Clinical Guidance for COVID-19 Vaccination

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

Version 23.1 15/09/2021

This document has been created and updated by the HSE National Immunisation Office
<table>
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<th>15/09/2021</th>
</tr>
</thead>
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<td>Revisions since last version (22)</td>
<td>Further addition of text to reflect recent policy decision by the Department of Health and the recommendations of the National Immunisation Advisory Committee:</td>
</tr>
<tr>
<td></td>
<td>• Section 5.2: Minimum interval for Spikevax® changed</td>
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<td></td>
<td>• Section 8: Booster doses for those aged 65 and older living in Long-term care facilities, and those aged 80 and older living in the community.</td>
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<td></td>
<td>• Section 10: Guillain-Barre syndrome added as a very rare adverse event for Vaxzevria®</td>
</tr>
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Clinical Guidance for COVID-19 Vaccination

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, dental hygienists, optometrists, radiographers and radiation therapists, paramedics, advanced paramedics, emergency medical technicians and relevant healthcare students (as per the Statutory Instruments for the administration of COVID-19 vaccines), in receipt of relevant training with regard to administration of the vaccines, who are administering vaccines on the direction of, or on behalf of, the HSE will be indemnified with regard to any adverse product liability-related events arising from their administration of the vaccine. Vaccinators working in GP surgeries and retail pharmacies however, will not be indemnified in respect of malpractice events occurring during the administration of the vaccine. Such malpractice events will be indemnified by their professional insurers.
2. Vaccine 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></th>
</tr>
</thead>
<tbody>
<tr>
<td>1. People aged 65 years and older who are residents of long-term care 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 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 risk of severe disease and death</td>
<td></td>
</tr>
<tr>
<td>6. Other people aged 65-69 Key workers essential to the vaccine programme</td>
<td></td>
</tr>
<tr>
<td>7. People aged 16-64 who have an underlying condition that puts 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></td>
</tr>
<tr>
<td>i.64-55 years</td>
<td></td>
</tr>
<tr>
<td>ii.54-45 years</td>
<td></td>
</tr>
<tr>
<td>iii.44-35 years</td>
<td></td>
</tr>
<tr>
<td>iv.34-25 years</td>
<td></td>
</tr>
<tr>
<td>v.24-16 years</td>
<td></td>
</tr>
<tr>
<td>People aged 16-64 living or working in crowded settings</td>
<td></td>
</tr>
</tbody>
</table>

*see Table overleaf*

Pregnant women should be offered COVID-19 vaccination following an individual benefit/risk discussion with their obstetric caregiver.
2.1 Medical conditions at very high risk and high-risk of severe COVID-19 disease

Those with conditions in areas shaded in blue may be associated with a suboptimal response to Vaccines. People with these conditions should be given an mRNA vaccine if practicable and timely. They also require an extended primary series (see Section 7.8)

<table>
<thead>
<tr>
<th>Medical condition†</th>
<th>Very high risk</th>
<th>High risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancer</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 All patients with advanced/metastatic cancers</td>
<td>Haematological - within 1 year  Non-haematological - within 1 year All other cancers on non-hormonal treatment</td>
</tr>
<tr>
<td>Chronic heart (and vascular) disease</td>
<td>On dialysis, or eGFR &lt;15 ml/min</td>
<td>With eGFR &lt;30ml/min</td>
</tr>
<tr>
<td>Chronic kidney disease</td>
<td>With eGFR &lt;30ml/min</td>
<td>e.g. cirrhosis or fibrosis</td>
</tr>
<tr>
<td>Chronic liver disease</td>
<td>With eGFR &lt;30ml/min</td>
<td>e.g. heart failure, hypertensive cardiac disease</td>
</tr>
<tr>
<td>Chronic neurological disease or condition</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>Chronic respiratory disease</td>
<td>Severe e.g. severe cystic fibrosis, severe COPD, severe pulmonary fibrosis</td>
<td>Other e.g. stable cystic fibrosis, severe asthma (continuous or repeated use of systemic corticosteroids), moderate COPD</td>
</tr>
<tr>
<td>Diabetes</td>
<td>HbA1c ≥58mmol/mol</td>
<td>All other diabetes (Type 1 and 2)</td>
</tr>
<tr>
<td>Immunocompromise due to disease or treatment</td>
<td>Severe e.g. Transplantation: - Listed for solid organ or haematopoietic stem cell transplant (HSCT) - Post solid organ transplant at any time - Post HSCT within 12 months Genetic diseases: - APECED2 - Inborn errors in the interferon pathway Treatment: - included but not limited to Cyclophosphamide, Rituximab, Alemtuzumab, Cladribine or Ocrelizumab in the last 6 months</td>
<td>Other e.g. High dose systemic steroids4 Persons living with HIV</td>
</tr>
<tr>
<td>Inherited metabolic diseases3</td>
<td>Disorders of intermediary metabolism/at risk of acute decompensation e.g. Maple Syrup Urine Disease</td>
<td>Disorders of intermediary metabolism not fulfilling criteria for very high risk</td>
</tr>
<tr>
<td>Intellectual disability3</td>
<td>Down syndrome</td>
<td>Intellectual disability excluding Down syndrome</td>
</tr>
<tr>
<td>Obesity</td>
<td>BMI ≥40 kg/m2</td>
<td>BMI &gt;35 kg/m2</td>
</tr>
<tr>
<td>Severe mental illness3</td>
<td>e.g. Schizophrenia, bipolar disorder, severe depression</td>
<td></td>
</tr>
<tr>
<td>Sickle cell disease</td>
<td>Sickle cell disease</td>
<td></td>
</tr>
</tbody>
</table>

1 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 ecto-dermal 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:
≥10mg per day for more than 4 weeks with one other immunosuppressant
≥20mg per day for more than 4 weeks.

