Clinical Guidance for COVID-19 Vaccination

Comirnaty® (Pfizer BioNTech)
COVID-19 Vaccine Moderna®
Vaxzevria® (AstraZeneca)
COVID-19 Vaccine Janssen®

Version 16 11/06/2021
### Revisions since last version (15)

- Comirnaty® (Pfizer BioNTech) vaccine licensed in those aged 12-15
- Vaxzevria® (AstraZeneca) second dose interval
- Change in duration of immunity post COVID-19 infection from 6 months to 9 months.
- Capillary leak syndrome added as contraindication for Vaxzevria® (AstraZeneca)
- Symptoms of capillary leak syndrome added to the post vaccination advice
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This guidance is intended for vaccinators administering COVID-19 vaccine.

This guidance is intended for vaccinators who are 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 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, optometrists, paramedics, advanced paramedics and emergency medical technicians 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 HSE will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. GPs, GP Practice Nurses and retail pharmacists, 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.
Vaccine priority groups

In December 2020, the Government published a COVID-19 vaccination strategy and implementation plan developed by the High-Level Task Force on COVID-19 Vaccination with input from the National Immunisation Advisory Committee (NIAC) and the National Public Health Emergency Team (NPHET). It provides the provisional sequencing for groups to be vaccinated based on clinical priorities and an ethical framework to minimise harm, and maintain fairness, moral equality and reciprocity. This was updated on March 31st 2021.

NOTE: The order and the groups/individuals may change as more information becomes available. The timeframe of vaccination will depend on several factors, e.g., availability of vaccines and vaccine characteristics. Groups may be vaccinated in parallel depending on vaccine supply.

<table>
<thead>
<tr>
<th>Group</th>
<th>Key workers essential to the vaccine programme</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. People aged 65 years and older who are residents of long-term care</td>
<td></td>
</tr>
<tr>
<td>facilities (likely to include all staff and residents on site)</td>
<td></td>
</tr>
<tr>
<td>2. Frontline healthcare workers</td>
<td></td>
</tr>
<tr>
<td>3. People aged 70 and older</td>
<td></td>
</tr>
<tr>
<td>4. People aged 16-69 with a medical condition that puts them at very</td>
<td></td>
</tr>
<tr>
<td>high risk of severe disease and death</td>
<td></td>
</tr>
<tr>
<td>5. People aged 65-69 whose underlying condition puts them at a high</td>
<td></td>
</tr>
<tr>
<td>risk of severe disease and death</td>
<td></td>
</tr>
<tr>
<td>6. Other people aged 65-69</td>
<td></td>
</tr>
<tr>
<td>7. People aged 16-64 who have an underlying condition that puts</td>
<td></td>
</tr>
<tr>
<td>them at high risk of severe disease and death</td>
<td></td>
</tr>
<tr>
<td>8. Residents of long-term care facilities aged 16-64</td>
<td></td>
</tr>
<tr>
<td>9. People aged 64 years and younger in the following order:</td>
<td>People aged 16-64 living or working in crowded</td>
</tr>
<tr>
<td>i. 64-55 years ii. 54-45 years iii. 44-35 years iv. 34-25 years</td>
<td>settings</td>
</tr>
<tr>
<td>v. 24-16 years</td>
<td></td>
</tr>
</tbody>
</table>

Pregnant women should be offered COVID-19 vaccination between 14-36 completed weeks gestation following an individual benefit/risk discussion with their obstetric caregiver.
### Medical Guidance for COVID-19 Vaccination

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

1. May also include other people who have been classed as at very high risk, based on clinical judgement and an assessment of their needs
2. APECED - autoimmune polyendocrinopathy candidiasis ectodermal dystrophy
3. Additional or updated medical conditions February 2021
4. The following doses of prednisolone (or equivalent dose of other glucocorticoid) may increase the risk of severe COVID-19 disease:
   - ≥10 mg per day for more than 4 weeks with one other immunosuppressant
   - ≥20 mg per day for more than 4 weeks.


<table>
<thead>
<tr>
<th>Medical condition</th>
<th>Very high risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancer</strong></td>
<td>All cancer patients actively receiving (and/or within 6 weeks of receiving) systemic therapy with cytotoxic chemotherapy, targeted therapy, monoclonal antibodies or immunotherapies and surgery or radical radiotherapy for lung or head and neck cancer</td>
<td>Haematological - within 1 year Haematological - within 1 - 5 years Non-haematological - within 1 year All other cancers on non-hormonal treatment</td>
</tr>
<tr>
<td><strong>Chronic heart (and vascular) disease</strong></td>
<td>e.g. heart failure, hypertensive cardiac disease</td>
<td></td>
</tr>
<tr>
<td><strong>Chronic kidney disease</strong></td>
<td>On dialysis, or eGFR &lt;15 ml/min</td>
<td>With eGFR &lt;30 ml/min</td>
</tr>
<tr>
<td><strong>Chronic liver disease</strong></td>
<td>e.g. cirrhosis or fibrosis</td>
<td></td>
</tr>
<tr>
<td><strong>Chronic neurological disease or condition</strong></td>
<td>With evolving ventilatory failure (requiring non-invasive ventilation) e.g. motor neurone 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><strong>Chronic respiratory disease</strong></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><strong>Diabetes Immunocompromise due to disease or treatment</strong></td>
<td>HbA1c ≥58 mmol/mol Severe e.g. <em>Transplantation:</em> - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months <em>Genetic diseases:</em> - APECED² - Inborn errors in the interferon pathway <em>Treatment:</em> - included but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months</td>
<td>All other diabetes (Type 1 and 2) Other e.g. High dose systemic steroids⁴ Persons living with HIV</td>
</tr>
<tr>
<td><strong>Inherited metabolic diseases³</strong></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><strong>Intellectual disability⁴</strong></td>
<td>Down syndrome</td>
<td>Intellectual disability excluding Down syndrome</td>
</tr>
<tr>
<td><strong>Obesity</strong></td>
<td>BMI &gt;40 kg/m²</td>
<td>BMI &gt;35 kg/m² e.g. Schizophrenia, bipolar disorder, severe depression</td>
</tr>
<tr>
<td><strong>Severe mental illness⁴</strong></td>
<td>Sickle cell disease</td>
<td></td>
</tr>
<tr>
<td><strong>Sickle cell disease</strong></td>
<td>Sickle cell disease</td>
<td></td>
</tr>
</tbody>
</table>
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3 COVID-19 vaccines

There are currently four COVID-19 Vaccines authorised for use in Ireland. The vaccines are not interchangeable.

For vaccines that have a two dose schedule, the same vaccine should be used for both doses.

mRNA Vaccines


On 28th May 2020 the EMA granted an extension for the COVID-19 vaccine Comirnaty to include use in children aged 12 to 15. However in Ireland the vaccine is still currently recommended by the National Immunisation Advisory Committee only for those aged 16 years of age and over.


Department of Health Policy is that people aged 70 years and older should be offered an mRNA vaccine. People aged <50 years should be offered an mRNA vaccine.

Viral Vector Vaccines

Vaxzevria® (AstraZeneca) was authorised for use in the EU following a positive scientific recommendation by the EMA on 29 January 2021.


The National Immunisation Advisory Committee recommends Vaxzevria® (AstraZeneca) for people aged 50 years and older. People under 50 should be vaccinated with an mRNA vaccine


This vaccine is licensed for active immunisation to prevent COVID-19 in individuals 18 years of age and older.

The National Immunisation Advisory Committee recommends COVID-19 Vaccine Janssen for people aged 50 years and older. They also advise that it can be used in those aged 18-49 where a 2 dose vaccine schedule is not feasible. However currently in the HSE programme, only people aged 50 and older are being offered COVID-19 Vaccine Janssen. People under 50 should be vaccinated with an mRNA vaccine.

The following table outlines the vaccines in the HSE COVID-19 vaccination programme
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
- Surgical mask 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 ≥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/
- Check HPSC website for latest guidance on infection prevention and control for healthcare workers:
  https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/

5  Vaccine details, storage and instructions for preparation and administration.

Please ensure vaccines are stored between +2°C and +8°C.
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Should vaccines be exposed to temperatures outside of these parameters please contact the National Immunisation Office immediately. Contacts include:

- Achal Gupta: mobile 087 4064810
- Cliona Kiersey: mobile 087 9915452
- Mariangela Toma: mobile 087 7575679

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). When deviating from the protocols outlined in this guidance (to enable the use of pre-drawn syringes) national clinical guidance specific to CVC settings on this matter should be adhered to.

### 5.1 Comirnaty® (Pfizer BioNTech)

#### Table 1: Details of Comirnaty® (Pfizer BioNTech)

<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</td>
<td>Comirnaty® (Pfizer BioNTech)</td>
</tr>
<tr>
<td></td>
<td>Note: This vaccine was called COVID-19 mRNA BNT162b2 (Pfizer/ BioNTech) before authorisation. This name will be on early batches of the vaccine.</td>
</tr>
<tr>
<td>Constituents</td>
<td>● Polyethylene glycol/macrogol (PEG) as part of ALC-0159.</td>
</tr>
<tr>
<td></td>
<td>● ALC-0315 = (4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2- hexyldecaneoate),</td>
</tr>
<tr>
<td></td>
<td>● ALC-0159 = 2-{(polyethylene glycol)-2000}-N,N-ditradecylacetamide</td>
</tr>
<tr>
<td></td>
<td>● 1,2-Distearoyl-sn-glycerol-3-phosphocholine</td>
</tr>
<tr>
<td></td>
<td>● Cholesterol</td>
</tr>
<tr>
<td></td>
<td>● Potassium chloride</td>
</tr>
<tr>
<td></td>
<td>● Potassium dihydrogen phosphate</td>
</tr>
<tr>
<td></td>
<td>● Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>● Disodium hydrogen phosphate dihydrate</td>
</tr>
<tr>
<td></td>
<td>● Sucrose</td>
</tr>
<tr>
<td></td>
<td>● Water for injections</td>
</tr>
<tr>
<td></td>
<td>This vaccine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially ‘potassium free’.</td>
</tr>
<tr>
<td></td>
<td>This vaccine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially ‘sodium free’.</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>6 doses.</td>
</tr>
<tr>
<td></td>
<td>If more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses.</td>
</tr>
<tr>
<td>Dilution</td>
<td>Yes with 0.9% Sodium Chloride (supplied separately)</td>
</tr>
<tr>
<td>Latex</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>The vial has a rubber (bromobutyl) stopper, aluminium seal and a flip-off plastic cap. Bromobutyl is a synthetic rubber – the vial stopper does not contain latex.</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Preservatives</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dosage</td>
<td>0.3ml</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>2</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>The recommended interval between doses is 28 days (The National Immunisation Advisory Committee recommends an interval of 21 to 28 days) The minimum interval between doses is 17 days.</td>
</tr>
</tbody>
</table>

**Comirnaty® (Pfizer BioNTech) vaccine efficacy and vaccine effectiveness**

Data from the randomised Phase 3 trial demonstrated a two-dose vaccine efficacy of 95% (95% confidence interval of 90.3% to 97.6%) in those aged 16 and above. Efficacy was similar in all age groups.

A matched control study of over one million people from Israel showed vaccine effectiveness of 87% (95% CI, 55 to 100) against hospitalisation and 92% (95% CI, 75 to 100) against severe disease at 7 or more days after the second dose of vaccine.

**Comirnaty® (Pfizer BioNTech) 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 as there is no stability data for vials stored on their side.

