valid vaccine. A third dose should be given 21 days after the second (invalid) vaccine.</td>
</tr>
<tr>
<td>19 to 21 days</td>
<td>No further action needed (Evidence from trial data is that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 21 days</td>
<td>Give the second dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

\(^{16}\)Note that the day the first dose of vaccine is given is day 0.
Prior to vaccination
- Check valid consent has been obtained
- Check for contraindications or precautions
- See later in this chapter and the NIAC Immunisation guidelines for COVID-19 available at www.immunisation.ie
- Vaccinators who are vaccinating using a medicines protocol should check vaccine recipient’s eligibility under the protocol
- Check the interval when administering a second dose
- Explain the procedure
- Answer questions
- Maintain privacy & dignity

Infection prevention and control
- Prior to preparation and administration of COVID-19 vaccines, hand hygiene should be performed as per the “WHO five moments of hand hygiene” with emphasis on:
  - Before vaccine preparation
  - Before drawing up and administering the vaccine
  - Before and after each recipient contact
- PPE should be worn as per HPSC guidance for healthcare staff.
- It is not necessary to use a skin disinfectant prior to injection. If the skin at the injection site is visibly dirty, clean with soap and water. If an alcohol swab is used, delay injection for $\geq 30$ seconds, to ensure the alcohol has evaporated.
- Gloves are not routinely recommended for vaccine preparation and administration
- There is no need to routinely check temperature either at registration or before vaccination.
- Follow HPSC standard precautions (sharps management, healthcare waste management etc.)
  https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/seinfectionpreventionandcontrolguidanceandframework/
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
  https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/

Vaccine Dilution and Preparation for Administration

Prior to dilution
- Perform hand hygiene
- Check you are using the correct formulation
- Verify that the vial of Comirnaty® COVID-19 mRNA vaccine has an orange plastic cap and a label with an orange border and states Age 5y to < 12y

Preparation for dilution
Prepare the equipment needed for dilution:
- A clean tray
- One Comirnaty® COVID-19 mRNA vaccine multidose vial
- One plastic ampoule of Sodium Chloride 0.9% Solution for Injection
- This should not be kept in the fridge
• A needle and a syringe to dilute
• Needles and syringes will be supplied
• Two 70% alcohol swabs

Check the *use before* date and time on the box containing the vials i.e., that the vial has **NOT** been stored in the fridge for more than **10 weeks**. Before dilution mix by inverting vaccine vial gently 10 times, do not shake. Inspect the liquid in the vial prior to dilution, the liquid is a white to off-white suspension and may contain opaque amorphous particles. Do not use if the liquid is discoloured or if other particles are observed.

**Dilution**
• Take one ampoule of sodium chloride and check expiry date
• Clean with 70% alcohol swab
• Open the ampoule by twisting the cap
• Connect the syringe tightly (No needle is required)
• Follow Aseptic technique
• Do not touch the key parts of the ampoule & syringe
• Withdraw 1.3 ml of Sodium Chloride 0.9% Solution for Injection
• **The volume of diluent is smaller than for the adult formulation**
• Cross check with colleague
• Discard the ampoule and any remaining diluent in it
• Attach needle to the syringe
• Insert diluent into the vaccine vial
• You may feel some pressure in the vial as you add the diluent

• Do not remove the needle and syringe from the vial until you have equalised the vial pressure by slowly withdrawing 1.3 ml of air into the empty diluent syringe before removing the needle from the vial

• Gently invert the diluted solution 10 times, do not shake
• Inspect the vial
• The diluted vaccine should be an off-white suspension
• Do not use if vaccine is discoloured or contains particulate matter

Labelling the diluted vial
• Label the diluted vial with the discard time and date (12 hours after time of dilution) using a 24-hour format. Do not use it after this time and date
• E.g. time of dilution was 08.00 20/12/2021. The discard time and date is 20.00 20/12/2021
• After dilution, the vial contains up to 12 doses of 0.2 mL
• **The volume of each dose is smaller than the adult dose**
• Diluted vaccines can be stored between +2°C and +30°C but must be used within 12 hours following dilution
• Bring the vial to your vaccination table/site.

Vaccine Dose Preparation
• Check that the time of vaccine dilution was within the last 12 hours
• Perform hand hygiene
• Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
• Attach 23g blue hub needle to 1ml syringe
• The needle size is the same as for those aged 12 years and older
• Withdraw **0.2 mL** of diluted product

• Make sure correct dose is drawn up as smaller dose may not provide protection
• Before the needle is withdrawn ensure all air bubbles have been removed
• Do not change the needle between the vial and the patient unless the needle is contaminated or damaged.
Vaccine Administration

- Administer vaccine to patient intramuscularly, into the deltoid muscle
- Dispose the syringe and the needle into the sharps bin
- If more than ten 0.2ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses
- **There is a maximum of 12 doses in each vial**
- Do not leave the empty vials unattended
- Dispose the empty vials safely into a sharps bin
- Low dead space syringes should be used if available in order to maximise the number of doses that can be drawn from the vial
- There should be no pooling of vaccine solution from different vials

Method of IM Vaccine Administration

- Intramuscular injection technique for children aged 5-11 is the same as for older children and adults
- Vaccine to be given Intramuscularly into the deltoid muscle
- The light triangle in figure indicates site for IM injection into the deltoid muscle

![Deltoid Muscle Diagram](image)

- The upper border of the triangle is approximately two finger-breadths below the acromion process and the apex is at the midpoint of the humerus
- The needle size for IM injection is the same as that for adults (23g blue hub needle)
- At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand
- Do not bunch up the skin as this leads to administering the vaccine into subcutaneous tissue inadvertently
- Further information is available at [www.immunisation.ie](http://www.immunisation.ie)

Positioning for vaccination

For younger/smaller children:
- The child sits on the parent/carer’s lap or stands in front of them as they sit
• The parent/carer embraces the child during the process, holding both the child’s arms as they do so both of the child’s legs are anchored between the parent/carer’s thighs

Source: Immunisation guidelines of the NIAC

**Alternative positioning**

• Sit child facing to the side. One arm is tucked under the parent/carer’s armpit (A cuddle position)