Pregnant women with any of these high-risk conditions should not be excluded from timely vaccination.

3. COVID-19 vaccines

There are currently four COVID-19 Vaccines authorised for use in Ireland. In general, the vaccines are not interchangeable. The same vaccine should be used for both doses, unless contraindicated.

Most recently the National Immunisation Advisory Committee has issued recommendations regarding heterologous/mixed schedules for those who have received a 1st dose of Vaxzevria® which have been accepted by the Department of Health. Heterologous schedules have not yet been granted authorization by the European Medicines Agency.

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.

The Moderna COVID-19 vaccine, marketed as Spikevax® (COVID-19 Vaccine Moderna) was authorised for use in the EU for people aged 18 years and older following a positive scientific recommendation by the EMA on 06 January 2021.


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 following table summarises the vaccines in the HSE COVID-19 vaccination programme:

<table>
<thead>
<tr>
<th>Age Range</th>
<th>Comirnaty® (Pfizer BioNTech)</th>
<th>Spikevax® (COVID-19 Vaccine Moderna)</th>
<th>Vaxzevria® (AstraZeneca)</th>
<th>COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td>12-&lt;18 years</td>
<td>✓</td>
<td>✓</td>
<td>Unlicensed</td>
<td>Unlicensed</td>
</tr>
<tr>
<td>18 - 49 years</td>
<td>✓</td>
<td>✓</td>
<td>Should be offered an mRNA vaccine</td>
<td>Should be offered an mRNA vaccine</td>
</tr>
<tr>
<td>50-69 years</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>70 years and older</td>
<td>✓</td>
<td>✓</td>
<td>Should be offered an mRNA vaccine (but can receive the vaccine)</td>
<td>Should be offered an mRNA vaccine (but can receive the vaccine)</td>
</tr>
</tbody>
</table>
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.

Vaccines undergo rigorous checks and quality steps prior to final release from the manufacturer. During the manufacturing process, approximately 75% of manufacturing time is in quality or regulatory steps, with continuous monitoring and checks until the vials are released.

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

When a vaccinator is concerned regarding a vial the following steps should be followed:

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

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

Should vaccines be exposed to temperatures outside of these parameters please contact the National Immunisation Office immediately.

Contacts include:
Achal Gupta: mobile 087 4064810
Cliona Kiersey: mobile 087 9915452
Mariangela Toma: mobile 087 7575679
Email the immunisation inbox

Pre-drawn syringes of COVID-19 vaccines from multi-dose vials that are prepared within designated vaccine preparation areas may be available within the HSE centralised vaccination clinics (CVCs). National clinical guidance specific to CVC settings on this matter should be adhered to.
5.1 Comirnaty® (Pfizer BioNTech)

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

Table 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 initially called COVID-19 mRNA BNT162b2 (Pfizer/BioNTech). This name was displayed 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-hexydecanoate),</td>
</tr>
<tr>
<td></td>
<td>• ALC-0159 = 2-[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide</td>
</tr>
<tr>
<td></td>
<td>• 1,2-Distearoyl-sn-glycero-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>Concentrated solution of vaccine is contained in a multidose clear glass vial.</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Post dilution 6 doses.</td>
</tr>
<tr>
<td></td>
<td>If a seventh dose of 0.3ml can be safely and accurately withdrawn from a diluted vial, it is a valid dose.</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>
<tr>
<td>Preservatives</td>
<td>No</td>
</tr>
<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 21 days</td>
</tr>
<tr>
<td></td>
<td>(The National Immunisation Advisory Committee recommends an interval of 21 to 28 days)</td>
</tr>
<tr>
<td></td>
<td>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.

In a study of Comirnaty® in adolescents without evidence of prior infection aged 12 to 15 years, there were no COVID-19 cases in 1,005 participants who received the vaccine, and 16 cases out of 978 who received a placebo. The point estimate for efficacy was 100% (95% confidence interval 75.3, 100.0).

Comirnaty® (Pfizer BioNTech) storage

- The vaccine is delivered from the manufacturer to the HSE National Cold Chain Service (NCCS) at -80°C to -60°C and this storage condition is continued as 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). This new “use before” time and date is labelled by NCCS once vials are removed from ULT.
- The vaccine in each multi-dose vial requires dilution with 1.8ml of 0.9% sodium chloride.
- 0.9% sodium chloride is supplied separately to the vaccine and should be stored at room temperature.
- Undiluted vials of Comirnaty® (Pfizer/BioNTech) have a shelf life of 1 month (31 days) when stored at +2 to +8°C (labelled “use before” time and date)
- Prior to use, the unopened vial can be stored for up to 2 hours at temperatures up to 30 °C.
- After dilution, the vaccine must be kept at +2°C to +30°C and used within 6 hours after which the vial must be discarded.
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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 when stored in an ultra-cold temperature (ULT) freezer at -80°C to -60°C. This is 6 months from the date of manufacturer. 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</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). This time and date will be labelled on the box by NCCS. Before the 1 month (31 days) has passed, vials must be removed from fridge.</td>
</tr>
<tr>
<td>Maximum time from removal from ultra-low temperature freezer to expiry, when stored at +2°C to +8°C</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>Maximum time allowed from removal from storage at +2°C to +8°C fridge to dilution</strong></td>
<td>When the vaccine is diluted it must be used within 6 hours. The “discard” date and time i.e. 6 hours after dilution must be written on the vial using a 24 hour format. <strong>Note:</strong> Early batches of vials had a space for date and time of dilution. All vial labels now contain space for “discard” date and time. EMA has advised that “discard” date and time i.e. 6 hours after dilution must be written on all vials using a 24 hour format. <strong>e.g.</strong> Vial is diluted 01/01/2021 at 10.00. Discard time 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>“Discard” date and 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 within 6 hours of dilution.</td>
</tr>
</tbody>
</table>