- On arrival into the HSE National Cold Chain Service the vaccine is stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C.
- The vaccine is supplied to sites/clinics by the HSE National Cold Chain Service at +2 to +8°C with a shelf life of 1 month (31 days).
- The vaccine in each multi dose vial requires dilution with 1.8ml of 0.9% sodium chloride. This is supplied separately to the vaccine.
- Undiluted vials of Comirnaty® (Pfizer BioNTech) have a shelf life of 1 month (31 days) when stored at +2 to +8°C and another 2 hours undiluted at room temperature.
- After dilution, the vaccine should be kept at +2°C to +30°C and used within 6 hours after which the vial should be discarded.
Table 2: 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><strong>Expiry date</strong></td>
<td>The date the vaccine expires if stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C. This is 6 months from the date of manufacture. 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 = 1 month (31 days) from the time vials are removed by HSE National Cold Chain from ULT and stored at +2°C to +8°C (must be recorded on patient’s notes). Before the 1 month (31 days) has passed, vials must be removed from fridge.</td>
</tr>
<tr>
<td><strong>Maximum time allowed from removal from storage at +2°C to +8°C fridge to dilution</strong></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><strong>“Discard” date and time Maximum time allowed from dilution to expiry</strong></td>
<td>When the vaccine is diluted it must be used within 6 hours. The “discard” date and time i.e. <strong>6 hours after dilution</strong> must be written on the vial using a 24 hour format.</td>
</tr>
<tr>
<td><strong>Note:</strong></td>
<td>The labels on the first batches of vaccine have a space for date and time of dilution. These were printed before EMA authorisation. EMA has advised that “discard” date and time i.e. <strong>6 hours after dilution</strong> must be written on all vials using a 24 hour format.</td>
</tr>
<tr>
<td></td>
<td>e.g. Vial is diluted 01/01/2021 at 10.00. <strong>Discard time</strong> is 01/01/2021 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><strong>Transportation time</strong></td>
<td><strong>Undiluted vial maximum of 12 hours</strong> - cumulative time from removal from the ULT freezer to the delivery location and any subsequent movement of the undiluted vaccine, within the 1 month limit for storage at +2°C to +8°C, until time of dilution. The total transportation time from NCCS to the delivery location is written on the box. <strong>Diluted vial:</strong> maximum of 6 hours from the time of dilution (this is in addition to the maximum transportation time of 12 hours for the undiluted vial). Please note that all doses of the vaccine must be given with 6 hours.</td>
</tr>
</tbody>
</table>
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Any unused vials should be sent back to the CHO or Hospital Pharmacy in the original box. For General Practice, please return any used vials to the National Cold Chain Service at your next delivery.

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

Comirnaty® (Pfizer BioNTech) dosage, scheduling and site of vaccination

- Two doses of 0.3mls Comirnaty® should be administered intramuscularly with an interval of 28 days between doses (the National Immunisation Advisory Committee recommends an interval of 21 to 28 days)
- The minimum interval between the first and second dose is 17 days.
- The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.
- A vaccine course started with Comirnaty® should be completed with this product. COVID-19 vaccines are not interchangeable.

Table 3: 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>Evidence on efficacy for a dose interval of less than 17 days is lacking but currently the recommendation is that a 3rd dose is not indicated.</td>
</tr>
<tr>
<td>17 to 27 days</td>
<td>No further action needed</td>
</tr>
<tr>
<td></td>
<td>(Evidence from trial data is 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>

Dilution of Comirnaty® (Pfizer BioNTech)

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/ does not need to be kept in the 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 discoloration 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 more than six 0.3ml doses can be safely and accurately withdrawn from a diluted vial, they can be used as valid doses.
If it is not possible to withdraw more than six 0.3mls doses from the vial, it 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. beside the person to be vaccinated.
- 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.
- Doses should not routinely be drawn up in advance as per best practice and the manufacturer’s instructions. 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
- x 1ml syringes

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

1. Check the date and "discard time" has not expired (dilution was within last 6 hours)
2. Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
3. Attach 23 gauge blue needle to 1ml syringe
4. Withdraw 0.3ml of diluted product
5. Make sure correct dose is drawn up as smaller dose may not provide protection
6. Ensure all air bubbles have been removed before the needle is withdrawn
7. Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated
8. Administer vaccine to patient intramuscularly (See Appendix 1)
9. Dispose of used needle and syringe in a sharps bin

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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.
Clinical Guidance for COVID-19 Vaccination

Once all doses have been administered, discard the vial and record the time and date of discard (See vial traceability form https://www.hse.ie/eng/health/immunisation/hcpinfo/covid19vaccineinfo4hps/comirnaty/).

Checklist before administering 2nd dose

- dose interval
- if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.
5.2 COVID-19 Vaccine Moderna®

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 as there is no stability data for vials stored on their side.

Table 4: details of COVID-19 Vaccine Moderna®

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>mRNA</td>
<td></td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>COVID-19 Vaccine Moderna®</td>
</tr>
</tbody>
</table>
| Constituents        | Lipid SM-102 
1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC) 
1,2-Dimyristoyl-rac-glycero-3-methoxypolyethylene glycol-2000 (PEG2000 DMG) 
Tromethamol 
Tromethamol hydrochloride 
Acetic acid 
Sodium acetate trihydrate 
Sucrose 
Water for injections |
| Presentation        | The vaccine is contained in a multidose clear glass vial.                                                                                         |
| Number of doses in each vial | Up to 10 doses 
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 |
| Dilution            | NOT REQUIRED                                                                                                                                   |
| Latex               | No. The vial has a rubber stopper (chlorobutyl rubber) and a flip-off plastic cap with seal (aluminium seal). Chlorobutyl is a synthetic rubber – the vial stopper does not contain latex. |
| Preservatives       | No                                                                                                                                              |
| Dosage              | 0.5ml                                                                                                                                          |
| Number of doses required | 2                                                                                             |
| Interval between doses | 28 days is the recommended interval between doses 
24 days is the minimum interval                                                                 |
| Transportation time | Once thawed, COVID-19 Vaccine Moderna® cannot be moved from one site to another. Within the same site or campus, it can only be hand carried once with shaking and vibration minimised. The duration of this single journey must not exceed 1 hour. |
Clinical Guidance for COVID-19 Vaccination

COVID-19 Vaccine Moderna® vaccine efficacy

Data from the randomised Phase 3 trial demonstrated a two-dose vaccine efficacy for COVID-19 Vaccine Moderna® of 94.1% (95% confidence interval of 89.3% to 96.8%) in those aged 18 and above. Efficacy was similar in all age groups.

High efficacy (286%) was observed across age, sex, and ethnicity categories and among persons with underlying medical conditions.

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 as there is no stability data for vials stored on their side.

The vaccine is transported to vaccination sites/clinics frozen at -25°C to -15°C. The vaccine must be thawed prior to administration.

The vaccine may be thawed as follows:

- **In the refrigerator** (Between +2°C and +8°C) for 2 hours and 30 minutes – then the vial should sit at room temperature for 15 minutes before administration OR
- **At room temperature** (Between +8°C and +25°C) for 1 hour

Never refreeze thawed vaccine.

The person receiving the vaccine at the vaccination clinic/site should record the time and date the vaccine is received from the National Cold Chain Service. The “use before” date is 30 days from this date if the vaccine is thawed and stored at +2 to +8 °C. The “use before” date should be recorded on the vaccine box.

Once a vial is punctured to draw up the first dose, there is a maximum time of 6 hours before the vial should be discarded. 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. e.g. vial is first punctured 20/01/2021 at 11.00. Discard date and time is 20/01/2021 at 17.00

| Table 5: Storage of unopened vials of COVID-19 Vaccine Moderna® |
|----------------------|---------------------|------------------|
| Method of Vaccine Storage | Temperature          | Duration          |
| Frozen               | Between -25°C and -15°C | Until expiry date |
| Refrigerator         | Between +2°C and +8°C  | Up to 30 days (until “use before” date) |
| Room Temperature     | Between +8°C and +25°C | Up to 12 hours    |
Table 6: Storage of opened (needle punctured) vials of 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>Up to 6 hours (until discard date and time)</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +2°C and +25°C</td>
<td>Up to 6 hours (until discard date and time)</td>
</tr>
</tbody>
</table>

Table 7: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Moderna®

<table>
<thead>
<tr>
<th>Description</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry date</td>
<td>The date the vaccine expires if 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>“Use before” date and time</td>
<td>The vaccine is transported by the HSE National Cold Chain service to vaccination sites/clinics frozen at -25°C and -15°C. At vaccination sites/clinics the vaccine is stored at +2°C and +8°C and thawed. If thawed and stored between +2°C and +8°C, the unopened vaccine has a shelf life of 30 days. This “use before” date and time is 30 days from date and time of delivery of vaccines by the NCCS van driver. The recipient must record the “use before” date and time on the vaccine box. The vials must be discarded when the “use before” date and time has been reached.</td>
</tr>
<tr>
<td>Maximum time from when vaccine is thawed to expiry</td>
<td>Once the vaccine has been punctured for the first time it must be used within 6 hours. The “discard” date and time i.e. <strong>6 hours after the vial is first punctured</strong> must be written on the vial using a 24 hour format. e.g. vial is first punctured 20/01/2021 at 11.00. Discard date and time is 20/01/2021 at 17.00. Any unused or partially unused diluted vials must be discarded when this time has been reached.</td>
</tr>
</tbody>
</table>

Any unused/expired vials should be sent back to the CHO or Hospital Pharmacy in the original box.

For General Practice, please return any unused/expired vials to the National Cold Chain Service by giving at your next delivery.

Further regulatory information on COVID-19 vaccines can be found in the approved product information (Summary
Clinical Guidance for COVID-19 Vaccination

of Product Characteristics (SmPC) for health care professionals, and Package Leaflet (PL) for the public, is available via the EMA website https://www.ema.europa.eu/en

COVID-19 Vaccine Moderna® dosage, scheduling and site of vaccination

A vaccine course started with COVID-19 Vaccine Moderna® should be completed with this product. COVID-19 vaccines are not interchangeable.

Two doses of 0.5mls of COVID-19 Vaccine Moderna® are required with an interval of 28 days between doses. The minimum interval between the first and second dose is 24 days.

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

Table 8: Interval between 2 doses

<table>
<thead>
<tr>
<th>Interval between 1&lt;sup&gt;st&lt;/sup&gt; and 2&lt;sup&gt;nd&lt;/sup&gt; doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 24 days</td>
<td>Evidence on efficacy for a dose interval of less than 24 days is lacking but currently the recommendation is that a 3&lt;sup&gt;rd&lt;/sup&gt; dose is not indicated.</td>
</tr>
<tr>
<td>24-27 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 2&lt;sup&gt;nd&lt;/sup&gt; dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

Preparation of COVID-19 Vaccine Moderna®

Thaw frozen vaccine prior to preparing.

Frozen vaccine may be thawed in the refrigerator or at room temperature.

- Refrigerator: Between +2°C and +8°C for 2 hours and 30 minutes. Allow thawed vaccine stored at +2 and +8°C to come to room temperature for 15 minutes,
- Room temperature: Between +15°C and +25°C for 1 hour

Vials that have not been punctured may be kept at room temperature between +8°C and +25°C for up to 12 hours. NEVER refreeze thawed vaccine.
Clinical Guidance for COVID-19 Vaccination

STEP 1. PREPARING THE VACCINE

- Check the “use before” date and time on the box containing the vials with a colleague
- Ensure vaccine is thawed prior to preparation and administration
- Allow thawed 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 thawed vial with the date and time vial was punctured and note “discard time”
- (6 hours after first dose withdrawn when at room temperature between +2°C and +25°C) using a 24 hour format.
- Bring the vial to the vaccination table

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

Requirements for administration of vaccine

- One COVID-19 Vaccine Moderna® multidose vial (up to 12 doses)
- 12 x 70% alcohol swabs
- 12 x 23 gauge blue needles
- 12 x 1ml syringe
Clinical Guidance for COVID-19 Vaccination

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

**Unpunctured vials:** Check the use before date and ensure the vaccine is still in date.

**Punctured vials:** Check the discard time. Never use 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 1)

Dispose of used needle and syringe in a sharps bin

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

---

**Checklist before administering 2nd dose**

Check

- **dose interval** - at least 24 days for COVID-19 Vaccine Moderna® (4 day rule may be applied)

- **if diagnosis of COVID-19 since last dose - delay second dose until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic**

- **if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)**

- **if pregnant since first dose - delay second dose until at least 14 weeks of pregnancy.**

---

2 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
5.3 Vaxzevria® (AstraZeneca)

People aged less than 50 years should be offered an mRNA vaccine

Table 9: Details of Vaxzevria® (AstraZeneca)

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Replication deficient adenovirus vector*</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>Vaxzevria® (AstraZeneca)</td>
</tr>
</tbody>
</table>
| Constituents           | One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S* recombinant) 5 x 10^10 viral particles (vp) Produced in genetically modified human embryonic kidney (HEK) 293 cells.** The product contains genetically modified organisms (GMOs)**  
                          | L-Histidine 9  
                          | L-Histidine hydrochloride monohydrate Magnesium chloride hexahydrate Polysorbate 80  
                          | Ethanol Sucrose Sodium chloride  
                          | Disodium edetate dihydrate Water for injections  
                          | Vaxzevria® (AstraZeneca) does not contain egg  
                          | None of the vaccine ingredients are of human or animal origin                                                                                                                                             |
| Presentation           | Multidose clear glass vial                                                                                                                                                                                  |
| Number of doses in each vial | 10 doses  
                          | If more than ten 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                                         |
| Dilution               | NO DILUTION REQUIRED                                                                                                                                                                                        |
| Latex                  | The multidose dose vial has a halobutyl rubber stopper and an aluminium overseal with a plastic flip-off cap. Halobutyl rubber is a synthetic rubber. There is no latex in the vial or stopper |
| Preservatives          | The vaccine does not contain any preservative. Standard aseptic technique should be used for withdrawing the dose for administration.                                                                    |
| Dosage                 | 0.5 mls                                                                                                                                                                                                     |
| Number of doses required | 2                                                                                                                                                                                                          |
| Interval between doses  | The recommended interval between doses is 8 weeks*                                                                                                                                                         |

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.  
**Please refer to FAQ section 12.21  
*NIAC recommend 8-12 weeks, but that 8 weeks is preferable  
The result is a genetically modified organism (GMO) with a new combination of genetic material. These changes to the adenovirus allow the vaccine to deliver the spike protein genetic code to the cells without causing COVID-19.
Vaccine efficacy data presented to the EMA demonstrated a two-dose vaccine efficacy of 59.5% (95% confidence interval of 45.8% to 69.7%) in those aged 18 and above. There was insufficient clinical data to allow reliable calculation of efficacy in those aged 55 and older. However, as a similar immune response was shown in all age groups, including those aged 65 and older, the EMA authorised the vaccine for all adults.