Source: Australian Immunisation handbook

For older/bigger children

• It may be appropriate to ask the parent/carer and the child the preferred sitting position for vaccine administration
• They may prefer to sit on the parent/carer’s lap or to sit independently

**Techniques for vaccinating children**

• Be honest and calm. Take time to explain in simple terms what to expect. Explain that the child may feel a little pinch and it will go away very quickly.
• Use words like “pressure” or “pinch” rather than “pain” or “shot”
• Distraction techniques can help in reducing pain and anxiety during vaccination. Keep the distraction going after the vaccine is given
• Looking at toys, books, etc.
• Pointing out interesting things in the room
• Telling or reading stories
• Taking deep breaths to help “blow out” the pain
• Counting to five backwards

**What to do if the child does not want to be vaccinated**

• Only one person should hold the child for vaccination at any time (to avoid risk of needle stick injury)
Clinical Guidance for COVID-19 Vaccination | HSE National Immunisation Office

- If the child cannot be held/positioned by the parent/carer so that vaccination is possible, then the child should not be vaccinated
- Repeated attempts to vaccinate the child are unlikely to help
- Check with your clinical lead for advice
- It may be better to bring the child back another time
- With the parent if parent was not present.
- They may benefit from vaccination during quiet times

Prevention and Management of Syncope in Vaccination Clinics
- Syncope is rare in younger children, it is more common in adolescents
- Syncope episodes mostly occur within 15 minutes of vaccine administration
- Reassurance about the procedure may help to prevent fainting
- Recipients should be seated (or lying down - if past history of fainting) when being administered their vaccines in case of an immediate faint
- There should be facilities in place in case of fainting
- So that the person can be placed in a recumbent position/lie down or sit with head between knees for several minutes if lying down is not possible
- It may be helpful to loosen any tight clothing and apply cool, damp cloths to the person’s face and neck
- Further information is available on the www.immunisation.ie and at https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/

Contraindications and precautions to COVID-19 vaccination in children

Contraindications
- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG)). The constituents of the formulation of Comirnaty® for children include trometamol

Appropriate support should be available in case of anaphylaxis or fainting after vaccine administration. Precautions should be in place to minimise injury from fainting

Precautions:
- Acute severe febrile illness; defer until recovery
- Previous history of myocarditis or pericarditis after any COVID-19 vaccine – seek specialist advice
- Vaccination should be postponed in children with a previous history of MIS-C, until clinical recovery or until 90 days or more since diagnosis, whichever is the longer.

If vaccination is advised for a child with prior history of mastocytosis, observe for 30 minutes after vaccination.

The following are not contraindications or precautions to vaccination:
- Food allergy (non-anaphylactic)
- Family history of allergy, including anaphylaxis
- Previous local reaction to any vaccine
• Underlying asthma
• Hay fever
• Hereditary angioedema
• Contact dermatitis to PEG containing cosmetic product
• NSAID allergy
• Chronic spontaneous urticarial

Post-vaccination Procedures

Documentation post vaccination
• Record vaccine batch number in the record/IT system
  • It will automatically link to the expiry date, so there is no need to record the expiry date
• Boxes delivered by NCCS will be labelled with a Use before date and time
• This use before date and time should be recorded in the patient record
• Give record card to vaccinee or parent/guardian
• Give post vaccination information sheet to vaccinee or parent/guardian

Observation post-vaccination
• Vaccine recipients: 15 minutes of observation
• Those with a history of mastocytosis: 30 minutes of observation
• Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated

Advice following vaccination
• Give the parent/carer the after-care leaflet information
• Parent/carer should be advised that COVID-19 vaccines may cause a fever which usually resolves within 48 hours. This is a common, expected reaction and isolation and further investigation is not required unless COVID-19 is suspected
• If fever lasts for > 48 hours, or if other symptoms of Covid-19 are present, the person should self- isolate and seek medical advice
• Paracetamol or ibuprofen can be taken after vaccination if the child develops pain, fever or myalgia
• Advise the child’s parent/carer that vaccinated children may still get infected and transmit the virus so they should continue to follow all current public health guidance to protect themselves and others
• Please refer to the NIAC immunisation guidelines available at www.immunisation.ie
**Adverse Events**

Overall, the safety profile seen in clinical trials for children aged 5-11 years was similar to that seen in older trial participants. No cases of myocarditis were noted and no new safety concerns were observed however the study size did not allow for detection of rare or very rare adverse events. Vaccination of children age 5-11 is underway in US, Canada, Israel. More than four million first doses and approximately 450,000 second doses have been given to children in this age group in the US. No immediate safety issues have been notified but follow up time has been short.

The most frequent adverse reactions in children 5 to 11 years of age were

- Injection site pain (>80%)
- Fatigue (>50%)
- Headache (>30%)
- Injection site redness and swelling (>20%)
- Myalgia and chills (>10%)

The side effects were usually mild or moderate in intensity and resolved within a few days after vaccination. A higher rate of pyrexia is seen after the second dose.

**Myocarditis and pericarditis**

Myocarditis and pericarditis are inflammatory conditions of the heart. Symptoms can vary but often include breathlessness, palpitations and chest pain. An EMA review listed Pericarditis and Myocarditis as a **very rare** side effect of Comirnaty® vaccine. The risk is highest in younger males and is more often observed after the second dose. Two European studies have estimated the risk of myocarditis after the second dose of the vaccine:

- One additional case for every 38,000 men aged 12 to 29 (within 7 days)
- One additional case for every 17,500 men aged 16-24 (within 28 days)

**Data are very limited on those 5 to 11 years of age.**

Myocarditis has also been associated with COVID-19 infection and these events can also occur in all age groups unrelated to vaccines or to COVID-19. Available data suggest that the course of myocarditis and pericarditis following vaccination is similar to the typical course of these conditions and in most individuals, symptoms resolved with conservative management. The long-term follow-up of these cases is ongoing.