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](http://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 21 days between doses (the National Immunisation Advisory Committee recommends an interval of 21 to 28 days). The day the first dose is given is day 0.
- 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.
- For those receiving Comirnaty® as a 2nd dose following a 1st dose of Vaxzevria, only one dose of Comirnaty® is required to complete the schedule in this situation. There should be an interval of 28 days between the Vaxzevria® (dose1) and Comirnaty® (dose 2).

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>This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.</td>
</tr>
<tr>
<td>17 to 21 days</td>
<td>No further action needed (Evidence from trial data is that this is a valid vaccine).</td>
</tr>
<tr>
<td>Longer than 21 days</td>
<td>Give the 2nd dose at whatever interval. The course does not need to be restarted.</td>
</tr>
</tbody>
</table>

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 discolouration are present

**STEP 3. LABELLING THE VIAL**

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

*If a seventh 0.3ml dose can be safely and accurately withdrawn from a diluted vial, then it can be used as valid doses
Clinical Guidance for COVID-19 Vaccination

If it is not possible to withdraw more than six 0.3mls doses from the vial, the remaining vaccine solution should be discarded. **There should be no pooling of vaccine solution from different vials.**

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

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

**Coring issues with Comirnaty® reconstitution**

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

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

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

The presence of rubber stopper particles inside the solution may be due to incorrect technique used during product administration.
STEP 1. Preparation and administration of one dose of vaccine

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

Clean top of vial with a single use 70% alcohol swab and allow it to air dry fully
Attach 23 gauge blue needle to 1ml syringe
Withdraw 0.3ml of diluted product¹
Make sure correct dose is drawn up as smaller dose may not provide protection

Ensure all air bubbles have been removed before the needle is withdrawn
Do not change the needle between the vial and the patient unless the needle is contaminated or damaged or if indicated
Administer vaccine to patient intramuscularly (See Appendix 1)
Dispose of used needle and syringe in a sharps bin

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)
- discuss very rare adverse event of myocarditis and pericarditis following vaccination and explain symptoms and to seek medical advice should they develop (see section 10)

¹ 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
5.2 Spikevax® (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>
<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>Spikevax® (COVID-19 Vaccine Moderna)</td>
</tr>
<tr>
<td>Constituents</td>
<td>Lipid SM-102 Cholesterol 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</td>
</tr>
<tr>
<td>Presentation</td>
<td>The vaccine is contained in a multidose clear glass vial.</td>
</tr>
</tbody>
</table>
| 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
21 days is the minimum interval                                                                 |
| Transportation time          | Within the 30 days storage of the unopened vaccine at +2°C to +8°C, up to 12 hours may be used for transportation.                            |
Clinical Guidance for COVID-19 Vaccination

Spikevax® (COVID-19 Vaccine Moderna) vaccine efficacy

Data from the randomised Phase 3 trial demonstrated a two-dose vaccine efficacy for Spikevax® 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 (≥86%) was observed across age, sex, and ethnicity categories and among persons with underlying medical conditions.

In a study of Spikevax® in adolescents without prior infection aged 12-17 years, there were no symptomatic COVID-19 cases in 2,163 participants who received the vaccine and 4 cases out of 1,073 who received a placebo.

Spikevax® (COVID-19 Vaccine Moderna) storage

mRNA vaccines are fragile vaccines. Correct storage is essential to ensure the stability of the vaccine. Store vials upright. DO NOT store on their side 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 19 hours before the vial should be discarded. The “discard” date and time i.e. up to 19 hours after the vial is first punctured must be written on the vial using a 24 hour format. e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00

Table 5: Storage of unopened vials of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen</td>
<td>Between -25°C and -15°C</td>
<td>Until expiry date</td>
</tr>
<tr>
<td>Refrigerator</td>
<td>Between +2°C and +8°C</td>
<td>Up to 30 days (until “use before” date)</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +8°C and +25°C</td>
<td>Up to 24 hours</td>
</tr>
</tbody>
</table>
Clinical Guidance for COVID-19 Vaccination

Table 6: Storage of opened (needle punctured) vials of Spikevax® (COVID-19 Vaccine Moderna)

<table>
<thead>
<tr>
<th>Method of Vaccine Storage</th>
<th>Temperature</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refrigerator</td>
<td>Between +2°C and +8°C</td>
<td>Up to 19 hours (until discard date and time)</td>
</tr>
<tr>
<td>Room Temperature</td>
<td>Between +2°C and +25°C</td>
<td>Up to 19 hours (until discard date and time)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Description</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Expiry date</strong></td>
<td>The date the vaccine expires 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><strong>“Use before” date and time</strong></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>
</tbody>
</table>
| **“Discard” date and time**                                                 | The vaccine has been punctured for the first time it must be used within 19 hours (within the allowed use period of 30 days at +2°C to +8°C and 24 hours at +8°C to +25°C). The “discard” date and time i.e. 19 hours after the vial is first punctured must be written on the vial using a 24 hour format.  
  e.g. vial is first punctured 29/06/21 at 11.00. Discard date and time is 30/06/2021 at 06.00  
  Any unused or partially unused diluted vials must be discarded when this time has been reached. |

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.
Clinical Guidance for COVID-19 Vaccination

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

A vaccine course started with Spikevax® should be completed with this product. The same vaccine should be used for both doses, unless contraindicated.