The World Health Organization (WHO) Strategic Advisory Group of Experts (SAGE), subsequently reported the overall vaccine efficacy at 63.1%. There were no cases of COVID-19 hospitalisation, severe disease, or death in those aged 65 and older who received the vaccine.

Evidence shows that protection starts from approximately 3 weeks after the first dose of vaccine and persists up to 12 weeks. Studies show 76% protection overall against symptomatic COVID-19 disease in the first 90 days. Modelling showed no evidence of waning of protection in the first three months after vaccination.

A prospective population study of 5.4 million people from Scotland found that the first dose of vaccine showed effectiveness of 94% (95% CI 73 to 99) for COVID-19 related hospitalisation at 28-34 days post-vaccination.

It is generally recommended the two doses are given 8-12 weeks apart because there is evidence which shows that higher efficacy of 82% was reported when the second dose was given after 12 weeks. The threat of new variants in circulation and evidence of suboptimal protection against the delta variant after one dose of Vaxzevria® means that the shorter 8-week interval is preferable to ensure earlier protection, if practicable.1

**Vaxzevria® (AstraZeneca) storage**
The vaccine will be delivered by the National Cold Chain Service at +2°C to +8°C.

**Unopened (unpunctured) multidose vials**
- Must be stored in a pharmaceutical grade refrigerator (+2°C to +8°C)
- Vaccines must not be frozen
- Vials must be stored in the outer carton in order to protect from light.

**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 6 hours at room temperature (of up to +30°C). The product should not be returned to the refrigerator after this time3

---

1 The recommended 8 weeks and is being operationalised by the HSE on a phased basis.

---
Table 10: Definitions of terms for expiry date and usage times of Vaxzevria® (AstraZeneca)

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expiry date</td>
<td>The date the vaccine expires if stored at +2°C to +8°C This is 6 months from the date of manufacture.</td>
</tr>
<tr>
<td></td>
<td>The batch number and expiry date on the side of each vial should be recorded in the patient record.</td>
</tr>
<tr>
<td>“Discard” date and time Maximum time allowed from first puncture to expiry</td>
<td>When the vaccine is first punctured it must be used within 6 hours. Do not return to the refrigerator after this time.</td>
</tr>
<tr>
<td></td>
<td>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. This should be written on the vial e.g. Vial is first punctured on 01/01/2021 at 10.00. <strong>Discard time</strong> is 01/01/2021 at 16.00. This is the date and time that should be written on the vial.</td>
</tr>
<tr>
<td></td>
<td>Any unused or partially used vials must be discarded when this time has been reached.</td>
</tr>
</tbody>
</table>

Any unused/expired vials should be sent back to the CHO or Hospital Pharmacy preferably in the original box. For General Practice, please return any unused/expired vials to the National Cold Chain Service by giving at your next delivery.

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 (PL) for the public), is available via the EMA website [https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-astrazeneca](https://www.ema.europa.eu/en/medicines/human/summaries-opinion/covid-19-vaccine-astrazeneca)

**Vaxzevria® (AstraZeneca) dosage, scheduling and site of vaccination**

A single dose of vaccine is 0.5 ml

A vaccine course started with Vaxzevria® (AstraZeneca) should be completed with this product.

**COVID-19 vaccines are not interchangeable.**

Two doses of Vaxzevria® (AstraZeneca) are required.

The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.
Clinical Guidance for COVID-19 Vaccination

Recommended intervals between doses of Vaxzevria® (AstraZeneca)

Individuals who have already received one dose of Vaxzevria® (AstraZeneca) should receive their second dose of Vaxzevria® 8 weeks after the first dose. There is no evidence of an increased risk of Thrombosis and Thrombocytopenia Syndrome (TTS) after the second dose of Vaxzevria® (current evidence suggests the risk is much lower after the second dose). Anyone who has a second dose scheduled between 13 and 16 weeks later should attend when scheduled, because it is known that immunity does not reduce within the 16 weeks after the first dose. The interval between the first and second dose can be reduced to between 4-8 weeks if required (e.g. if it allows for the schedule to be completed by 36 completed weeks of pregnancy or for those with planned immunosuppressive therapy to allow for completion of vaccination before treatment).

Table 11: 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 24 days</td>
<td>No further action needed</td>
</tr>
<tr>
<td>24 to 27 days</td>
<td>No further action needed</td>
</tr>
<tr>
<td></td>
<td>(evidence from trial data is that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 12 weeks (84 days)</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

Preparation and administration of Vaxzevria® (AstraZeneca)

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

Requirements for administration of vaccine

- One Vaxzevria® (AstraZeneca) multidose vial (up to 12 doses)
- 12 x 70% alcohol swabs
- 12 x 23 gauge blue needles or 25 gauge orange needles
- 12 x 1ml syringes

2 The recommended interval has been reduced from 12 weeks to 8 weeks and this is currently being operationalised by the HSE on a phased basis.
Preparation and administration of 1 dose of Vaxzevria® (AstraZeneca)

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

**Check the vial**

- **Unpunctured vials**: Check the expiry date. Never use expired vaccine.
- **Punctured vials**: Check the discard time. Never use vaccine after the discard time. The vial should not be shaken but the vaccine can still be used if it has been shaken.

**Examine the vaccine**

- It should be a colourless to slightly brown, clear to slightly opaque suspension
- 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**

**Administer vaccine to the patient intramuscularly (see Appendix 1)**

**Dispose of used needle and syringe in a sharps bin**

---

Checklist before administering 1st or 2nd dose of Vaxzevria® (AstraZeneca)

Check

- dose interval
- if history of allergic reaction to the vaccine after first dose (or any new allergic reactions since first dose)
- Check dosing interval
- vaccine recipients should be informed of very rare complicated thromboembolic events that have been reported in a small number of people who have recently received Vaxzevria® (see section 11.2 for details)
- Recipients of Vaxzevria® should be advised to seek immediate medical attention if they develop symptoms suggestive of thromboembolic events (see section 11.2)

---

5 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.
5.4 COVID-19 Vaccine Janssen®

People aged less than 50 years should be offered an mRNA vaccine.

Table 12. Details of COVID-19 Vaccine Janssen®

<table>
<thead>
<tr>
<th>Title</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of vaccine</td>
<td>Adenovirus vector vaccine*</td>
</tr>
<tr>
<td>Name of vaccine</td>
<td>COVID-19 Vaccine Janssen Ad26.COV2.S</td>
</tr>
<tr>
<td>Constituents</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>Presentation</td>
<td>Multidose clear glass vial The vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 6 doses 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>Dilution</td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>No, the vaccine is latex free The vial contains a rubber stopper (chlorobutyl with fluoropolymer coated surface), aluminum crimp, and blue plastic cap</td>
</tr>
<tr>
<td>Preservatives</td>
<td>The vaccine does not contain any preservative.</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.5 mls</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>1</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>No interval – single dose schedule</td>
</tr>
</tbody>
</table>

COVID-19 Vaccine ® Janssen vaccine efficacy

The EMA licensed documentation states that pooled analysis of the randomised Phase 2/3 trials demonstrated a one-dose vaccine efficacy for COVID-19 Vaccine Janssen® against moderate COVID-19 of 66.9% (95% confidence interval of 59% to 73%) and against severe COVID-19 of 76.7% (95% confidence interval of 54.6% to 89.1%) in those aged 18 and above, 14 days after vaccination. The efficacy against severe disease increased to 85.4% (95% confidence interval of 54.2% to 96.9%) in those aged 18 and above, 28 days after vaccination.

Evidence shows that protection starts from approximately 14 days after the vaccine.
Clinical Guidance for COVID-19 Vaccination
COVID-19 Vaccine Janssen® storage

The vaccine will be delivered by the National Cold Chain Service 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 expiry date

Vials must be stored in outer carton in order to protect from light.

Vials may be stored at 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 13: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Janssen®**

<table>
<thead>
<tr>
<th>Description</th>
<th>Use before date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use before date</td>
<td>Is 3 months from date the vials were removed from the freezer and stored refrigerated at +2°C to +8°C, The use before date will be written on the vaccine box.</td>
</tr>
<tr>
<td>“Discard” date and time maximum time allowed from first puncture to expiry</td>
<td>When the vaccine is first punctured it must be used within 3 hours. Do not return to the refrigerator after this time. The “discard” date and time i.e. <strong>3 hours</strong> from first puncture of the vial, should be written on the vial using a 24 hour format. <strong>E.g. Vial is first punctured on 01/01/2021 at 10.00. Discard date and time is 01/01/2021 at 13.00. This is the date and time that should be written on the vial.</strong> Any unused or partially used vials must be discarded when this time has been reached.</td>
</tr>
</tbody>
</table>

* 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**

Any unused/expired vials should be sent back to the CHO or Hospital Pharmacy preferably in the original box.

Clinical Guidance for COVID-19 Vaccination
COVID-19 Vaccine Janssen® dosage, scheduling and site of vaccination

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

There are no data available on the use of the COVID-19 Vaccine Janssen® to complete a vaccination series initiated with another COVID-19 vaccine.

COVID-19 vaccines are not interchangeable.

Preparation and administration of COVID-19 Vaccine Janssen®

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 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 COVID-19 Vaccine Janssen® 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 of vaccine

Check the vial

**Unpunctured vials:** Check the expiry date. Never use expired vaccine.

**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 1)

Dispose of used needle and syringe in a sharps bin

Repeat for each dose

Once all doses have been administered, discard the vial and record the time and date of discard. (see session report form/vial traceability form [www.immunisation.ie](http://www.immunisation.ie))

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7 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.
6 Contraindications to COVID-19 vaccines

Comirnaty® (Pfizer BioNTech) and COVID-19 Vaccine Moderna®

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG)).

Vaxzevria® (AstraZeneca)

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80).
- A second dose of Vaxzevria® (AstraZeneca) should not be given to anyone who developed TTS after the first dose.
- People who have previously had capillary leak syndrome should not be vaccinated with Vaxzevria® (AstraZeneca).³

COVID-19 Vaccine Janssen®

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80).
- COVID-19 Vaccine Janssen® should not be given to anyone who developed TTS after the first dose of Vaxzevria® (AstraZeneca).

7 Precautions to COVID-19 vaccines

Acute severe febrile illness:

defer until recovery. NIAC guidance states

“Routine physical examination and temperature measurement of persons who appear to be healthy are not necessary prior to vaccination. Ask if the proposed recipient is well; postpone vaccination if an acute severe febrile illness is present.”

https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/chapter2.pdf

History of immediate allergic reaction to any other vaccine or injectable therapy:

Advice from a relevant specialist should be sought for a person with a history of an immediate allergic reaction to any other vaccine or injectable therapy or, if administering COVID-19 mRNA vaccines to polysorbate 80 (because of the possibility of cross reactivity with PEG). The risks should be weighed against the benefits of vaccination. They should be observed for 30 minutes after vaccination. Patients with planned immunosuppressive therapy should ideally complete vaccination two weeks before treatment. The recommended minimum interval may be used for vaccines that have a two-dose schedule.