**Reporting of adverse events following immunisation**

Clinical Guidance for COVID-19 Vaccination | HSE National Immunisation Office

Clinical considerations

Vaccination after COVID-19 infection
Vaccination after COVID-19 Vaccination should be deferred until clinical recovery from COVID-19 infection and for at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic. Those with persisting symptoms post COVID-19 may be vaccinated unless there is evidence of recent clinical deterioration. Serological testing prior to vaccination is not recommended.

For children who are immunocompromised and receiving an additional/3rd dose: if they have had a laboratory-confirmed /antigen positive with symptoms breakthrough infection following their 2nd vaccine dose, the third dose should be delayed for at least 3 months.

Co-administration with other vaccines
COVID-19 vaccine may be given at the same time or at any interval as other vaccines (live and non-live) including influenza vaccine and the vaccines administered in the school immunisations programme. The only exception to this is children who have received monkeypox vaccine. In this instance, there should be a 4 week interval between monkeypox vaccine and a subsequent COVID-19 vaccine. There is however no evidence of the safety or efficacy of Nuvaxovid in these circumstances and an individual benefit-risk assessment should take place.

Children who are immunocompromised
Children who are immunocompromised due to disease or treatment may be vaccinated if they have no contraindications. Data indicates that those with severe immunocompromise do not have adequate protection following a primary COVID-19 vaccine course. There is evidence that protection can be enhanced by an additional mRNA vaccine dose, representing an extension of the primary vaccination series. See Table 5a.2 of the NIAC guidelines for conditions that may be associated with a suboptimal response to vaccines.

An additional Comirnaty® dose (10 micrograms 0.2ml) should be given to those aged 5-11 years with immunocompromise associated with a suboptimal response to vaccines at the time of vaccination, who have completed their primary course. This is an extended primary vaccination course.

Children who are severely immunocompromised at the time of vaccination can have the additional (3rd dose) at least 28 days after the second dose.

Children with planned immunosuppressing therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used. Specialists should consider the child’s risk and likelihood of disease exposure, and provide advice based on knowledge and understanding of their immune status and likely immune response to vaccination.
Booster vaccination of children who are immunocompromised

A booster dose is recommended for children aged 5 – 11 years with immunocompromise associated with a sub optimal response to vaccines at the time of their primary vaccination.

A booster dose is also recommended in children who have become immunocompromised following their primary vaccination course.

The booster dose (10 micrograms 0.2ml) is recommended at least 4 months after the last vaccine dose. In exception circumstances, a 3 month interval may be used.

In individuals who have had a laboratory-confirmed /antigen positive with symptoms breakthrough infection following their last dose of vaccine, the booster dose should be delayed for at least 4 months. In exceptional circumstances a 3 month interval may be used.

Vaccination of those with bleeding disorders or on anticoagulants

Individuals with a bleeding disorder or receiving anticoagulant therapy may develop haematomas in IM injection sites. Prior to vaccination, inform the parent or guardian about this risk.

For those with thrombocytopenia (platelet count <50 x 10^9 /L consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra) do not require haemostatic cover for vaccination.

Those with inherited coagulopathies who require factor replacement therapy should receive it on the day of vaccination, prior to the IM vaccination. If there is uncertainty about the need for replacement therapy, contact the child's supervising consultant.

Those receiving long-term anticoagulation with either Warfarin or heparin are not considered to be at higher risk of bleeding complications following vaccination. There is no reason to expect that there is a greater risk of bleeding complications with the oral anticoagulants or antiplatelet agents, than with other anticoagulants.

See Chapter 2 of the NIAC guidelines, sections 2.4.6 and 2.4.7 for further information, including technique for IM injection, in this patient group.

Duration of immunity

There is insufficient information to determine the duration of protection from the vaccine. Vaccine recipients may not have optimal protection until seven days after the second dose, and the vaccine may not protect all those vaccinated. After vaccination, vaccine recipients should continue to follow all public health guidance should be followed.
18. Useful links

- Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions


- Information for women who are pregnant or breastfeeding and their doctors about COVID-19 vaccine

- HSE Management of cold chain guidance (2-8°C)

- HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool boxes

- Licensed documentation for vaccines: Summary of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public, available via the European Medicines Agency websites

- Health Products Regulatory Authority. Human Medicines Adverse Reaction Report

- HPSC COVID-19 guidance www.hpsc.ie
APPENDIX A: INTRAMUSCULAR INJECTION TECHNIQUE
1. Landmark injection site
   Base of triangle: Two finger widths down from the acromion process; Bottom edge: At an imaginary line drawn from the axilla.

2. Identify injection site
   The recommended site is the middle of the triangle. Do not inject too high or too low.

3. Administer
   At the injection site spread the skin taut between the thumb and forefinger with the non-dominant hand. Do NOT bunch up the skin. Inject at a 90-degree angle. Inject medication over 1-2 seconds.

4. Technique
   Swift needle entry, slow injection of medication, swift needle withdrawal = less pain

HSE National Immunisation Office
www.immunisation.ie
Version 1. 02/03/2022
This document contains:

Guidance at sites for management of Comirnaty for 12 years of age and older including:

- Comirnaty 30 micrograms/dose concentrate for dispersion for injection – Purple cap
- Comirnaty 30 micrograms/dose dispersion for injection - Grey cap.
- Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection - Grey cap.
- Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - Grey cap.

And

Guidance at sites for management of Comirnaty 10 micrograms/dose concentrate for dispersion for injection for children 5 to 11 years
1. Background

Comirnaty 30 micrograms/dose concentrate for dispersion for injection – Purple cap vials are packed in original boxes of 195 vials or prepacked into boxes with less vials.

Comirnaty 30 micrograms/dose dispersion for injection - Grey cap vial is in Ready To Use presentation and packed in original boxes of 10 vials

Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection- Grey cap vial is in Ready To Use presentation and packed in original boxes of 10 vials

Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - Grey cap.

Comirnaty vaccines (above presentations) are at a temperature of +2°C to +8°C when delivered to the site by the National Cold Chain Service (NCCS). Unopen vials can be stored for up to approximately 30 days (purple capped vials) and 10 weeks (grey capped vials) when stored at a temperature of +2°C to +8°C.