Two doses of 0.5mls of Spikevax® COVID-19 Vaccine Moderna are required with an interval of 28 days between doses. The minimum interval between the first and second dose is 21 days\(^2\). The day the 1st dose is given is day 0.

For those receiving Spikevax® as a 2nd dose following a 1st dose of Vaxzevria, only one dose of Spikevax® is required to complete the schedule in this situation. There should be an interval of 28 days between the Vaxzevria® (dose1) and Spikevax® (dose 2).

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

Preparation of Spikevax® (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°C 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 24 hours.

**NEVER** refreeze thawed vaccine.

\(^2\) The 4 day rule does not apply to the 21 days
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”
- (19 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

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

- Vaccine dose preparation and administration should be carried out at the point of administration i.e. beside the person to be vaccinated
- The same needle and syringe should be used to draw up and administer the vaccine
- Doses should not routinely be drawn up in advance as per best practice and the manufacturer’s instructions
- Each dose should be drawn up and immediately administered to the patient
- There should be no pooling of vaccine from different vials

Requirements for administration of vaccine

- One Spikevax® (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
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
- 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)
- discuss very rare adverse event of myocarditis and pericarditis following vaccination and explain symptoms and to seek medical advice should they develop (see section 10)

3 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>
<tr>
<td>Constituents</td>
<td>One dose (0.5 ml) contains: COVID-19 Vaccine (ChAdOx1-S*recombinant) 5 x 1010 viral particles (vp) **</td>
</tr>
<tr>
<td></td>
<td>Produced in genetically modified human embryonic kidney (HEK) 293 cells. **</td>
</tr>
<tr>
<td></td>
<td>The product contains genetically modified organisms (GMOs)**</td>
</tr>
<tr>
<td></td>
<td>L-Histidine 9</td>
</tr>
<tr>
<td></td>
<td>L-Histidine hydrochloride monohydrate Magnesium chloride hexahydrate</td>
</tr>
<tr>
<td></td>
<td>Polysorbate 80</td>
</tr>
<tr>
<td></td>
<td>Ethanol Sucrose Sodium chloride</td>
</tr>
<tr>
<td></td>
<td>Disodium edetate dihydrate Water for injections</td>
</tr>
<tr>
<td></td>
<td>Vaxzevria® (AstraZeneca) does not contain egg</td>
</tr>
<tr>
<td></td>
<td>None of the vaccine ingredients are of human or animal origin</td>
</tr>
<tr>
<td>Presentation</td>
<td>Multidose clear glass vial</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>10 doses</td>
</tr>
<tr>
<td></td>
<td>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</td>
</tr>
<tr>
<td>Dilution</td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>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</td>
</tr>
<tr>
<td>Preservatives</td>
<td>The vaccine does not contain any preservative. Standard aseptic technique should be used for withdrawing the dose for administration.</td>
</tr>
<tr>
<td>Dosage</td>
<td>0.5 ml</td>
</tr>
<tr>
<td>Number of doses required</td>
<td>2</td>
</tr>
<tr>
<td>Interval between doses</td>
<td>4-12 weeks*** 4 weeks is preferred The minimum interval is 21 days***</td>
</tr>
</tbody>
</table>

*Recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 Spike (S) glycoprotein.

**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. Please refer to FAQ section 14.21

*** The threat of new variants in circulation and evidence of suboptimal protection against the Delta variant after 1 dose means that a shorter interval (4 weeks) is preferable

4 The 4 day rule does not apply to the 21 days.
Clinical Guidance for COVID-19 Vaccination

Vaxzevria® (AstraZeneca) vaccine efficacy and effectiveness
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. This level of protection may not be the same for all COVID-19 variants.

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 was 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 a shorter 4-8 week interval is preferable to ensure earlier protection, if practicable.

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 time.

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5 The SmPC states: Alternatively, an opened vial may be stored in a refrigerator (2°C – 8°C) for a maximum of 48 hours if it is immediately returned to the refrigerator following each puncture. From a microbiological point of view, after first opening the vaccine should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user. BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE
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. 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</td>
<td>When the vaccine is first punctured it must be used within 6 hours. Do not return to the refrigerator after this time. 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. Discard time is 01/01/2021 at 16.00. This is the date and time that should be written on the vial. 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/EPAR/vaxzevria‐previously‐covid‐19‐vaccine‐astrazeneca

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

A single dose of vaccine is 0.5 ml. Two doses of Vaxzevria® (AstraZeneca) are required. The vaccine should be administered intramuscularly (IM). The preferred site of administration is the deltoid muscle.

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6 The SmPC states: Alternatively, an opened vial may be stored in a refrigerator (2°C – 8°C) for a maximum of 48 hours if it is immediately returned to the refrigerator following each puncture. From a microbiological point of view, after first opening the vaccine should be used immediately. If the vaccine is not used immediately, in-use storage times and conditions are the responsibility of the user. BEST PRACTICE IS THAT ALL VACCINE IS USED WITHIN 6 HOURS OF FIRST PUNCTURE.
A vaccine course started with Vaxzevria® (AstraZeneca) should preferably be completed with this product. The National Immunisation Advisory Committee have advised that homologous schedules (two doses of the same vaccine) are recommended for all age groups and are preferred especially for those aged under 50 years. This is recommended because of the proven effectiveness and safety of two Vaxzevria® doses against COVID-19. Therefore, Vaxzevria® should be used for both doses unless contraindicated.