³ The EMA conducted a safety review and advised that capillary leak syndrome be added as a contra-indication to Vaxzevria, this is a very rare condition and EMA concluded that due to risk of recurrence with Vaxzevria it should be listed as a contra-indication.
Clinical Guidance for COVID-19 Vaccination

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

Vaccination after COVID-19:

- Vaccination should be deferred until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.
- Vaccination is not contraindicated for people with persisting symptoms post COVID-19 unless there is evidence of recent clinical deterioration.
- For people aged under 65 years, vaccination may be deferred for those who are not immunocompromised for up to six months after diagnosis, symptom onset, or from the first PCR or antigen positive specimen.
- Those who have had laboratory confirmed COVID-19 infection within 9 months after a first dose of COVID-19 vaccine should complete the course.

Precautions with Vaxzevria® (AstraZeneca)

Vaxzevria® (AstraZeneca) is not recommended for those aged under 50 years, including those with medical conditions with very high or high risk of severe COVID-19 disease.

Individuals who have already received one dose of Vaxzevria® should receive their second dose of Vaxzevria® as scheduled. There is no evidence of an increased risk of TTS after the second dose of Vaxzevria® compared with the first dose (current evidence suggests the risk is much lower after the second dose). The interval between the first and second dose can be reduced to between 4-8 weeks if required (e.g. if it allows for the schedule to be completed by 36 completed weeks of pregnancy or for those with planned immunosuppressive therapy to allow for completion of vaccination before treatment).

COVID-19 Vaccine Janssen®

People aged less than 50 years, including those with underlying medical conditions should be offered an mRNA vaccine.

The National Immunisation Advisory Committee advise that in circumstances where a two-dose mRNA vaccination schedule is not a feasible alternative for those aged 18 – 49 years, the single dose COVID-19 Vaccine Janssen® can be considered. However for the HSE vaccination programme, all people aged 18-49 should be offered an mRNA vaccine.
Clinical Guidance for COVID-19 Vaccination

8 Clinical considerations for COVID-19 vaccines

8.1 Pregnancy

Pregnant women should be offered mRNA COVID-19 vaccines (Comirnaty® (Pfizer/BioNTech) or COVID-19 Vaccine Moderna®) between 14-36 weeks gestation following an individual benefit/risk discussion with their obstetric care giver.

Pregnant women are at similar risk of COVID-19 infection to non-pregnant women of the same age. However, pregnant women with COVID-19 infection are more likely to develop serious disease or to die than either pregnant women without COVID-19 or similar aged non-pregnant women with COVID-19. COVID-19 in pregnancy is a risk factor for admission to ICU and although absolute numbers are not high, they are disproportionate to the number of pregnant women in the population.

There is evidence of an increase in premature delivery and in the stillbirth rate in Ireland and the UK in 2021.

Pregnant women were not included in the initial clinical trials of the COVID-19 but trials are now taking place in pregnant women, and results are expected in the coming months.

Animal reproductive toxicology studies of the mRNA and COVID-19 Vaccine Janssen® vaccines did not identify any safety concerns. A preliminary animal reproductive toxicity study of Vaxzevria® (AstraZeneca) did not show toxicity.

There is no evidence that any COVID-19 vaccine affects the fetus or fertility.

Because there is more data available about mRNA vaccines in pregnancy, compared to viral vector vaccines, these vaccines are recommended for pregnant women; Over 96,000 mRNA vaccinations in pregnancy have been reported the US as of 13 April 2021. A similar number have received Comirnaty® (Pfizer BioNTech) in Israel. All information shows pregnancy complication rates similar to what would normally be expected. No unexpected pregnancy or infant outcomes have been observed related to COVID-19 vaccination during pregnancy. Long term follow up of vaccine recipients is on-going.

There is limited data regarding efficacy of vaccines in pregnancy but no evidence to show they are less efficacious than in the population. Emerging data indicates that the maternal COVID-19 antibodies can cross the placenta, which may offer neonatal protection.

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.

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.

8 The NIAC and the Institute of Obstetricians and Gynaecologists have developed decision aids, Q and A and an infographic to support women and their healthcare providers in decision making. These are being updated to reflect the most recent NIAC recommendations https://www.rcpi.ie/policy-and-advocacy/national-immunisation-advisory-committee/niac-and-covid-19-vaccine/
Clinical Guidance for COVID-19 Vaccination

Second dose of Vaxzevria® (AstraZeneca) in pregnancy

The advice for pregnant women who received a first dose of Vaxzevria® (AstraZeneca) is as follows:

- They should complete the vaccination course with Vaxzevria® (AstraZeneca).
- However, the interval can be between 4 and 8 weeks if this enables them to complete the vaccination schedule by 36 completed weeks of gestation.

COVID-19 vaccines are:

- not recommended for pregnant women at less than 14 completed weeks of gestation.
- not recommended for pregnant women at more than 36 completed weeks of gestation.

8.2 Breastfeeding

There is no known reason to avoid breastfeeding.

All COVID-19 vaccines can be given to women who are breastfeeding.

8.3 Fertility

There is no biologically plausible reason why the vaccines would have any effect of fertility.

8.4 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 thrombocytopenia (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](http://www.stjames.ie/services/hope/nationalcoagulationcentre)

Those with inherited coagulopathies receiving factor replacement therapy should receive it 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.

8.5 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.

---

4 The recommended interval between doses has recently been changed from 12 weeks to 8 weeks
8.6 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.

8.7 Co-administration of COVID-19 vaccines with other inactivated or live vaccines

Recent NIAC recommendations have been updated to enable co-administered of other vaccines with COVID-19 vaccines. Other vaccines may be administered with COVID-19 vaccines at the same time or at any interval. If other vaccines are being given at the same time as COVID-19 vaccines it is preferable to give them indifferent limbs.

8.8 Immunosuppression due to disease or treatment

Data are not currently available to establish vaccine safety and efficacy in these groups. Individuals with immunosuppression due to disease or treatment may be vaccinated if they have no contraindications.

People, for whom immunosuppressive therapy is planned, should ideally complete vaccination 2 weeks before treatment begins. The recommended minimum interval may be used. This also applies to individuals aged <50 who received a 1st dose of Vaxzevria® (AstraZeneca) and are awaiting their second dose.

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.

8.9 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).

8.10 People under 18 years of age

While Comirnaty® (Pfizer BioNTech) is licensed for active immunisation to prevent COVID-19 in individuals 12 years of age and older, currently the vaccine is recommended by the National Immunisation Advisory Committee from 16 years of age only. Those of 16 years and older may give their own consent. COVID-19 Vaccine Moderna®, Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® are not licensed for active immunisation to prevent COVID-19 in individuals under 18 years of age.
Clinical Guidance for COVID-19 Vaccination

8.11 Children

The Comirnaty® (Pfizer BioNTech) vaccine has been authorised for use in children aged 12-15 years by the EMA, however currently recommendations from the National Immunisation Advisory Committee have not changed and it is recommended for those aged 16 years and older. There is insufficient data on the safety and efficacy in children for COVID-19 Vaccine Moderna® or Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® in individuals less than 18 years.

Vaccination may be considered for children aged 12 years and older with serious neurodisabilities (including cerebral palsy, severe autism and Down syndrome) who spend regular time in specialised residential care settings for children with complex needs. Vaccination of other children aged 12 years and older living in these settings may also be considered.

9 Duration of protection of COVID-19 vaccines

Vaccine recipients may not be protected until:

- 7 days after the second dose of Comirnaty® (Pfizer BioNTech)
- 14 days after second dose of COVID-19 Vaccine Moderna®.
- 15 days after the second dose of Vaxzevria® (AstraZeneca) (however protection starts three weeks after the first dose)
- 14 days after COVID-19 Vaccine Janssen®
- Clinical trial follow-up is on-going to determine the length of protection from COVID-19 vaccines.

Vaccinated persons should be informed that they should continue to follow all current public health guidance to protect themselves and others.

10 Post vaccination

10.1 Recording vaccination

The individual should be given a record of vaccination and HSE advice leaflet for after vaccination.

Following a first dose of vaccine, check that the vaccinated person knows when to return for their second dose if they have received a vaccine with a two dose schedule. Vaccine administration should be recorded in the IT system.

Table 14. Recording vaccine details

<table>
<thead>
<tr>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>COVID-19 Vaccine Moderna®</th>
<th>Vaxzevria® (AstraZeneca)</th>
<th>COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use before date and time of vaccine</td>
<td>Use before date of vaccine</td>
<td>Expiry date of vaccine</td>
<td>Use before date of vaccine</td>
</tr>
<tr>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
</tr>
<tr>
<td>Batch number of Sodium Chloride diluent</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Clinical Guidance for COVID-19 Vaccination

**Comirnaty® (Pfizer BioNTech)**

The *use before* date and time of the vaccine must be recorded in the IT system (The *use before* date and time will be stamped on the vaccine box delivered by HSE National Cold Chain Service). The batch number of the vaccine must be recorded.

The batch number of the 0.9% Sodium Chloride solution should also be recorded.

**COVID-19 Vaccine Moderna®**

The *use before* date of the vaccine must be recorded in the IT system (the use before date and time should be written on the vaccine box by the person receiving the vaccine at the vaccination clinic). The batch number of the vaccine must be recorded.

**Vaxzevria® (AstraZeneca)**

The expiry and batch number of the vaccine must be recorded on the IT system.

**COVID-19 Vaccine Janssen®**

The use before date of the vaccine must be recorded in the IT system (the use before date will be labelled on the vaccine box delivered by HSE National Cold Chain Service). The batch number of the vaccine must be recorded.

### 10.2 Observation period

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

NIAC advises the following in relation to required period of observation after vaccine administration:

- Those with no history of anaphylaxis from any cause: 15 minutes of observation
- Those with a history of anaphylaxis (serious systemic allergic reaction requiring medical intervention) from any cause: 30 minutes of observation
- Those with immediate itching, swelling or urticarial reaction at the vaccination site: 30 minutes or longer as clinically indicated
11 Adverse reactions

11.1 Adverse reactions of COVID-19 vaccines

The adverse events are listed below in Table 15 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).

Table 15: 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>COVID-19 Vaccine Moderna®</th>
<th>Vaxzevria® (AstraZeneca)</th>
<th>COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very Common (≥ 1/10)</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 tenderness, pain, warmth, pruritus, bruising</td>
<td>Local: injection site pain</td>
</tr>
<tr>
<td></td>
<td>General: arthralgia, fatigue, fever, headache, myalgia, diarrhoea</td>
<td>General: fatigue, headache, myalgia, arthralgia, fever, chills, nausea and vomiting</td>
<td>General: fatigue, malaise, feverishness, chills, myalgia, arthralgia, nausea, headache</td>
<td>General: headache, malaise, myalgia, fatigue</td>
</tr>
<tr>
<td>Common (≥ 1/100 to &lt; 1/10)</td>
<td>Local: injection site erythema, injection site urticaria, injection site rash</td>
<td>Local: injection site swelling,</td>
<td>Local: injection site erythema, injection site swelling</td>
<td>Local: Injection site erythema, injection site swelling</td>
</tr>
<tr>
<td></td>
<td>General: nausea, vomiting</td>
<td>General: rash</td>
<td>General: vomiting, diarrhoea, fever (measured fever ≥38°C), thrombocytopenia*</td>
<td>General: cough, fever, chills, joint pain,</td>
</tr>
<tr>
<td>Uncommon (≥ 1/1,000 to &lt; 1/100)</td>
<td>Local: injection site pruritus</td>
<td>Local: injection site pruritus</td>
<td>General: lymphadenopathy, decreased appetite, somnolence, dizziness, rash, pruritus, hyperhidrosis,</td>
<td>General: Tremor, sneezing, oropharyngeal pain, rash, hyperhidrosis, muscle pain, pain in extremities, back pain, asthenia, malaise</td>
</tr>
</tbody>
</table>
Rare (≥ 1/10,000 to < 1/1,000)

<table>
<thead>
<tr>
<th></th>
<th>General: acute peripheral facial paralysis/Bell’s Palsy, facial swelling in those who have had dermatological fillers</th>
<th>General: acute peripheral facial paralysis/Bell’s Palsy, facial swelling in those who have had dermatological fillers</th>
<th>General: Hypersensitivity, urticarial,</th>
</tr>
</thead>
</table>

Very rare (< 1/10,000)

<table>
<thead>
<tr>
<th></th>
<th>Thrombosis in combination with thrombocytopenia**</th>
<th>Thrombosis in combination with thrombocytopenia**</th>
</tr>
</thead>
</table>

Not known, cannot be estimated from the available data

<table>
<thead>
<tr>
<th></th>
<th>Anaphylaxis</th>
<th>Hypersensitivity Anaphylaxis</th>
<th>Anaphylaxis</th>
</tr>
</thead>
</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, splanchic vein thrombosis, as well as arterial thrombosis. See section 11.2 for further information.