The site will be responsible for the vaccine upon delivery.

Additional information is provided about the vaccination programme in the document Clinical Guidance for COVID-19 Vaccination available at www.immunisation.ie

These vaccines are authorised by the European Medicines Agency (EMA).
2. Responsibilities
The Responsible Person should ensure that this SOP is followed.

3. Scope
The scope of this document is to set a standardised protocol of procedures in the provision of the
- Comirnaty 30 micrograms/dose concentrate for dispersion for injection – Purple cap
- Comirnaty 30 micrograms/dose dispersion for injection - Grey cap
- Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection - Grey cap
- Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - Grey cap

Separate documents are available for other COVID-19 vaccines.

4. Purpose
The purpose of this document is to outline the management of Comirnaty vaccines for 12 years of age and older and to provide supporting guidance in relation to:
- Receipt & Storage
- Handling & Transportation
- Vaccines decommissioning

The documents provided may be used as templates to be adapted for local use or may be used as reference sources to check that existing local procedures are robust and comprehensive.

4.1 Receipt & Storage
Upon arrival at your site and prior to receipt of vaccine delivery:
- Read the temperature of the fridge/s,
- Record maximum, minimum and current temperature,
- Reset after recording

For additional information please see the following document

Vaccines will be at a temperature of +2°C to +8°C when delivered to the site by the NCCS.
Note and retain details of the transportation label affixed to the delivery box.

Scan the HSE SCAN ME label with Use Before Date. This label will have been affixed onto the vaccine box by NCCS.

Check against the delivery docket. Place the stock in the fridge at a temperature of +2°C to +8°C, retained in original boxes to protect vials from light.

- Comirnaty 30 micrograms/dose concentrate for dispersion for injection (Purple cap – Dilution required before administering vaccine) will be labelled with USE BEFORE date up to one month as per affixed label. The USE BEFORE date and time specified on the label indicates the time by which the vial must be diluted, irrespective of the expiry date. The USE BEFORE date reflects the duration the unopened vial can be stored at +2°C to +8°C.

- Comirnaty 30 micrograms/dose dispersion for injection (Grey cap – No Dilution required- Ready To USE) will be labelled with USE BEFORE date up to 10 weeks as per affixed label.

- Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection, and Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection- (Grey cap – No Dilution required, Ready To Use) and will be labelled with USE BEFORE date up to 10 weeks as per affixed label.

The USE BEFORE date and time specified on the label affixed by the NCCS on the box indicates the time by which the grey cap vials must be administered, irrespective of the expiry date. The USE BEFORE date reflects the duration the unopened vial can be stored at +2°C to +8°C.

Place the stock immediately in the fridge at a temperature of +2°C to +8°C.

The vials should not be refrozen.

Retain details of the transportation label affixed to the delivery box.

### 4.2 Handling & Transportation

**Comirnaty 30 micrograms/dose concentrate for dispersion for injection (Purple cap).**

Comirnaty 30 micrograms/dose concentrate for dispersion for injection comes in a multi-dose vial and **before use, must be diluted with 1.8 ml of sodium chloride (0.9%) solution for injection**. Each vial contains 0.45 ml antigen and after dilution the vial contain 2.25 ml and therefore up to 7 doses of 0.3 ml may be available. One dose (0.3 ml) contains 30 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
**Undiluted vial**

An **undiluted vial** of Comirnaty 30 micrograms/dose concentrate for dispersion for injection may be stored until the **USE BEFORE date and time** at temperatures between +2°C and +8°C. The **USE BEFORE date and time** is the time by when the vial must be taken out from +2°C and +8°C for dilution. RECORD the **USE BEFORE date** in the patient's record.

Prior to use, the unopened vial can be stored for up to 2 hours at room temperature up to +30°C.

The **following information is intended to guide healthcare professionals only in case of temporary temperature excursion.**

Stability data indicate that the unopened vial is stable for up to:

- 24 hours when stored at temperatures from -3 °C to +2 °C
- A total of 4 hours when stored at temperatures from +8 °C to +30 °C; this includes the 2 hours at up to +30°C detailed above.

**Diluted medical product**

Once diluted a “**DISCARD date and time**” is applied and written on the vial, it is calculated by adding 6 hours to the time of dilution.

Chemical and physical in-use stability, has been demonstrated for **6 hours** at +2 °C to +30 °C **after dilution.** From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

Do not use the vaccine if the vial contains particulates or if the solution is discoloured.

**Transportation**

An appropriate container should be used to minimize the potential for vials to be jostled. If vials are inadvertently bumped, they should be righted, however the risk to the product is minimal and vials, which are temporarily knocked over, may still be used.

The total or cumulative duration of transit of the **undiluted** product at temperatures between +2 °C and +8°C, must not exceed 48 hours. The 48 hours must include all travel time commencing at time of departure from NCCS to the vaccination centre and all other transportation of the undiluted vaccine thereafter. These times must be taken within the **USE BEFORE dates and time.** Each delivery box is over...
labelled with time of departure label which is stamped when leaving NCCS and is completed by driver at
time of handover to recipient.

During the 6 hours in-use period **after dilution** the medical product can be transported.

For additional information the following document may be consulted:
HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes (Updated 15 April 2020)

**Comirnaty – GREY Cap- Ready to Use**
Comirnaty 30 micrograms/dose dispersion for injection (Grey cap – No Dilution required- Ready to Use)

And

Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection and
Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - (Grey cap
– No Dilution required)

The strains targeted by the vaccine (Grey Cap) for “12 years and Older, Ready to Use” may differ however all
storage, handling, preparation and administration will remain the same.

**Comirnaty 30 micrograms/dose dispersion for injection (Grey cap) - Ready to Use**
Comirnaty 30 micrograms/dose dispersion for injection comes in a multi-dose vial.
One vial (2.25 ml) contains 6 doses of 0.3 ml. One dose (0.3 ml) contains 30 micrograms of tozinameran, a
COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

**Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection and Comirnaty Original/Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection - (Grey cap – No Dilution required)**
Comirnaty Original/Omicron BA.1 (15/15 micrograms)/dose dispersion for injection and Comirnaty Original/
Omicron BA.4-5 (15/15 micrograms)/dose dispersion for injection comes in a multi-dose vial with a grey
cap. One vial (2.25 mL) contains 6 doses of 0.3 ml. One dose (0.3 ml) contains 15 micrograms of
tozinameran and 15 micrograms of riltozinameran, a COVID-19 mRNA Vaccine (embedded in lipid
nanoparticles).