However, in the event where a person who has received a first dose of Vaxzevria® does not wish to get a second dose, they should be offered an mRNA vaccine as their second dose. Only one dose of an mRNA vaccine is required to complete the schedule. The mRNA vaccine should be given at least 28 days after the 1st dose of Vaxzevria®.

**Recommended intervals between doses of Vaxzevria® (AstraZeneca)**

Individuals who have already received one dose of Vaxzevria® (AstraZeneca) should receive their second dose of Vaxzevria® 4-12 weeks after the first dose. A shorter 4 week interval is preferable because of the threat of new variants in circulation and evidence of suboptimal protection against the delta variant after one dose of Vaxzevria®.

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).

**Table 11: Interval between 2 doses**

The day the 1st dose is given is day 0.

<table>
<thead>
<tr>
<th>Interval between 1st and 2nd doses</th>
<th>Action required</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 21 days</td>
<td>This is not considered a valid vaccine. A third dose should be given 28 days after the second (invalid) vaccine.</td>
</tr>
<tr>
<td>21 to 27 days</td>
<td>No further action needed (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

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7 The 4 day rule does not apply to the 21 days.
Each vaccine 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

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\(^8\)
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)
- all 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® and of the very rare risk of capillary leak syndrome (see relevant section of the vaccine for details)
- Recipients of Vaxzevria® should be advised to seek immediate medical attention if they develop symptoms suggestive of thromboembolic events or capillary leak syndrome (see section 11.2)

\(^8\) 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</td>
</tr>
<tr>
<td></td>
<td>The vaccine is a colourless to slightly yellow, clear to very opalescent sterile suspension for intramuscular injection</td>
</tr>
<tr>
<td>Number of doses in each vial</td>
<td>Up to 5 doses</td>
</tr>
<tr>
<td></td>
<td>If more than 5 doses of 0.5mls can be safely and accurately withdrawn from a vial, they can be used as valid doses. There should be no pooling of vaccine from different vials</td>
</tr>
<tr>
<td>Dilution</td>
<td>NO DILUTION REQUIRED</td>
</tr>
<tr>
<td>Latex</td>
<td>No, the vaccine is latex free</td>
</tr>
<tr>
<td></td>
<td>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>
<thead>
<tr>
<th>Table 13: Definitions of terms for expiry date and usage times of COVID-19 Vaccine Janssen®</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Use before date</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td><strong>“Discard” date and time</strong></td>
</tr>
<tr>
<td><strong>Maximum time allowed from first puncture to expiry</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td></td>
</tr>
</tbody>
</table>

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/EPAR/covid-19-vaccine-janssen

⁹ 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
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 being vaccinated.

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

Requirements for administration of vaccine

- One 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\(^{10}\)

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

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\(^{10}\) 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.

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))
6. Contraindications and precautions to COVID-19 vaccines

6.1 mRNA Vaccines Comirnaty® (Pfizer BioNTech) and Spikevax® (COVID-19 Vaccine Moderna)

Contraindications See Table 12 for more details

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polyethylene glycol (PEG)).
- Anaphylaxis following another mRNA vaccine.
- A history of myocarditis after a previous dose of an mRNA vaccine.

Those with a contraindication to one mRNA COVID-19 vaccine should not receive another authorised mRNA vaccine. Consideration may be given to viral vector vaccination (Vaxzevria® or COVID-19 vaccine Janssen®) for anyone 18 and older including pregnant women. This should be given after an interval of at least 28 days and should be given in a specialized setting.

For those aged 12-17 years of age, discuss with an allergist/immunologist.

Precautions See Table 12 for more details

- Acute severe febrile illness; defer until recovery. Routine physical examination and temperature measurement of persons who appear to be healthy are not necessary prior to vaccination.

- Those with the following history should receive a viral vector vaccine:
  - anaphylaxis to multiple, different drug classes, with no identified allergen (may indicate PEG allergy)
  - anaphylaxis after a vaccine or a medicine that contained PEG
  - Idiopathic anaphylaxis (may indicate PEG allergy).

- If vaccination is advised for a person with prior anaphylaxis to an unrelated allergen observe for 30 minutes after vaccination.

- For those aged 12-17 years, discuss with an allergist/immunologist.

- A history of pericarditis after a previous dose of an mRNA vaccine (seek specialist advice before vaccination).

For more information see Frequently Asked Questions about COVID-19 vaccines for people with pre-existing allergic conditions www.rcpi.ie
Table 12: Vaccination of those due an mRNA COVID-19 vaccine