*** Capillary leak syndrome will be added to the licensed documentation by the EMA as a very rare adverse event

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.

Table 16 lists the most frequent adverse reactions reported during clinical trials.

**Table 16: Details of most frequent adverse reactions reported during clinical trials of COVID-19 Vaccines**

<table>
<thead>
<tr>
<th></th>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>COVID-19 Vaccine Moderna®</th>
<th>Vaxzevria® (AstraZeneca)</th>
<th>COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Most frequent adverse reactions reports (percentage)</td>
<td>injection site pain (&gt;80%)</td>
<td>injection site pain (&gt;90%)</td>
<td>injection site tenderness (&gt;60%)</td>
<td>injection site pain (&gt;40%)</td>
</tr>
<tr>
<td></td>
<td>fatigue (&gt;60%)</td>
<td>fatigue (&gt;70%)</td>
<td>fatigue (&gt;50%)</td>
<td>fatigue (&gt;30%)</td>
</tr>
<tr>
<td></td>
<td>headache (&gt;50%)</td>
<td>headache (&gt;60%)</td>
<td>headache (&gt;50%)</td>
<td>headache (&gt;30%)</td>
</tr>
<tr>
<td></td>
<td>myalgia and chills (&gt;30%)</td>
<td>myalgia (&gt;60%)</td>
<td>myalgia (&gt;50%)</td>
<td>myalgia (&gt;30%)</td>
</tr>
<tr>
<td></td>
<td>arthralgia (&gt;20%)</td>
<td>arthralgia (&gt;40%)</td>
<td>arthralgia (&gt;30%)</td>
<td>arthralgia (&gt;20%)</td>
</tr>
<tr>
<td></td>
<td>pyrexia and injection site swelling (&gt;10%)</td>
<td>pyrexia and injection site swelling (&gt;15%)</td>
<td>pyrexia (&gt;15%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>axillary swelling/tenderness (&gt;20%)</td>
<td>injection site swelling and redness (&gt;10%)</td>
<td>injection site swelling and redness (&gt;15%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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These were usually mild or moderate in intensity and resolved within a few days after vaccination. A slightly lower frequency of adverse events was associated with greater age.

A higher rate of pyrexia (after Comirnaty®) and local and systemic adverse events (after COVID-19 Vaccine Moderna®) were seen after the second dose. NIAC advises consideration to staggering healthcare worker vaccinations.

A higher rate of pyrexia and local and systemic adverse events were seen after the first dose of Vaxzevria® (AstraZeneca).

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.

11.2 Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® and cases of Thrombosis and Thrombocytopenia Syndrome (TTS)

The National Immunisation Advisory Committee has issued new recommendations in relation to Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® following the reports of the European Medicines Agency (EMA) of rare thromboembolic events associated with thrombocytopenia after vaccination, now called Thrombosis and Thrombocytopenia Syndrome (TTS) and review of data from the US, and the EMA in relation to COVID-19 Vaccine Janssen®.

These events are very rare and overall, the benefits of COVID-19 vaccination far outweigh the potential risks.

For Vaxzevria® (AstraZeneca), the EMA estimates the risk of TTS after vaccination to be around 1 in 100,000. The risk of this rare condition is higher in younger people. Preliminary UK evidence suggests that the risk of TTS may not be higher and is possibly substantially lower (1.6/ million) after the second dose.

For COVID-19 Vaccine Janssen®, based on recent data from the United States, the estimated risk of TTS after vaccination is 1 in 312,000. The risk of this rare condition is higher in younger people, especially women.

The clinical features of TTS include cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis and thrombosis at other sites in combination with thrombocytopenia. CVST and thrombosis without thrombocytopenia can occur in the general population, however the biological mechanism in these and other thrombosis such as a deep vein thrombosis differs from that in TTS.

The risks associated with COVID-19 increase with age and are much greater than the risk of TTS associated with either vaccine. The risk of TTS appears higher in younger age groups. These are the groups where risk of severe
COVID-19 outcome is less, although the age-related risk of long-COVID is unknown. Although most cases have been reported in females, this may be because more women have been vaccinated. Cases have been reported in men.

There is no evidence of an increased risk for those with clotting or platelet disorders e.g. idiopathic or heparin induced thrombocytopenia, autoimmune conditions, history of cerebral venous sinus thrombosis, acquired or hereditary thrombophilia, or antiphospholipid syndrome.

However, the risk/benefit of these vaccines is different in different age groups therefore NIAC recommended that these vaccines should be given to people aged 50 years and older, and that younger people should be offered an mRNA vaccine.

Early recognition and prompt treatment are important in the management of TTS. Clinical treatment guidelines have been developed, and appropriate management has improved the outcome. Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia.

- Recipients of Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® 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 Vaxzevria® (AstraZeneca).

  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).
11.3 Vaxzevria and very rare cases of Capillary Leak Syndrome

The EMA’s safety committee (PRAC) released their report on 11th June 2021 of an in-depth review of 6 cases of capillary leak syndrome in people who had received Vaxzevria. Most of the cases occurred in women and within 4 days of vaccination. Three of those affected had a history of capillary leak syndrome and one of them subsequently died. This is very rare: as of 27 May 2021, more than 78 million doses of Vaxzevria had been administered in the EU/EEA and the UK, and just 6 cases were identified by the EMA.

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 a very rare syndrome called capillary leak syndrome, must not be vaccinated with Vaxzevria® vaccine (AstraZeneca). The Committee also concluded that capillary leak syndrome should be added to the product information as a new side effect of the vaccine, together with a warning to raise awareness among healthcare professionals and patients of this very rare risk.

Recommendations

- **Any authorised COVID-19 vaccine, including Vaxzevria® (AstraZeneca), is recommended for those aged 50 years and older including those with medical conditions with very high or high risk of severe COVID-19 disease.**
- **An mRNA vaccine should be offered to those aged 16-49.**
- **For those aged 18 to 49 years the single dose COVID-19 Vaccine Janssen® can be considered if a two-dose mRNA vaccination schedule is not feasible (this is not being implemented by the HSE so everyone aged 18-49 should be offered an mRNA vaccine)**
- **A second dose of Vaxzevria® (AstraZeneca) should not be given to anyone who developed unusual blood clots with low platelets after the first dose. COVID-19 Vaccine Janssen® should not be given to anyone who developed TTS after the first dose of Vaxzevria®.**
- **Vaxzevria® is contraindicated in people with a history of Capillary Leak Syndrome**

Recommendations for people who have already received a 1st dose of Vaxzevria® (AstraZeneca)

- **Individuals who have already received one dose of Vaxzevria® (AstraZeneca) should receive their second dose of Vaxzevria® as scheduled. There is no evidence of an increased risk of Thrombosis and Thrombocytopenia Syndrome (TTS) after the second dose of Vaxzevria® compared with a first dose (current evidence suggests the risk is much lower with the second dose).**
- **The interval between the first and second dose can be reduced to between 4-8 weeks if required (e.g. if it allows for the schedule to be completed by 36 completed weeks of pregnancy or for those with planned immunosuppressive therapy to allow for completion of vaccination before treatment).**
- **Healthcare professionals and vaccine recipients should be informed that very rare, complicated thromboembolic events have occurred in a small number of people who have recently received Vaxzevria®.**
- **Healthcare professionals should be alert to the signs and symptoms of thromboembolism and/or thrombocytopenia and report any suspected adverse reactions to the Health Products Regulatory Authority.**
- **Healthcare professionals should be aware of the signs and symptoms of capillary leak syndrome**
- **Healthcare professionals should tell people receiving the vaccine that they must seek medical attention if they...**
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have the following symptoms in the days after vaccination, which may be associated with feeling faint (due to low blood pressure):

- oedema in the extremities
- sudden weight gain.

• People who have been vaccinated with Vaxzevria should seek immediate medical assistance if they experience rapid swelling of the arms and legs or sudden weight gain in the days following vaccination. These symptoms are often associated with feeling faint (due to low blood pressure).

11.4 Reporting adverse reactions

The Health Products Regulatory Authority (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. As much information as is known should be provided, and where possible, the vaccine batch number should be included.

11.5 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. Vital signs should be recorded and the vaccine recipient should be reviewed by a medical practitioner.

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 is 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/nirf-01-v11-person.pdf

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.
Differentiating between a reaction to the vaccine and symptoms of COVID-19 disease

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 and isolation and further investigation is not required unless COVID-19 is suspected.

If the fever lasts for more than 48 hours, or if other symptoms of COVID-19 are present, the person should self-isolate and seek medical advice.

As has always been recommended, any fever after vaccination should be monitored and if individuals are concerned about their health at any time, they should seek medical advice.

See Appendix 4 for a statement from the National Immunisation Advisory Committee.

Effect of COVID-19 vaccines on COVID-19 tests

Receiving a COVID-19 vaccine will not result in a false positive PCR or antigen COVID-19 test.

Comirnaty® (Pfizer BioNTech) and COVID-19 Vaccine Moderna® are mRNA vaccines. They encode the spike protein of the virus that, when expressed on the cell surface, provokes generation of neutralising antibodies and activation of T-cells. The mRNA vaccines are rapidly degraded.

Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® contain a modified adenovirus that binds to the surface of human cells and delivers the genetic code for the coronavirus spike protein, where it is processed to form the spike protein itself.

The spike protein is not a molecular target of either PCR or antigen COVID-19 tests. The antibodies produced following vaccination may affect the result of a COVID-19 antibody test, but only if the test looks for antibodies against the spike protein of the coronavirus.
14 Guidance for vaccination of those who are contacts of a case of COVID-19

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

Asymptomatic close contacts of cases of COVID-19 may receive COVID-19 vaccine. It is preferable to proceed with vaccination of residents of long term care facilities and for frontline healthcare workers who are contacts given the risk of infection associated with their circumstances and the risk that they may repeatedly be contacts. This is subject to appropriate Infection Prevention and Control precautions to protect the vaccinator and other vaccine recipients.

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. This applies also to healthcare staff who have undergone serial testing.

For other settings including general practice and central vaccination clinics or hubs, vaccination of close contacts should be deferred until the period of restriction of movements has ended.

Vaccination is a low contact clinical activity so following IPC measures to be applied which include

- Hand hygiene
- The seating area to be cleaned as per the HPSC 2021 Interim Guidance on Infection Prevention and Control for the Health Service Executive V1.3 available at [https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/](https://www.hpsc.ie/a-z/respiratory/coronavirus/novelcoronavirus/guidance/infectionpreventionandcontrolguidance/hseinfectionpreventionandcontrolguidanceandframework/)
15  Frequently asked questions about Covid-19 vaccines

15.1  Should people who have had COVID-19 infection be offered COVID-19 vaccine?

Yes. People who have had COVID-19 infection should be offered COVID-19 vaccines.

Vaccination should be deferred until clinical recovery from COVID-19 and 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 who have had laboratory confirmed COVID-19 infection within 9 months after a first dose of COVID-19 vaccine should complete the course.

15.2  What if somebody is diagnosed with COVID-19 infection after a first dose of vaccine?

Vaccination should be deferred until clinical recovery from COVID-19 and at least four weeks after diagnosis or onset of symptoms, or four weeks from the first PCR positive specimen in those who are asymptomatic.

- For those who are aged under 65 years and are not immunocompromised who have had confirmed SARS-CoV-2 infection (symptomatic or asymptomatic), vaccination may be deferred, if the person vaccinated chooses to do so, for up to nine months after diagnosis, symptom onset, or from the first PCR or antigen positive specimen for those with asymptomatic infection. This is because there is evidence of natural immunity for up to nine months after natural infection.