**Unopened vial**
Unopened vials can be stored for up to 10 weeks at temperatures between +2°C and +8°C. When delivered,
cartons will have a label created by the NCCS displaying the **USE BEFORE date and time**. The **USE BEFORE
date and time** is the time by when the vaccine must be administered.

**RECORD** the **USE BEFORE date** in the patient’s record.
Prior to use, the unopened vial can be stored for up to 12 hours at temperatures up to 30 °C.

The following information is intended to guide healthcare professionals only in case of temporary temperature excursion.

Stability data indicate that the unopened vial is stable for up to:

- 10 weeks when stored at temperatures from -2°C to +2°C, within the 10-week storage period between +2°C and +8°C.
- 24 hours at temperatures of +8°C to +30°C, including up to 12 hours following first puncture.

**Opened vial**

DISCARD date and time must be written on the vial once the vial is initially punctured. This is calculated by adding 12 hours to the time of first puncture. During this period the vaccine can be stored at room temperature of up to +30 °C. From a microbiological point of view, unless the method of opening precludes the risks of microbial contamination, the product should be used immediately.

**Transportation**

**Unopened vials** can be transported during the 10 weeks storage between +2°C to +8°C.

**Punctured vials** can be transported for up to 6 hours during the 12 hours period after first puncture.

### 4.3 Vaccine decommissioning

Boxes have been re-worked and decommissioned by NCCS.
5. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment

A national distribution service will provide all necessary supplies, to handle, prepare and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

Other Equipment includes:

- **Anaphylaxis Kits**
  Refer to National Immunisation Advisory Committee Guidelines
  The epinephrine will be provided by a pre-determined community/hospital pharmacy as agreed by the lead governance organization CHO/HG.

- **Storage Equipment**
  A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at +5 °C +/- 3 °C, and alarms should take into account the need to maintain the temperature above +2 °C and less than +8 °C.
  Fridges should be validated and monitored in accordance with existing local procedures.

6. Stock Control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should match the stock count recorded on the IT system.
Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal. All waste must be handled in such a way as to prevent theft and/or misuse, both on site and after removal from the site.
Dispose empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.
Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

7. Health & Safety

There are no special handling requirements for routine handling and dealing with spillages of Comirnaty COVID-19 vaccine.
Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
A quick reference to dosing, dilution, and storage information for Comirnaty COVID-19 mRNA vaccine

<table>
<thead>
<tr>
<th>Formulation</th>
<th>12 years and older, Dilute to use</th>
<th>12 years and older, Ready to use</th>
<th>12 years and older, Ready to use</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Multi-dose Vial</td>
<td>Multi-dose Vial</td>
<td>Multi-dose Vial</td>
</tr>
<tr>
<td>Vial cap colour</td>
<td>Purple</td>
<td>Grey</td>
<td>Grey</td>
</tr>
<tr>
<td>Dosage</td>
<td>30 mcg</td>
<td>30 mcg</td>
<td>30 mcg</td>
</tr>
<tr>
<td>Injection Volume per Dose</td>
<td>0.3 ml</td>
<td>0.3 ml</td>
<td>0.3 ml</td>
</tr>
<tr>
<td>Dilution</td>
<td>Dilution required</td>
<td>No Dilution READY TO USE</td>
<td>No Dilution READY TO USE</td>
</tr>
<tr>
<td>Fill Volume per Vial</td>
<td>0.45 ml</td>
<td>2.25 ml</td>
<td>2.25 ml</td>
</tr>
<tr>
<td>Amount of Diluent Needed per Vial*</td>
<td>1.8 ml</td>
<td>NO DILUENT</td>
<td>NO DILUENT</td>
</tr>
<tr>
<td>Doses per Vial</td>
<td>6 doses per vial (after dilution)</td>
<td>6 doses per vial</td>
<td>6 doses per vial</td>
</tr>
<tr>
<td>Refrigeration Storage Time (2 °C to 8 °C)</td>
<td>Up to 1 month</td>
<td>Up to 10 weeks</td>
<td>Up to 10 weeks</td>
</tr>
<tr>
<td>Room Temperature (8 °C to 30 °C)</td>
<td>2 hours prior to dilution</td>
<td>12 hours prior to first puncture</td>
<td>12 hours prior to first puncture</td>
</tr>
<tr>
<td>After First Puncture (2 °C to 30 °C)</td>
<td>Discard after 6 hours</td>
<td>Discard after 12 hours</td>
<td>Discard after 12 hours</td>
</tr>
</tbody>
</table>

* Diluent: sterile sodium chloride 9 mg/ml (0.9%) solution for injection. Bacteriostatic saline or other diluents must NOT be used.
Management of Comirnaty 10 micrograms/dose concentrate for dispersion for injection for children 5 to 11 years

Guidance at vaccination clinics

This document is under regular review and will be updated when relevant new information becomes available. Please check www.immunisation.ie for the current version.

1. Background

Comirnaty 10 micrograms/dose concentrate for dispersion for injection (for 5 to 11 years) is at a temperature of +2°C to +8°C when delivered to the site by the NCCS. The vaccine has approximately 10 weeks shelf life once delivered. The site will be responsible for the vaccine upon delivery.

Additional information is provided about the vaccination programme in the document Clinical Guidance for Covid-19 Vaccination available at www.immunisation.ie

COVID-19 vaccine Comirnaty 10 micrograms/dose concentrate for dispersion for injection (for 5 to 11 years) was granted conditional marketing authorisation by the European Commission on 26th November 2021. The SmPC is accessible at


2. Safe Handling

Comirnaty 10 micrograms/dose concentrate for dispersion for injection comes in a multi-dose vial and before use, must be diluted with 1.3 ml of sodium chloride (0.9%) solution for injection. Each box contains 10 vials and one vial (1.3 ml) contains 10 doses of 0.2 ml after dilution.