<table>
<thead>
<tr>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contraindication</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis after a previous dose of Comirnaty® or Spikevax® (COVID-19 vaccine Moderna®)</td>
<td>If aged 12-17, discuss with allergist/immunologist</td>
</tr>
<tr>
<td>• Anaphylaxis after polyethylene glycol (PEG) e.g. some bowel preparations for endoscopy, certain laxatives such as Movicol®</td>
<td>If aged ≥18¹ year Consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen® in a suitable facility. Observe for 30 minutes or Discuss with allergist/immunologists</td>
</tr>
<tr>
<td>• Anaphylaxis after Trometamol®: Spikevax® (COVID-19 vaccine Moderna) is contraindicated</td>
<td>Vaccinate with alternative vaccine</td>
</tr>
<tr>
<td>Special precautions</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis after multiple, different drug classes, with no identified allergen (may indicate PEG allergy)</td>
<td>Clarify if PEG is tolerated (see FAQs) If 12-17 years, discuss with allergist/immunologist</td>
</tr>
<tr>
<td>• Anaphylaxis after a vaccine, or a medicine which contained PEG</td>
<td>If aged ≥18 years¹, consider vaccination with Vaxzevria® or COVID-19 vaccine Janssen®</td>
</tr>
<tr>
<td>• Idiopathic anaphylaxis (may indicate PEG allergy)</td>
<td>Observe for 30 minutes</td>
</tr>
<tr>
<td>• Mastocytosis</td>
<td>Vaccinate as scheduled Observe for 30 minutes</td>
</tr>
<tr>
<td>• Anaphylaxis after food, venom or medication</td>
<td></td>
</tr>
<tr>
<td>Not a contraindication or a precaution</td>
<td></td>
</tr>
<tr>
<td>• Food allergy</td>
<td>Vaccinate as scheduled Observe for 15 minutes</td>
</tr>
<tr>
<td>• Family history of allergy, including anaphylaxis</td>
<td></td>
</tr>
<tr>
<td>• Previous local reaction to any vaccine</td>
<td></td>
</tr>
<tr>
<td>• Hereditary angioedema</td>
<td></td>
</tr>
<tr>
<td>• Contact dermatitis to PEG containing cosmetic product</td>
<td></td>
</tr>
<tr>
<td>• Patients with stable asthma on biologic therapy</td>
<td></td>
</tr>
<tr>
<td>• NSAID allergy</td>
<td></td>
</tr>
</tbody>
</table>

¹ including pregnant women

6.2 Viral vector vaccines Vaxzevria® and COVID-19 Vaccine Janssen®

Contraindication Vaxzevria® (AstraZeneca) See Table 13 for more details

- Anaphylaxis (serious systemic allergic reaction requiring medical intervention) following a previous dose of the vaccine or any of its constituents (including polysorbate 80) (see table 13)
- A second dose of Vaxzevria® should not be given to anyone who developed Thrombosis with Thrombocytopenia Syndrome (TTS) after a first dose of Vaxzevria®
Clinical Guidance for COVID-19 Vaccination

- Previous history of capillary leak syndrome
- Those with a contraindication to one viral vector COVID-19 vaccine should not receive another authorised viral vector vaccine. Consideration may be given to mRNA vaccination (Comirnaty® or Spikevax®) which should be given after an interval of at least 28 days

**Precautions Vaxzevria® (AstraZeneca) See Table 13 for more details**

- Acute severe febrile illness; defer until recovery.
- Advice from a relevant specialist should be sought for those with a history of an immediate severe allergic reaction to:
  - multiple, different drug classes, with no identified allergen
  - a vaccine, injected antibody preparation or a medicine likely to contain polysorbate 80
  - idiopathic anaphylaxis. If vaccination is advised, in a patient with prior anaphylaxis to an unrelated allergen, the patient should be observed for 30 minutes after vaccination.
- Those aged under 50 years including those with medical conditions with very high or high risk of severe COVID-19 disease should be offered an mRNA vaccine.
- If they have already received one dose of Vaxzevria® they should receive their second dose as scheduled in line with the NIAC recommendation that homologous schedules are preferred. However, in the event that a person has had their first dose of Vaxzevria® and does not wish to receive their second dose, they should be offered an mRNA vaccine (Comirnaty® or Spikevax®).

**Contraindications to COVID-19 Vaccine Janssen® (See Table 13)**

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

**Precautions to COVID-19 Vaccine Janssen® (See Table 13)**

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

If vaccination is advised in a person with prior anaphylaxis to an unrelated allergen, the person should be observed for 30 minutes.

mRNA vaccines are recommended for those aged under 50 years including those with medical conditions with very high or high risk of severe COVID-19 disease.

People aged 18-34 may choose to be vaccinated with COVID-19 Vaccine Janssen® for earlier protection.
Table 13: Vaccination of those due a viral vector vaccine

<table>
<thead>
<tr>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contraindication</strong></td>
<td>Consider vaccination with Comirnaty® or Spikevax® (COVID-19 vaccine Moderna®) in a suitable facility Observe for 30 minutes OR Discuss with allergist/immunologist</td>
</tr>
<tr>
<td>• Anaphylaxis after a previous dose of Vaxzevria®</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis after Polysorbate 80</td>
<td></td>
</tr>
</tbody>
</table>

**Special precautions**

<table>
<thead>
<tr>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Anaphylaxis after a vaccine, injected antibody preparation, or a medicine known to contain Polysorbate 80</td>
<td>Clarify if polysorbate 80 is tolerated (see FAQs)&lt;sup&gt;11&lt;/sup&gt; Consider vaccination with Comirnaty® or Spikevax® (COVID-19 vaccine Moderna) Observe for 30 minutes</td>
</tr>
<tr>
<td>• Unexplained anaphylaxis (may indicate polysorbate 80 allergy)</td>
<td>Discus with allergist/immunologist Vaccinate as scheduled Observe for 30 minutes</td>
</tr>
<tr>
<td>• Mastocytosis</td>
<td>Vaccinate as scheduled Observe for 30 minutes</td>
</tr>
<tr>
<td>• Idiopathic anaphylaxis</td>
<td></td>
</tr>
<tr>
<td>• Anaphylaxis after food, venom or medication</td>
<td></td>
</tr>
</tbody>
</table>

**Not a contraindication or a precaution**

<table>
<thead>
<tr>
<th>History</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Non-anaphylactic food allergy</td>
<td>Vaccinate as scheduled Observe for 15 minutes</td>
</tr>
<tr>
<td>• Family history of allergy, including anaphylaxis</td>
<td></td>
</tr>
<tr>
<td>• Previous local reaction to any vaccine</td>
<td></td>
</tr>
<tr>
<td>• Hereditary angioedema</td>
<td></td>
</tr>
<tr>
<td>• Contact dermatitis to PEG containing cosmetic product</td>
<td></td>
</tr>
<tr>
<td>• Patients with stable asthma on biologic therapy</td>
<td></td>
</tr>
<tr>
<td>• NSAID allergy</td>
<td></td>
</tr>
</tbody>
</table>

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.