Those who have had laboratory confirmed COVID-19 infection within 6 months after a first dose of COVID-19 vaccine should complete the course

15.3  What if the second dose of COVID-19 vaccine is administered at less than the recommended interval?

15.3.1 Comirnaty® (Pfizer BioNTech)

The advice of the National Immunisation Advisory Committee is that evidence of efficacy of doses given before 17 days is lacking. However, there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore a further dose is not required. This should be reported to HPRA and an incident report form completed.

If a dose is given between 17 and 27 days, this is considered a valid dose.
15.3.2 COVID-19 Vaccine Moderna®

The advice of the National Immunisation Advisory Committee is that evidence of efficacy of doses given before 24 days is lacking. However, there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore, a further dose is not required. This should be reported to HPRA and an incident report form completed.

If a dose is given between 24 and 27 days, this is considered a valid dose.

15.3.3 Vaxzevria® (AstraZeneca)

The advice of the National Immunisation Advisory Committee is that evidence of efficacy of doses given before 24 days is lacking. However, there is also no safety and efficacy date in relation to repeating vaccination in this situation (giving a total of 3 doses). Therefore, a further dose is not required. This should be reported to HPRA and an incident report form completed.

If a dose is given between 24 and 27 days, this is considered a valid dose.

15.4 What if the second dose of a COVID-19 vaccine is administered at longer than the recommended interval?

If the interval between doses is longer than the recommended interval, the second dose should still be given. The course does not need to be restarted.

15.5 What if the vaccine leaks during administration?

If some of the vaccine leaks out of the syringe during administration this is not a valid dose. A further dose of the vaccine should be administered at a separate site at the same visit.

15.6 What if a vaccine is given after the expiry date of after the use before or discard time?

If a vaccine is given after the expiry date or after the use before or discard date and time it is considered an invalid dose, and the dose should be repeated that day or as soon as possible.

This should be explained to the person and a correctly diluted dose of the vaccine should be given as soon as possible. This should be reported to HPRA and an incident report form completed.
15.7 What if the whole multi-dose vial of vaccine is administered instead of the recommended dose?

Trial data showed that higher doses of a similar vaccine were not harmful but the person is more likely to have more local reactions with very painful arms being reported.

The person should be reassured that this is not harmful but that they are more likely to experience pain in their injected arm. They should be given their second dose of vaccine according to the recommended schedule. This should be reported to HPRA and an incident report form completed.

15.8 What if only the diluent of Comirnaty® (Pfizer BioNTech) is given?

The diluent for Comirnaty® (Pfizer BioNTech) is sodium chloride, which is salt and purified water so no adverse reactions would be expected.

This should be explained to the person and a correctly diluted dose of the vaccine should be given as soon as possible. This should be reported to HPRA and an incident report form completed.

15.9 What if an over-diluted Comirnaty® (Pfizer BioNTech) vaccine is administered?

In this case, the person will not have received a sufficient dose of vaccine for protection.

This should be explained to the person and a correctly diluted dose of the vaccine should be given as soon as possible. This should be reported to HPRA and an incident report form completed.

15.10 What if a person under 16 years is given Comirnaty® (Pfizer BioNTech) vaccine inadvertently?

The vaccine is currently licensed for those aged 12-15 however it is not currently routinely recommended by the National Immunisation Advisory Committee for this age group. However as it is licensed in this age group, the person and parent/guardians should be informed. A HSE incident form should be completed but this does not require reporting to HPRA.
15.11 What if a person under 18 years is given COVID-19 Vaccine Moderna® or Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® inadvertently?

If a person under the age of 18 years receives the vaccine inadvertently, this should be reported to the HPRA and an incident form completed. The person (and their parents/guardians if less than 16 years old) should be advised regarding the common adverse events expected after vaccination. If Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® is given inadvertently, they should be advised of the clotting events reported very rarely after vaccination, and of the symptoms and signs to be aware of, and to seek urgent medical attention should these appear.

15.12 Will a booster dose of COVID-19 vaccines be needed?

The need for and timing of booster doses has not been established. No additional doses beyond the two-dose primary series (or one dose for COVID-19 Vaccine Janssen®) are recommended at this time.

15.13 What if a woman becomes pregnant between the first and second dose of a COVID-19 vaccine?

If a woman reports that they are pregnant between the first and second dose, this should be reported to the Health Products Regulatory Authority (www.hpra.ie).

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryo/foetal development, parturition or post-natal development. The available safety data do not indicate any safety concern or harm to pregnancy, although there is insufficient evidence to recommend routine use of COVID-19 vaccines during pregnancy.

If a woman has received a first dose of a COVID-19 vaccine, they should be advised to speak to their Obstetric care giver regarding the risks and benefits of receiving the second dose of COVID-19 vaccine, once they are at or over 14 weeks gestation. For vaccines that have a two-dose schedule, the second COVID-19 vaccine dose should not be given while less than 14 weeks or more than 36 completed weeks of gestation.

15.14 Does a woman who wishes to conceive need to leave any interval after getting COVID-19 vaccines before getting pregnant?

It is not necessary to leave any interval after having the vaccine and becoming pregnant. If a woman becomes pregnant following the first dose, they should wait until 14 weeks or after to get the second dose and should discuss the risks and benefits with their Obstetrician or GP.
15.15 What if someone has a history of anaphylaxis or severe allergic reaction to a type of food - can they receive a COVID-19 vaccine?

A history of anaphylaxis or severe allergic reaction to a type of food (e.g. egg allergy) is not a contraindication to vaccination (see Immunisation Guidelines for Ireland from the National Immunisation Advisory Committee. [https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/covid19.pdf].

Persons with such a history can receive a COVID-19 vaccine. They should be monitored for a period of 30 minutes after vaccination.

See also Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions [https://www.rcpi.ie/news/releases/frequently-asked-questions-about-covid-19-vaccines-for-people-with-pre-existing-allergic-conditions/]

15.16 What if someone has had a reaction to a first dose of vaccine, should they get the second dose of the vaccine?

The contraindications and precautions to vaccination are detailed in section 4; these are as per the recommendations of the National Immunisation Advisory Committee.

If someone has had a reaction to the first dose of vaccine but it is not listed as a contraindication, then they can receive the second dose of the vaccine.

15.17 Where can COVID-19 vaccine be given in the event that a person cannot receive the vaccine in the deltoid muscle?

In the event that a person cannot receive the vaccine in the deltoid muscle, the vaccine can be given into the vastus lateralis muscle.

15.18 What size needle should be used to vaccinate people with an elevated BMI?

If it is available, it is recommended to use a 23-25 gauge 40mm needle when vaccinating females >90kg and males >120kg. If a 38-40 mm needle is not available, a 23-25 gauge 25mm needle should be used.

(As an example, the quadrivalent inactivated influenza flu vaccine that is licensed and used in Ireland and in Europe comes in a prefilled syringe with a fixed needle attached, and the needle is not the longer 40mm in length).
15.19 Can mRNA vaccines like Comirnaty® (Pfizer BioNTech) and COVID-19 Vaccine Moderna® interact with a person’s DNA?

No, they cannot. The mRNA contained in these vaccines does not enter the nucleus of human cells, which is where DNA is contained. mRNA does not interact with a person’s DNA. The cell breaks down and gets rid of the mRNA soon after it is finished using the instructions.

15.20 Can viral vector vaccines like Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® interact with a person’s DNA?

No, they cannot. The viral vector enters the body’s cells and delivers the genetic code for the spike protein. The human cells then produce the spike protein but there are no changes to the human DNA.

15.21 Can COVID-19 vaccines affect fertility?

As explained in section 12.19 and 12.20 there is no biologically plausible reason why the vaccines would affect fertility. The European Medicines Agency licensed documentation states that animal studies do not indicate direct or indirect harmful effects on fertility.

15.22 Do Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® contain genetically modified organisms?

Yes. Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® contain genetically modified adenoviruses. Two genetic alterations have been made in order to make the vaccines:

- Genes essential for adenovirus replication have been deleted.
- The coronavirus (SARS-CoV-2) spike protein gene has been added.

The results for both vaccines are a genetically modified organism (GMO) with a new combination of genetic material. These changes to the adenovirus in each of the vaccines allow the vaccines to deliver the spike protein genetic code to the cells without causing COVID-19.

15.23 Does Vaxzevria® (AstraZeneca) contain cells of human embryonic origin?

No. The foetal cells were used only to begin the cell strains that were used in the preparation of the vaccine virus. Since that time (the early 1970s) the cell lines have grown independently. The descendant cells are not the cells of the terminated foetus. There has been no further use of foetus cells to develop the vaccine.

The cell-lines used in Vaxzevria® (AstraZeneca) are HEK (human embryonic kidney) 293 cell lines, which were started
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in the 1970s using small quantities of kidney cells taken from a foetus following a termination. The termination was legal and agreed to by the mother, and it was not performed for the purpose of vaccine development.

The original foetal cells have long since disappeared. None of these cells remain at the time the vaccine is administered.

Other vaccines are developed using cell lines that were originally of foetal origin e.g. MMR vaccine.

The Irish Catholic Bishops Conference has released a statement that it is morally permissible for Catholics to accept a vaccine which involves the use of foetal cell-lines, especially if the potential risk to life or health is significant, as in the case of a pandemic. For full statement see https://www.catholicbishops.ie/2021/01/19/bishops-conference-statement-welcoming-vaccines-for-the-common-good-2/

15.24 Does COVID-19 Vaccine Janssen® contain cells of human embryonic origin?

No. The foetal cell lines were used only to begin the cell strains that are used in the preparation of the adenovirus vector. Since that time (the late 1980s) the cell lines have grown independently. The descendant cells are not the cells of the terminated foetus.

The cell line in the COVID-19 Vaccine Janssen® are PER.C6 line. The PER.C6 cell line is derived from human embryonic retinal cells, originally from the retinal tissue of an 18 week old foetus from a termination in 1985.

The original foetal cells have long since disappeared. None of these cells remain at the time the vaccine is administered.

Other vaccines are developed using cell lines that were originally of foetal origin e.g. MMR vaccine.

The Irish Catholic Bishops Conference has released a statement that it is morally permissible for Catholics to accept a vaccine which involves the use of foetal cell-lines, especially if the potential risk to life or health is significant, as in the case of a pandemic. For full statement see https://www.catholicbishops.ie/2021/01/19/bishops-conference-statement-welcoming-vaccines-for-the-common-good-2/

15.25 Can people who have recently had a blood clot or are taking blood thinning treatments receive Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®?

Yes, they can still have the Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® if they have recently had a blood clot or are on blood thinning treatments. There is no reason to delay vaccination.

Like anyone who has received Vaxzevria® or COVID-19 Vaccine Janssen® or , they should be aware of the symptoms
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to look out for and to seek urgent medical attention in the few weeks after receiving the vaccine if they experience any of the following:

- 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

8 The only exception to this is if they developed an unusual blood clot with low platelets after a previous dose of Vaxzevria® (AstraZeneca)

15.26 Can people who have a condition or are on a treatment that may make them more likely to get a blood clot receive Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®?

Yes, they can still have Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®. There is no reason to delay vaccination. Like anyone who has received Vaxzevria® or COVID-19 Vaccine Janssen®, they should be aware of the symptoms to look out for as listed above and seek urgent medical attention if they experience any of these.

There is no evidence that those with clotting or platelet disorders are at an increased risk e.g. idiopathic or heparin induced thrombocytopenia, autoimmune conditions, history of cerebral venous sinus thrombosis unrelated to vaccination, acquired or hereditary thrombophilia, or antiphospholipid syndrome.

15.27 Can people with a family history of thromboembolic disease receive Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®?

Yes, they can still have Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®. There is no reason to delay vaccination. Like anyone who has received Vaxzevria® or COVID-19 Vaccine Janssen®, they should be aware of the symptoms to look out for as listed above and seek urgent medical attention if they experience any of these.

15.28 What advice can we give people under 50 who have already received a first dose of Vaxzevria® (AstraZeneca)?

They should receive their second dose of Vaxzevria® (AstraZeneca) 12 weeks after the first dose. There is no evidence of an increased risk of TTS after the second dose of Vaxzevria® (current evidence suggests the risk may be much lower after the second dose). Anyone who has a second dose scheduled between 13 and 16 weeks later should attend when scheduled, because it is known that immunity does not reduce within the 16 weeks after the first dose. The interval between the first and second dose can be reduced to between 4-12 weeks if required (e.g. if it allows for the schedule to be completed between 14-36 completed weeks of pregnancy or imminent immunotherapy)
15.29 Should a person who has already received a first dose of Vaxzevria® (AstraZeneca) be offered a different vaccine for their second dose?