Each vial contains 1.3 ml concentrate for dispersion. Dilute with 1.3 ml of sodium chloride (NaCl 0.9%) solution for injection. After dilution the vial will contain 2.6 ml.

One 0.2 ml dose contains 10 micrograms of tozinameran, a COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for 12 doses. The National Immunisation Advisory Committee (NIAC) advises that if more than 10 doses can be safely and accurately withdrawn from a vial they can be used as valid doses.
• Each dose must contain 0.2 ml of vaccine.
• If the amount of vaccine remaining in the vial cannot provide a full dose of 0.2 ml, discard the vial and any excess volume.
• Do not pool excess vaccine from multiple vials.

3. Unopened vial

An undiluted vial of Comirnaty 10 micrograms/dose concentrate for dispersion for injection may be stored until the USE BEFORE date and time (this may be up to 10 weeks) at temperatures between +2°C and +8°C. The vials should not be refrozen.

When delivered, boxes will have a label created by the NCCS displaying the USE BEFORE date and time. The USE BEFORE date and time is the time by when the vial must be taken out from +2°C and +8°C for dilution. The USE BEFORE date is the date that should be recorded in the patient's record.

Prior to use, the unopened vials can be stored for up to 12 hours at temperatures between +8 °C and +30 °C. This is within the USE BEFORE date and time.

Handling of temperature excursions during refrigerated storage

• Stability data indicate that the unopened vial is stable for up to 10 weeks when stored at temperatures from -2 °C to +2 °C, and within the 10 weeks storage period between +2 °C and +8 °C.
• Stability data indicate the vial can be stored for up to 24 hours at temperatures of +8 °C to +30 °C, including up to 12 hours following first puncture.

This information is intended to guide healthcare professionals only in case of temporary temperature excursion.

Note:

• The USE BEFORE dates and time must be recorded in the IT system (as per the HSE SCAN ME label on the vaccine box delivered by the HSE National Cold Chain Service).

• The batch number of the vaccine must be recorded, to be selected on Scanvax.

• The batch number of the 0.9% Sodium Chloride solution must be recorded on Scanvax.
4. Diluted vial

Once diluted with sodium chloride 9 mg/ml (0.9% NaCl) solution for injection the **DISCARD Date and Time** is calculated as **12 hours** after dilution. **DISCARD Date and Time** is written on the vial which is stored at +2°C to +30°C. From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user.

The diluted vaccine should present as a white to off-white dispersion with no particulates visible. Do not use the diluted vaccine if particulates or discolouration are present.

**Note:** The doses must be administered before the Discard date and time.

5. Transportation of vaccines

**Unopened vials** can be transported during the 10 weeks storage between +2 °C to +8 °C.

**Diluted vial:** During the 12 hours in-use period after dilution the vial can be transported for 6 hours.

For additional information the following document may be consulted:

HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes (Updated 15 April 2020)

6. Consumables, Patient Information Leaflet (PIL) & Record Cards and Other Equipment

A national distribution service will provide all necessary supplies, to handle, prepare and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

**Other Equipment includes:**

**Anaphylaxis Kits**

Refer to NIAC Guidelines


The epinephrine will be provided by a pre-determined community/ hospital pharmacy as agreed by the lead governance organization CHO/HG.
Storage Equipment

A pharmaceutical fridge must be used to store vaccines. The fridge should be set to maintain the temperature at $+5^\circ C \pm 3^\circ C$, and alarms should take into account the need to maintain the temperature above $+2^\circ C$ and less than $+8^\circ C$.

 Fridges should be validated and monitored in accordance with existing local procedures.

7. Stock Control, Security & Monitoring of Wastage

A physical stock count of COVID-19 vaccine vials should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal.

All waste must be handled in such a way as to prevent theft and/or misuse, both on site and after removal from the site.

Dispose empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

8. Health & Safety

There are no special handling requirements for routine handling and dealing with spillages of Comirnaty COVID-19 vaccine.

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of Spikevax® (previously COVID-19 Vaccine) Moderna and Spikevax Original/Omicron BA.1 Guidance

- Spikevax 0.2 mg/ml dispersion for injection
- Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/ml dispersion for injection

This document is under regular review and will be updated when relevant new information becomes available. Please check www.immunisation.ie for the current version.

1. Background

Spikevax 0.2mg/ml dispersion for injection and Spike bivalent Original/Omicron BA.1 (50mcg/50mcg)/ml dispersion for injection are at a temperature of +2°C to +8°C when delivered to the site by the National Cold Chain Service (NCCS). Unopen vials can be stored for up to approximately 30 days when stored at a temperature of +2°C to +8°C. The site will be responsible for the vaccine upon delivery.

Additional information is provided about the vaccination programme in the document Clinical Guidance for COVID-19 Vaccination available at www.immunisation.ie

Spikevax 0.2 mg/ml and Spikevax Bivalent Original/Omicron BA.1 are authorised by European Medicine Agency (EMA). The SPC is accessible at https://www.ema.europa.eu/en/medicines/human/EPAR/covid-19-vaccine-moderna

2. Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of Spikevax 0.2mg/ml dispersion for injection and Spike bivalent Original/Omicron BA.1 (50mcg/50mcg)/ml dispersion for injection. Separate documents are available for other COVID-19 vaccines.
4. Purpose

The purpose of this document is to outline the management of Spikevax 0.2 mg/mL and Spikevax bivalent Original/Omicron BA.1, and to provide supporting guidance in relation to:

- Receipt & Storage
- Handling
- Transportation
- Vaccines decommissioning

This document may be used as template for local use, or may be used as reference sources to check that existing local procedures are robust and comprehensive.

4.1 Receipt & Storage

Upon arrival at your site and prior to receipt of vaccine delivery:

- Read the temperature of the fridge(s)
- Record maximum, minimum, and current temperature
- Reset after recording

For additional information please see the following document


Spikevax 0.2 mg/mL and Spikevax bivalent Original/Omicron BA.1 will be at a temperature of +2°C to +8°C when delivered to the site by the NCCS.