6.3 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 nine 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.
7. Clinical considerations for COVID-19 vaccines

7.1 Pregnancy

Pregnant women should be offered mRNA COVID-19 vaccines (Comirnaty® (Pfizer BioNTech) or COVID-19 Vaccine Moderna®) at any stage of pregnancy following an individual 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, if pregnant women become infected with SARS-COV2 they are at increased risk of hospitalisation, at increased risk of premature delivery if symptomatic in the third trimester and at significantly higher risk of ICU admission.

There is now a growing body of evidence on the safety and effectiveness of COVID-19 vaccination – in both animal and human studies – clearly indicating that that the benefits of vaccination outweigh any known or potential risks of COVID-19 vaccination during pregnancy. Vaccination is the best way to protect both mother and baby from serious harm and mRNA vaccines should be available to pregnant women at all stages of pregnancy.

Because there is more data available about mRNA vaccines in pregnancy, compared to viral vector vaccines, these vaccines are recommended for pregnant women; 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 ongoing.

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.

Emerging data indicates that the maternal COVID-19 antibodies can cross the placenta, which may offer neonatal protection.

Second dose of Vaxzevria® (AstraZeneca) in pregnancy

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

- They may complete the vaccination course with Vaxzevria® (AstraZeneca) between 14 and 36 weeks completed gestation.
- In the event that a person has had their first dose of Vaxzevria® and does not wish to receive their second dose, they may receive an mRNA vaccine. The mRNA vaccine can be given at any stage of pregnancy at least 28 days after the dose of Vaxzevria.
7.2 Breastfeeding
There is no known reason to avoid breastfeeding. All COVID-19 vaccines can be given to women who are breastfeeding.

7.3 Fertility
There is no biologically plausible reason why the vaccines would have any effect of fertility. There is no evidence that any of the COVID-19 vaccines have any effect on fertility.

7.4 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 103/ml) consult the supervising consultant. People with mild bleeding disorders or on maintenance dose Emicizumab (Hemlibra®) do not require haemostatic cover for vaccination. Details of haemostatic cover for all others can be found in the Patient Information tab at http://www.stjames.ie/services/hope/nationalcoagulationcentre

Those with inherited coagulopathies receiving factor replacement therapy should receive 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.

7.5 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.

7.6 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.

7.7 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.
7.8 Immunosuppression due to disease or treatment
Indiviuals with immunosuppression due to disease or treatment may be vaccinated if there are no contraindications.

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

An additional mRNA vaccine dose should be given to those aged 12 and older with immunocompromise associated with a suboptimal response to vaccines who have completed their primary course, regardless of whether the primary course was of an mRNA or an adenoviral vector vaccine. This is an extended primary vaccination course.

The additional vaccine should be given after a minimum interval of two months following the last dose of an authorised COVID-19 vaccine.

See section 2 conditions that may be associated with a suboptimal response to vaccines.

This has not yet been implemented. Additional considerations need to be finalised including the statutory instrument, information materials and information for the public.

7.9 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).

7.10 People under 18 years of age
Comirnaty® (Pfizer BioNTech) and Spikevax® (Moderna) are licensed for active immunisation to prevent COVID-19 in individuals 12 years of age and older. Those of 16 years and older may give their own consent. Vaxzevria® (AstraZeneca) and COVID-19 Vaccine Janssen® are not licensed for active immunisation to prevent COVID-19 in individuals under 18 years of age.

7.11 Children
Comirnaty® (Pfizer BioNTech) and Spikevax (Moderna) have been authorised for use in children aged 12-15 years by the EMA and recommended by the National Immunisation Advisory Committee for this age-group. There is insufficient data on the safety and efficacy in children for Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen® in individuals less than 18 years.
8. Booster COVID-19 Vaccines

The following groups who have completed their primary course with any COVID-19 vaccine type are recommended a single dose of an mRNA vaccine as a booster dose

- People aged 65 years and older living in residential care facilities
- Those aged 80 years and older living in the community

Comirnaty®/Pfizer-BioNTech or Spikevax®/Moderna may be used.

The booster dose should be given after an interval of six months following the last dose of an authorised COVID-19 vaccine and can be given at the same time or at any interval before or after seasonal influenza vaccine. In exceptional circumstances, a minimum interval of two months can be used between the booster dose and the last dose of an authorised COVID-19 vaccine.

This has not yet been implemented. Additional considerations need to be finalised including the statutory instrument, information materials and information for the public.
Clinical Guidance for COVID-19 Vaccination

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 Spikevax® (COVID-19 Vaccine Moderna).
- 15 days after the second dose of Vaxzevria® (AstraZeneca)
- 14 days after COVID-19 Vaccine Janssen®

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

- 7 days after the dose of Comirnaty® (Pfizer BioNTech)
- 14 days after the dose of Spikevax® (COVID-19 Vaccine Moderna).

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>Vaccine Brand</th>
<th>Use before date and time of vaccine</th>
<th>Expiry date of vaccine</th>
<th>Use before date of vaccine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comirnaty® (Pfizer BioNTech)</td>
<td>Use before date of vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spikevax® (COVID-19 Vaccine Moderna)</td>
<td>Use before date of vaccine</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaxzevria® (AstraZeneca)</td>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
<td></td>
</tr>
<tr>
<td>COVID-19 Vaccine Janssen®</td>
<td>Batch number of vaccine</td>
<td>Batch number of vaccine</td>
<td></td>
</tr>
</tbody>
</table>

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.