There is currently not sufficient evidence regarding safety and efficacy to recommend the use of a heterologous vaccination strategy (using a different vaccine for the first and subsequent doses of a multi-dose schedule). NIAC will continue to review the evidence as it becomes available.

15.30 Would you recommend taking paracetamol before being vaccinated?

It is not recommended that over the counter medicines such as paracetamol or ibuprofen are taken before being vaccinated with a COVID-19 vaccine for the purposes of preventing potential vaccine related side effects. However, if you are taking any of these medications regularly as prescribed by a doctor do continue to take them as usual.

15.31 Can other vaccines be co-administered with COVID-19 vaccines?

Yes, recent NIAC recommendations have been updated to enable co-administered of other vaccines with COVID-19 vaccines. Other vaccines may be administered with COVID-19 vaccines at the same time or at any interval. If other vaccines are being given at the same time as COVID-19 vaccines it is preferable to give them indifferently limbs.
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16 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


Health Products Regulatory Authority. Human Medicines Adverse Reaction Report

HPSC COVID-19 guidance www.hpsc.ie
Appendix 1. Intramuscular injection technique
Intramuscular (IM) injection technique

All vaccinators must be competent in IM injection technique. Below is a reminder of IM injection technique. Note: COVID-19 vaccine should be given IM only.

1. **Apply standard aseptic technique throughout the procedure.**

2. **It is not necessary to use gloves** if the vaccinator’s and patient’s skin is intact.

3. **It is not necessary to use a skin disinfectant e.g. alcohol swabs.**
   - 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 will have evaporated.

4. **Land mark the injection site in the deltoid muscle:**
   - Two finger widths down from the acromion process; the bottom edge is at an imaginary line drawn from the axilla
   - Injection site: 5cms below acromion process

5. **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.

   NOTE: COVID-19 vaccine should be given by IM only.

6. **Use the dominant hand to inject the medication.** This ensures control of the needle and syringe during the procedure.

7. Hold the syringe firmly between thumb and forefinger, with heel of hand resting on the thumb of the non-dominant hand. This ensures a 90-degree angle is achieved and the correct site is targeted

8. Insert the needle smoothly and swiftly.

9. Inject at a 90-degree angle, to ensure the medication reaches the muscle. Inject medication over 1-2 seconds.

10. After removing the needle, use gentle pressure with a cotton ball or gauze. Do not massage the injection site.

11. If there is a leakage at the injection site after withdrawal of needle: apply light pressure with gauze.

NIAC recommendations:

“It is not necessary to use gloves for vaccine injections, unless contact with potentially infectious body fluids is possible, or unless the health care worker has an infected lesion on the hand. If gloves are worn they should be changed for each patient.

If the skin at the injection site is visibly dirty it should be cleaned with soap and water. There is no need to use a disinfectant e.g. alcohol swabs.

If an alcohol swab is used, injection should be delayed for ≥30 seconds, to ensure the alcohol will have evaporated.”

---

Swift needle entry

Slow injection of medication

Swift needle withdrawal

Less pain

Read the guidelines
Appendix 2. SOP
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® (Pfizer/BioNTech) COVID-19 will be delivered at a temperature of +2 °C to +8 °C by the National Cold Chain Service (NCCS) to the site. The site will take ownership of 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

Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine was granted conditional marketing authorisation by the European Commission on 21 December 2020: The SmPC is accessible at https://www.ema.europa.eu/en/medicines/human/EPAR/comirnaty

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 Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine. Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of Comirnaty® vaccine at the vaccination centre level and to provide supporting guidance in relation to:
Management of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine Guidance

- Safe and temperature controlled storage,
- Safe vaccine handling and management of shelf life reduction processes following dilution.
- Transportation of vaccines
- Stock reconciliation

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 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:

NCCS will deliver Comirnaty® at a temperature of +2 °C to +8 °C in their original carton, or pre-packed into smaller labelled cartons. 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 vials should remain in an upright position and in the box in order to protect from light. The vials should not be refrozen.

4.2 Vaccine decommissioning

Unopened tray of 195 vials may require decommissioning by Hospitals and Retail Pharmacies. The vaccines will be decommissioned by the NCCS for the Article 23 locations e.g., GPs and HSE locations including Vaccination Clinics.

4.3 Safe handling

Comirnaty® comes in a multi dose vial and must be diluted with 1.8ml of sodium chloride (0.9%) solution for injection before use. Each vial contains 0.45ml antigen and after dilution will contain 2.25 ml and therefore up to 7 doses of 0.3mL may be available. One dose (0.3mL) contains 30 micrograms of COVID-19 mRNA Vaccine (embedded in lipid nanoparticles).
Management of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine Guidance

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose(s). The National Immunisation Advisory Committee (NIAC) advises that if more than six doses can be safely and accurately withdrawn from a vial they can be used as valid doses.

**DO NOT** pool excess vaccines from multiple vials.

**Undiluted vial**

An undiluted vial of Comirnaty® (Pfizer/BioNTech) COVID-19 vaccine may be stored for up to one month (31 days) at temperatures between +2°C and +8°C. Boxes will be labeled by the NCCS with the **USE BEFORE date and time** reflecting this new extended storage shelf life. This date should be recorded in the patient's record. Prior to use, the unopened vaccine 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 time**” is applied and written on the vial which is 6 hours from 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 discolored.

**To note:**

- The **USE BEFORE dates and time** of the vaccine must be recorded in the IT system (as stamped on the vaccine box delivered by the HSE National Cold Chain Service).
- The batch number of the vaccine must be recorded.
- The batch number of the 0.9% Sodium Chloride solution must also be recorded.
4.4 **Transportation of vaccines**

The total or cumulative duration of transit of the **undiluted** product at temperatures between +2 °C and +8 °C, must not exceed 12 hours. The 12 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.

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.

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

**There is no stability data for vials stored or transported on their side.**

For additional information the following document may be consulted:

[HSE Guidelines for maintaining the vaccine cold chain in vaccine cool boxes](#) (Updated 15/04/2020)

4.5 **Stock Reconciliation**

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for. Reconciliation forms for Comirnaty® (Pfizer/BioNTech) COVID-19 in an editable PDF format can be accessed at the following links

- [Comirnaty® -Vaccine Reconciliation Form for GP practices Version 1.0](#) 19 January 2021
- [Comirnaty® -Vaccine Reconciliation Form for clinic settings Version 1.0](#) 4 March 2021

5. **Consumables, Patient Information Leaflet (PIL) & RecordCards 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 provide all necessary supplies, to handle, prepare and
Management of Comirnaty® (Pfizer/BioNTech) COVID-19 Vaccine Guidance

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 purchased and FMDed 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 & Monitoring of Wastage**

A physical stock count of COVID-19 vaccine vials should be performed. 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 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.

Records of vaccine dose reconciliation should be maintained at the site.
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.
Management of COVID-19 Vaccine Moderna®
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

COVID-19 Vaccine Moderna® will be delivered frozen between -25°C and -15°C by the National Cold Chain Service (NCCS) to the site. The site will take ownership of 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


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 COVID-19 Vaccine Moderna®. Separate documents are available for other COVID-19 vaccines.
4. Purpose

The purpose of this document is to outline the management of the COVID-19 Vaccine Moderna® at the vaccination centre level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Safe vaccine handling including management of shelf life reduction processes following thawing and first puncture of the vial.
- Vaccines decommissioning
- Stock reconciliation

The document 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 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.

COVID-19 Vaccine Moderna® will be delivered frozen between -25°C and -15°C to each vaccination clinic. Each box of vaccine has 10 multidose vials (MDV).

Receipt delivery of stock and scan stock onto the system as you unpack the delivery. Place immediately in the fridge at a temperature of +2°C to +8°C, in original boxes to protect vials from light, for maximum 30 days.

4.2 Safe vaccine handling including management of shelf life reduction processes following thawing and first puncture of the vial

One dose (0.5 mL) of COVID-19 Vaccine Moderna® contains 100 micrograms of messenger RNA (mRNA) (embedded in SM-102 lipid nanoparticles).

When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for additional dose(s). The National Immunisation Advisory Committee advises that if more than ten doses can be safely and accurately withdrawn from a vial they can be used as valid doses. There
should be no pooling of excess vaccine volume from multiple vials.

Record the **USE BEFORE date and time** on the vaccine box by adding 30 days from date and time of arrival of the vaccines.

When ScanVax is available (Hospitals, HSE Central Vaccination Clinics) this will automatically recalculate Moderna USE BEFORE date and time when a Moderna box is scanned at the point of receiving it into stock. When a printer is available, print a new USE BEFORE label and apply it on the box. If a printer is not available, manually record the USE BEFORE date and time displayed on the screen onto the box.

Vaccines can be thawed in a pharmaceutical fridge or at room temperature as follows:

✔ Pharmaceutical fridge: Between +2°C and +8°C for 2 hours and 30 minutes. (The vaccine should remain at room temperature for 15 minutes prior to administration).

OR

✔ Room temperature: Between +15°C and +25°C for 1 hour

**Note:** Once thawed, the product should not be re-frozen.

**Unopened** vials may be kept between +8°C and +25°C for up to 12 hours after which the product must be discarded.

Once the vial is **punctured** for drawing up the **DISCARD date and time** should be recorded on the vial after the initial puncture. It is calculated by adding 6 hours to the time of this initial puncture.

The 12- hour storage at room temperature limitation must also be observed and tracked.

For example: if the unopened vial is at room temperature for 10 hours (from 08:00 until 18:00), the initial puncture is at 18:00 and the vial remains at room temperature, then the vial must be discarded at 20:00 (as it reached 12 hours at room temperature.

After initial puncture, the vaccine vial can be kept between 2°C to 25°C.

**4.3 Vaccine decommissioning**

COVID-19 vaccines will be serialised and once the serialised boxes become available these boxes will require to be decommissioned. Decommissioning will be done by Hospitals and by Retail Pharmacies or by NCCS as per Article 23.
COVID-19 vaccines delivered to GPs, HSE locations including Vaccination Clinics will be decommissioned by the NCCS as these locations are exempt.

Covid-19 Moderna vaccine is serialised and will require to be decommissioned.

4.4 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for.

COVID-19 Vaccine Moderna® Reconciliation Forms can be found at the links below. Please note they are editable PDF

- Moderna® -Vaccine Reconciliation Form for GP practices Version 1.0

- Moderna® -Vaccine Reconciliation Form for clinic settings Version 1.0

5. Consumables, Patient Information Leaflet (PIL), 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
  Refer to National Immunisation Advisory Committee Guidelines

  The epinephrine will be purchased and FMDed 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 & Monitoring of Wastage**

A physical stock count of COVID-19 vaccine vials should be performed. The physical stock count of the COVID-19 AstraZeneca® 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 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.

Records of vaccine dose reconciliation should be maintained at the site.

7. **Health & Safety**

There are no special handling requirements for routine handling and dealing with COVID-19 Vaccine Moderna®

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of COVID-19 Vaccine Moderna® Guidance at Vaccination Clinics

**Thaw Each Vial Before Use**
Vials images for illustrative purposes only

- **2 hours and 30 minutes in refrigerator**
  - 2° to 8°C
- **1 hour at room temperature**
  - 15° to 25°C

**Instructions Once Thawed**

**Unpunctured Vial**

- **Maximum times**
  - 30 days
  - 12 hours

**Cool storage up to room temperature**

**After first dose has been withdrawn**

- **Maximum time**
  - 6 hours

Vial should be held between 2° to 8°C. Record the date and time of first use on the vial label. Discard punctured vials after 6 hours.

With each 0.5 mL dose of vaccine from the vial using a new sterile needle and syringe for each injection to prevent transmission of infectious agents from one person to another. The dose in the syringe should be used immediately.

Once the vial has been punctured to withdraw the initial dose, the vaccine should be used immediately and be discarded after 6-hours.

Any unused vaccine or waste material should be disposed of in accordance with local requirements.