Note and retain details of the transportation label affixed to the delivery box.

Scan the HSE SCAN ME label with Use Before Date. This label will have been affixed onto the original box by NCCS. The USE BEFORE date and time specified on the label affixed by the NCCS on the box indicates the time by which the vaccine must be administered, irrespective of the expiry date. The USE BEFORE date reflects the duration the unopened vial can be stored at +2°C to +8°C and will be less than 30 days from delivery.

Check against the delivery docket. Place the stock in the fridge at a temperature of +2°C to +8°C, retained in original boxes to protect vials from light.
4.2  Handling & Transportation

**Spikevax 0.2 mg/ml dispersion for injection (5ml vial)**

For the primary vaccination course, one dose is 0.5 ml of Spikevax® (contains 100 micrograms of messenger RNA (mRNA) embedded in SM-102 lipid nanoparticles. On 29 October 2021, Spikevax® was authorised by the EMA for use as a booster dose (0.25mls). The booster dose (0.25mls) is half the dose used for the primary schedule.

Ten (10) doses (of 0.5 mL each) or a maximum of twenty (20) doses (of 0.25 mL each) can be withdrawn from each vial. Pierce the stopper preferably at a different site each time. Do not puncture the vial more than 20 times.

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for additional dose(s). There should be no pooling of excess vaccine volume from multiple vials.

**Spikevax bivalent Original/Omicron BA.1 (50 micrograms/50 micrograms)/mL dispersion for injection (2.5 ml vial)**

On 1 September 2022, Spikevax bivalent Original/Omicron BA.1 was authorised by the EMA for use as adapted booster dose. The adapted vaccine booster dose is 0.5ml.

Each vial (2.5ml) of Spikevax bivalent Original/Omicron BA.1 contains five doses of 0.5 ml.

Five (5) doses (of 0.5 mL each) can be withdrawn from each vial.

Both Spikevax 0.2 mg/ml and Spikevax bivalent Original/Omicron BA.1 present as 10 multi-dose vials (MDV) in original carton and will be labelled with a HSE SCAN ME label detailing the USE BEFORE date and time.

The following information applies to both Spikevax 0.2 mg/ml and Spikevax bivalent Original/Omicron BA.1:

Unopened vial can be stored at +2°C to +25°C for 24 hours.

After the first dose has been withdrawn, the vial can be stored at +2°C to +25°C for a maximum of 19 hours.

The DISCARD date and time should be written on the vial after the initial puncture calculated by adding 19 hours to the time of initial puncture. The vial once punctured can be stored at +2°C to +25°C for a maximum of 19 hours. Discard punctured vial when the discard time is reached.

Note: For sites using TrackVax, the system can accept 19 hours or midnight whatever is the first to be reached.
The USE BEFORE date and time is printed on the HSE SCAN ME label and the vaccine must be administered before this time. Record the USE BEFORE date in the patient's record.

The DISCARD date and time is calculated by adding 19 hours to time of initial puncture. The vial must be discarded once this time is reached.

Vials should not be re-frozen.

4.3 Transportation

Up to 12 hours may be used for transportation of the unopened vaccine stored at +2°C to +8°C and within the timeframe of the USE BEFORE date and time for both formulations. The NCCS delivery box will have a transportation label affixed to it, which will indicate the time of the dispatch from NCCS and the time of delivery at the site. This transportation duration must be taken into consideration for any onward transportation.

4.4 Vaccine Decommissioning

Boxes have been re-worked and decommissioned by NCCS.

5. Consumables, record cards and other equipment

These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered/supplied. A national distribution service will purchase and deliver all necessary supplies, to handle, prepare, and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

- Anaphylaxis Kits

  The epinephrine will be purchased and decommissioned by a pre-determined community/hospital pharmacy as agreed by the lead governance organization CHO/HG.

- Storage Equipment
  A pharmaceutical fridge must be used to store vaccines. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2°C to prevent freezing and remain less than +8°C. The temperature should be set to maintain +5°C +/- 3°C.

  Fridges should be validated and monitored in accordance with existing local procedures.
6. **Stock control, security and monitoring of wastage**

A physical stock count of COVID-19 vaccine vials should match the stock count recorded on the IT system. Sites will need to ensure that vaccines are stored securely at all points between receipt and use or disposal. Dispose empty vials into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

Original cartons must have their labels defaced using permanent black marker pens, and placed into appropriate waste sack for incineration, as soon as possible after they become empty.

7. **Health & Safety**

There are no special handling requirements for routine handling and dealing with SpikeVax® (Moderna). Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of JCOVDEN (JANSSEN COVID-19) Vaccine Guidance at vaccination Clinics

This document is under regular review and will be updated when relevant new information becomes available. Please check [www.immunisation.ie](http://www.immunisation.ie) for the current version.

1. Background

JCOVDEN is at a temperature of +2°C to +8°C when delivered to vaccination sites. The vial will be boxed and labelled with a HSE SCAN ME label which contains the updated shelf life also known as the **Use Before date**. The **USE BEFORE** date is calculated in NCCS by adding 11 months from date of removal from freezer. This does not exceed the manufacturer expiry date.

The site receives delivery of the vaccine at temperature of +2°C to +8°C and should continue to store at this temperature.

2. Responsibilities
It is the responsibility of the Responsible Person to ensure that this SOP is followed.

3. Scope
The scope of this document is to set a standardised protocol of procedures to be followed in the provision of the JCOVDEN Vaccine. Separate documents are available for other COVID-19 vaccines.

4. Purpose
The purpose of this document is to outline the management of the JCOVDEN® vaccine at the vaccination clinic level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Safe handling, including management of shelf life reduction processes following first puncture of the vial

The document provided may be used as a template to be adapted for local use, or may be used as reference sources to check that existing local procedures are robust and comprehensive.
4.1 Safe and temperature controlled storage
Upon arrival at your vaccination centre:

- Read the temperature of the fridge/s
- Record maximum, minimum and current temperature
- Reset after recording

For additional information the following document may be consulted:

4.2 Safe handling, including management of shelf life reduction processes following first puncture of the vial
JCOVDEN vaccine comes as a multi dose vial (MDV) containing at least 5 doses.

Receipt delivery of stock and scan stock onto the system as you unpack the delivery.

Place the stock immediately in the fridge at a temperature of +2°C to +8°C. The vial(s) should remain in their box to be protected from light, for a single period of up to 11 months (and within original expiry date).

Unopened JCOVDEN is stable for a total of 12 hours at 9°C to 25°C. It is not a recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions during the 11 month storage at 2°C to 8°C.

**DISCARD date and time** must be recorded on the vial once the vial is initially **punctured.** This is calculated by adding 3 hours to the time of first puncture. During this 3 hour period the vaccine can be stored at room temperature of up to +25°C.

Currently, Jcovden® is only available in Central Vaccination Clinics.

5. Consumables, Patient Information Leaflet (PIL), Record Cards & other equipment
These will be delivered in advance by HSE in the required quantities to match the quantity of vaccine ordered/supplied. A national distribution service will purchase and deliver all necessary supplies, to handle, prepare, and administer the vaccine including PPE and critical clinical and non-clinical consumables. These are not included in this SOP.

- Anaphylaxis Kits
Refer to National Immunisation Advisory Committee Guidelines:
In the HSE central vaccination clinics settings, the epinephrine will be purchased and decommissioned by a pre-determined community/hospital pharmacy as agreed by the lead governance organization CHO/HG.

- **Storage Equipment**
  A pharmaceutical fridge must be used to store vaccines. The set point for the fridge temperature and alarms should take into account the need to maintain the temperature above +2°C to prevent freezing and remain less than +8°C. The temperature should be set to maintain +5°C +/- 3°C.

  Fridges should be validated and monitored in accordance with existing local procedures.

**6. Stock control and Security**

A physical stock count of COVID-19 vaccine vials should be performed. In the HSE central vaccination clinics settings the physical stock count of the vaccine should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use and including disposal of vials.

Dispose empty vials after vial reconciliation, into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

**7. Health & Safety**

There are no special handling requirements for routine handling of JCOVDEN vaccine. Should a spillage occur this should be disinfected with an appropriate antiviral disinfectant (active on adenovirus).

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of Nuvaxovid® (COVID-19 vaccine Novavax) Guidance

1. Background

Nuvaxovid® (Covid-19 vaccine Novavax) will be stored and delivered by the National Cold Chain Service (NCCS) at temperature between +2°C and +8°C.


Additional information is provided about the vaccination programme in the document Clinical Guidance for COVID-19 Vaccination available at www.immunisation.ie

2. Responsibilities

It is the responsibility of the Responsible Person to ensure that this SOP is followed.

3. Scope

The scope of this document is to set a standardised protocol of procedures to be followed in the provision of Nuvaxovid. Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of Nuvaxovid® at the vaccination clinic level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Safe storage and handling, including management of shelf life reduction following first puncture of the vial

The document provided may be used as a template to be adapted for local use, or may be used as reference sources to check that existing local procedures are robust and comprehensive.
Management of Nuvaxovid (Covid-19 vaccine Novavax) Guidance

4.1 Safe and temperature controlled storage

Upon arrival at your vaccination centre:

- Read the temperature of the fridge/s
- Record maximum, minimum and current temperature
- Reset after recording.

For additional information the following document may be consulted:

4.2 Safe storage and handling, including management of shelf life reduction following first puncture of the vial

Nuvaxovid® comes as a Multi Dose Vial (MDV). An overfill is included per vial to ensure that a maximum of ten (10) doses of 0.5 mL each can be extracted.

Nuvaxovid® will be stored and delivered at temperature of +2°C to +8°C by NCCS and the EXPIRY DATE will be printed on the vial label and original carton.

Place the stock immediately in the fridge at a temperature of +2°C to +8°C. The vials should be stored upright and kept in their original box to be protected from light.

Unopened Nuvaxovid® vaccine has been shown to be stable up to 12 hours at +8°C to +25°C. Storage at 25°C is not the recommended storage or shipping condition but may guide decisions for use in case of temporary temperature excursions during storage at 2°C to 8°C.

Immediately prior to use, remove the vaccine vial from the carton in the refrigerator. The vaccine is in ready to use presentation. Gently swirl the multidose vial before and in between each dose withdrawal. Do not shake.

Opened Nuvaxovid® vaccine must display a DISCARD date and time on the vial. When the vial is first punctured, calculate the DISCARD date and time on the vial. This is done by adding 6 hours to the time of the initial puncture and this time and date must be recorded on the vial. The vaccine can be stored between 2°C to 25°C during this 6 hour period.
5. **Stock control and Security**

A physical stock count of COVID-19 vaccine vials should be performed. In the HSE central vaccination clinics settings the physical stock count of the vaccine should match the stock count recorded on the IT system.

Sites will need to ensure that vaccines are stored securely at all points between receipt and use and including disposal of vials.

Dispose empty vials after vial reconciliation, into sharps bins safely as per health care management policy. Dispose syringes and needles into sharps bins according to normal local waste management procedures.

6. **Health & Safety**

There are no special handling requirements for routine handling of Nuvaxovid® vaccine. Any unused medicinal product or waste material should be disposed of in accordance with local requirements.
APPENDIX C: ADVICE FROM THE NATIONAL IMMUNISATION ADVISORY COMMITTEE REGARDING FEVER AFTER COVID-19 VACCINATION THE NATIONAL IMMUNISATION ADVISORY VACCINATION
National Immunisation Advisory Committee

29 December 2020

Statement on fever following COVID-19 vaccination

Clinical judgement should be used based on the individual case. Carers and patients should be advised that if they have any concerns, they should seek advice from their GP.

Post immunisation fever

Vaccinated individuals should be advised that COVID-19 vaccines may cause a mild fever which usually resolves within 48 hours. This is a common, expected reaction. Isolation and further investigation are not generally required.

Fever may be managed symptomatically with an antipyretic, provided there are no other concerns.