**NEVER** refreeze thawed vaccine

**Administration**

Swirl vial gently after thawing and before each withdrawal. The vaccine comes ready to use once thawed. **Do not shake or dilute.**

Prior to injection, inspect each dose to:
- Confirm liquid is white to off-white in colour in both vial and syringe
- Verify syringes volume of 0.5 mL

The COVID-19 Vaccine Moderna may contain white or translucent product-related particulates. If dosage is incorrect, or discoloration and other particulate matter is present do not administer the vaccine.
Management of COVID-19 Vaccine Vaxzevria® (AstraZeneca) 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 current version

1. Background

Vaxzevria® (AstraZeneca) will be delivered at a temperature of +2 °C to +8 °C by the National Cold Chain Service (NCCS) to the site. The site will take ownership of the vaccine upon delivery.

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

EMA has recommended granting a conditional marketing authorisation for Vaxzevria® (AstraZeneca) on the 29th January 2021. The product information approved by the CHMP contains prescribing information for healthcare professionals can be found below:


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 Vaxzevria® (AstraZeneca). Separate documents are available for other COVID-19 vaccines.
4. **Purpose**

The purpose of this document is to outline the management of the Vaxzevria® (AstraZeneca) at the vaccination centre level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Safe vaccine handling including management of shelf life reduction processes following first puncture of the vial.
- Vaccine decommissioning
- Stock reconciliation

The document 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 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:


Vaxzevria® (AstraZeneca) will be delivered at a temperature of +2 °C to +8 °C

Each box will contain 10 multidose vials (MDV). 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 vials should remain in their original box to be protected from light.

### 4.2 Safe handling

Vaxzevria® (AstraZeneca) comes ready to use, and each vial contains at least 10 doses. One dose (0.5 mL) contains not less than 2.5 x 10^8 infectious units (Inf. U).
When low dead volume syringes and/or needles are used, the amount remaining in the vial may be sufficient for an additional dose(s). The National Immunisation Advisory Committee advises that if more than ten doses can be safely and accurately withdrawn from a vial they can be used as valid doses. There should be no pooling of excess vaccine volume from multiple vials.

The shelf life of the unopened vials is less than 6 months and they should remain in their original boxes in the fridge until the time of usage.

From the time of vial opening (first needle puncture) to administration, the product may be kept and used at temperatures up to 30°C for a single period of up to 6 hours. After this time period, the product must be discarded.

4.3 Vaccine decommissioning

COVID-19 vaccines will be serialised and once the serialised boxes become available these boxes will require to be decommissioned. Decommissioning will be done by Hospitals and by Retail Pharmacies or by NCCS as per Article 23.

COVID-19 vaccines delivered to GPs, HSE locations including Vaccination Clinics will be decommissioned by the NCCS as these locations are exempt.

Vaxzevria is serialised and must be decommissioned.

4.4 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for.

Vaxzevria® (AstraZeneca) Reconciliation Form can be found at the following links below. Please note they are editable PDFs:

- Vaxzevria® (AstraZeneca) - Vaccine Reconciliation Form for GP practices Version 1.0
  
  https://www.hse.ie/eng/health/immunisation/hcpi/co/uid19vaccineinfo4hps/azavcavaccinereconciliati
  onfor m.pdf

- Vaxzevria® (AstraZeneca) - Vaccine Reconciliation Form for clinic settings Version 1.0
  
5. **Consumables, Patient Information Leaflet (PIL) & 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 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**


The epinephrine will be purchased and FMDed 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 & Monitoring of Wastage**

A physical stock count of COVID-19 vaccine vials should be performed. The physical stock count of the Vaxzevria® (AstraZeneca) 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.

Records of vaccine dose reconciliation should be maintained at the site.

7. **Health & Safety**

There are no special handling requirements for routine handling of Vaxzevria® (AstraZeneca). However, Vaxzevria® (AstraZeneca) contains genetically modified organisms (GMOs). Should a spillage occur this should be disinfected with an appropriate antiviral disinfectant (active on coronavirus). To note that genetically modified organisms (GMOs) refers to the chimp adenovirus vector system which has been inactivated and cannot replicate *in vivo*.

Health and Safety risk assessments should be undertaken locally to ensure these risks are adequately controlled.
Management of COVID-19 Vaccine Janssen®

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


COVID-19 vaccine Janssen® will be delivered stored at -25°C to -15°C in freezers in the National Cold Chain Service (NCCS). Once removed from the freezers and transferred to fridge conditions of +2°C to +8°C, a label will be applied to the box with a “use before” date and time calculated at 3 months from removal from freezer. The box will be labelled prior to dispatch.

The site will take ownership of the vaccine stored at +2°C to +8°C upon delivery.

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 COVID-19 Vaccine Janssen®. Separate documents are available for other COVID-19 vaccines.

4. Purpose

The purpose of this document is to outline the management of the COVID-19 vaccine Janssen® at the vaccination clinic level, and to provide supporting guidance in relation to:

- Safe and temperature controlled storage
- Vaccines decommissioning
- Safe handling, including management of shelf life reduction processes following thawing and first puncture of the vial
- Stock reconciliation
Management of COVID-19 Vaccine Janssen® Guidance at vaccination Clinics

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 Vaccines decommissioning

COVID-19 vaccines will be serialised and once the serialised boxes become available these boxes will require to be decommissioned. Decommissioning will be done by Hospitals and by Retail Pharmacies or by NCCS as per Article 23.

COVID-19 vaccines delivered to GPs, HSE locations including Vaccination Clinics will be decommissioned by the NCCS as these locations are exempt.

4.3 Safe handling, including management of shelf life reduction processes following thawing and first puncture of the vial

COVID-19 vaccine Janssen® comes as a multi dose vial (MDV) containing at least 5 doses. Boxes may contain 10 vials or 20 vials

Initially some boxes may not be serialised and therefore will not require to be decommissioned:
If boxes are NOT serialised (black rectangle) they will not need to be decommissioned. While if boxes are serialised (white with lines rectangle), they will need to be decommissioned.

The boxes must be checked to determine whether they are serialised and require decommission.

COVID-19 Janssen® will be delivered at temperature of +2°C to +8°C by NCCS.

Prior to delivery to vaccination sites by NCCS the boxes will have been thawed and stored at +2°C to +8°C. The NCCS will label the vaccine box with the new storage condition and **USE BEFORE date and time**: this is 3 months after thaw (and within original expiry date). This should be recorded in the patient record.

This “**USE BEFORE**” label will only be on the BOX.

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 vials should remain in their original box to be protected from light, for maximum of 3 months (and within original expiry date).

*Unopened* vials may be kept between +9°C and +25°C for up to 12 hours after which the product must be discarded. This is not recommended storage but may guide decisions for use in temporary temperature excursions.

**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.

4.4 Stock Reconciliation

It is a requirement that vaccines delivered are tracked and any vaccine “wastage” i.e. not used for any reason are accounted for.

COVID-19 Vaccine Janssen® Reconciliation Forms can be found at the links below. Please note they are editable PDF:


Management of COVID-19 Vaccine Janssen® Guidance at 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, Security & Monitoring of Wastage

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 COVID-19 vaccine Janssen® 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.

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.

Records of vaccine dose reconciliation should be maintained at the site.

Any un-opened and unused vaccines vials must also be accounted for. A reconciliation form must be completed and submitted as per standard procedure and vials returned to NCCS following collection arrangements.
7. Health & Safety

There are no special handling requirements for routine handling of COVID-19 Vaccine Janssen®. 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.
SAMPLE CHECKLIST FOR COVID-19 VACCINATION CLINICS

Note: This is a supportive document for the safe practices for COVID-19 vaccination. Additional requirements may arise based on the type of vaccines, cohort of vaccinators, recipients and location of the clinics.

### Before the Vaccine clinic

<table>
<thead>
<tr>
<th>Physical Environment / Layout of the Vaccine clinic</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES NO a designated space for registration</td>
</tr>
<tr>
<td>YES NO awaiting area for patients to be called for vaccination</td>
</tr>
<tr>
<td>YES NO a designated clean area for vaccine storage and preparation in the clinic.</td>
</tr>
<tr>
<td>YES NO a designated area for vaccine administration</td>
</tr>
<tr>
<td>YES NO area for post vaccine observation for 15-30 minutes with adequate space for physical distancing and also a private space for medical emergencies (anaphylaxis management)</td>
</tr>
</tbody>
</table>

### Documentation

(Check for most up to date version of documents www.immunisation.ie)

<table>
<thead>
<tr>
<th>YES NO Clinical and administrative guidance for Vaccinators</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES NO copy of a relevant COVID-19 vaccine medicine protocol (for nurse/midwife vaccinators only)</td>
</tr>
<tr>
<td>YES NO anaphylaxis management in the community- Copy of an algorithm <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf</a></td>
</tr>
<tr>
<td>YES NO copy of information on Cold chain management or access to the same <a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/">https://www.hse.ie/eng/health/immunisation/hcpinfo/vaccineordering/</a></td>
</tr>
<tr>
<td>YES NO vaccination record cards and HSE advice leaflets for after vaccination for the recipients (if hard copies are available)</td>
</tr>
<tr>
<td>YES NO current up to date copies of: HSE vaccine information leaflets and European Medicines Agency Patient Information Leaflets (please see <a href="http://www.ema.eu/en">www.ema.eu/en</a> for most up to date version)</td>
</tr>
</tbody>
</table>

### Infection Prevention & Control Precautions:

<table>
<thead>
<tr>
<th>YES NO posters in relation to COVID-19</th>
</tr>
</thead>
<tbody>
<tr>
<td>o do not visit if you have symptoms of COVID-19</td>
</tr>
<tr>
<td>o physical distancing</td>
</tr>
<tr>
<td>o cough etiquette/respiratory hygiene</td>
</tr>
<tr>
<td>posters are available from the HSE website</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>YES NO hand sanitiser (alcohol gel/foam sanitiser) for staff and patients</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>YES NO PPE for the vaccinator i.e. adequate stocks of surgical face masks</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>YES NO disposable tissues available for patients and a foot pedal bin for disposal</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>YES NO disinfectant wipes for worktops and other areas</th>
</tr>
</thead>
</table>

Version 2.0 05/01/2021
<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Signs and floor markers to instruct patients to remain 2 metres apart from other patients and clinic staff have been set up before the clinic.</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Appropriate seating arrangements with physical distancing markings displayed</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>Sharps waste bin, Clinical &amp; Non clinical risk waste bins</td>
</tr>
</tbody>
</table>

**Clinical equipment**

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Access to pharmaceutical fridge or validated cool box with external display of current temperature and data logger</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>An anaphylaxis medical kit as per Guidelines (<a href="https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf">https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/anaphylaxis.pdf</a>)</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>Gloves □ Sharps boxes □ Alcohol Gel □ Clinical Tray □ Cotton wool □ Tape □ Clinical waste bags □ 70% Alcohol swabs □ needles □ syringes</td>
</tr>
</tbody>
</table>

**After the vaccination**

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
<th>Post-vaccination monitoring (recommended for 15-30 minutes): Allocation of staff for post vaccine observation for 15-30 minutes</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td>NO</td>
<td>Post vaccine documentation Vaccinations administered recorded in HSE Covid-19 Vaccination Management System</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>All patient medical information placed in a secured storage location for data protection.</td>
</tr>
<tr>
<td>YES</td>
<td>NO</td>
<td>Session report form completed</td>
</tr>
</tbody>
</table>

**Useful resources & links:**

1) Immunisation Guidelines for Ireland
   https://www.hse.ie/eng/health/immunisation/hcpinfo/guidelines/

2) Anaphylaxis management

3) HSE Guidelines for maintenance of cold-chain in vaccine fridges and management of vaccine stock

4) HSE Guidelines for maintaining the vaccine cold-chain in vaccine cool box

5) Reporting adverse reactions to the Health Products Regulatory Authority (HPRA). Details of the brand name and batch number of the vaccine must be included)
   - Online reporting at www.hpra.ie
   - Using a downloadable report form also accessible from HPRA website, which may be completed manually and submitted to the HPRA via "freepost" available from the HPRA website https://www.hpra.ie/homepage/about-us/report-an-issue/covid-19-vaccine-adverse-reaction.

6) Summary of Product Characteristics (SmPC) for the Covid-19 vaccine used in the HSE COVID-1 vaccination programme available at https://www.ema.europa.eu/en

7) In the event of a sharps injury the local procedure must be followed. This will require immediate first aid and follow-up. For further information on sharps injury please see http://www.hpsc.ie/AZ/EMIToolkit/EMIToolkit.pdf
Appendix 4. Advice from the National immunisation Advisory Committee regarding fever after COVID-19 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.