Spikevax® (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

COVID-19 Vaccine Janssen:
- diarrhoea and paraesthesia (uncommon);
- hypoesthesia, lymphadenopathy, vomiting and tinnitus (rare)

Vaxzevria®:
- pain in extremity, influenza-like illness, asthenia (common)
- lethargy (uncommon), urticaria, abdominal pain (uncommon)

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, chills, 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, nausea, myalgia, fatigue</td>
</tr>
<tr>
<td>Common (≥ 1/100 to &lt; 1/10)</td>
<td>Local: injection site erythema, injection site urticarial, injection site rash</td>
<td>Local: injection site swelling,</td>
<td>Local: injection site erythema</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) pain in extremity, influenza-like illness, asthenia, 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: insomnia, lymphadenopathy, extremity pain (refer to the vaccinated arm)</td>
<td>General: lymphadenopathy, decreased appetite, somnolence, dizziness, rash, pruritus, hyperhidrosis, lethargy, urticaria, abdominal pain</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Rare (≥ 1/10,000 to &lt; 1/1,000)</td>
<td>General: acute peripheral facial paralysis</td>
<td>General: acute peripheral facial paralysis/Bell’s Palsy, facial swelling in those who have had dermatological fillers</td>
<td>Hypersensitivity reactions (e.g. rash, pruritus, urticaire, angioedema)</td>
<td>Hypersensitivity, urticarial,</td>
</tr>
<tr>
<td>Very rare (&lt; 1/10,000)</td>
<td>Myocarditis and pericarditis***</td>
<td>Guillain-Barré syndrome, Thrombosis in combination with thrombocytopenia**</td>
<td>Hypoesthesia, lymphadenopathy, vomiting, tinnitus. Thrombosis in combination with thrombocytopenia**</td>
<td>Capillary leak syndrome ***</td>
</tr>
<tr>
<td>Not known (cannot be estimated from the available Data)</td>
<td>Anaphylaxis</td>
<td>Hypersensitivity</td>
<td>Anaphylaxis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Facial swelling in those who have had dermatological fillers</td>
<td>Anaphylaxis</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Extensive swelling of the vaccinated limb</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Myocarditis and pericarditis***</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

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

EMA concluded that the cases primarily occurred within 14 days

On 9 July 2021, the EMA completed a review and recommended that myocarditis and pericarditis be added to the product information of Comirnaty® and Spikevax® as very rare adverse reactions (actual frequency unknown). EMA concluded that the cases primarily occurred within 14 days after vaccination, more often after the second dose and in younger adult men. For Comirnaty®, 145 cases of myocarditis were reported by 31 May 2021, by which time approximately 177 million doses had been administered in the EEA. For Spikevax® there were 19 cases of myocarditis reported in context of 20 million doses.

Overall, for both mRNA vaccines the observed/expected analysis in the US and Israel, has also shown a higher rate than expected in younger adult males.

In females aged 12-17 years, for each million second doses of vaccine administered, 8-10 cases of myocarditis or pericarditis might be anticipated. In males aged 12-17 years, for each million second doses of vaccine administered, 56 - 69 cases of myocarditis or pericarditis might be anticipated.

The EMA concluded that very rare cases of myocarditis and pericarditis have been reported following vaccination with mRNA vaccines, but the overall benefit risk remains favourable.

Healthcare professionals should be alert to the signs and symptoms of myocarditis and pericarditis. They should tell people receiving these vaccines to seek immediate medical attention if symptoms indicative of myocarditis or pericarditis occur. These include:

- breathlessness,
- palpitations and
- chest pain.

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

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

The National Immunisation Advisory Committee has issued 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.
Clinical Guidance for COVID-19 Vaccination

For Vaxzevria® (AstraZeneca), the EMA estimates the risk of TTS after vaccination to be around 1 in 100,000 in people aged 50 and older and 2/100,000 in people <50 years. 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. It is not yet known if there is a sex difference.

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.

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

People aged 18-34 may choose to be vaccinated with COVID-19 Vaccine Janssen® for earlier protection.

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
Clinical Guidance for COVID-19 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).

11.4 Vaxzevria® and COVID-19 vaccine Janssen® and very rare cases of Capillary Leak Syndrome (CLS)

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.

On the 9th of July 2021, the PRAC of EMA issued the results of a review of very rare cases of capillary leak syndrome following vaccination with COVID-19 vaccine Janssen®. Very rare cases of capillary leak syndrome (CLS) have been reported following vaccination with COVID-19 Vaccine Janssen, with an estimated reporting rate of one case per approximately 6 million doses. A history of CLS has been reported in at least one of the cases.

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

The EMA concluded that people who have previously had a very rare syndrome called capillary leak syndrome, must not be vaccinated with Vaxzevria® vaccine (AstraZeneca) or COVID-19 Vaccine Janssen®. 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.
(Refer to Section 6 for contraindications and precautions to Vaxzevria® and COVID-19 Vaccine Janssen®).

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 as per the NIAC recommendation that homologous schedules are recommended for all age groups and preferred for those aged under 50 years. This is recommended as the best option by NIAC because of the proven effectiveness and safety of two Vaxzevria® doses against COVID-19.
- The interval between the first and second dose should be reduced to 4 weeks if practicable to provide earlier protection against the Delta COVID-19 variant.
Clinical Guidance for COVID-19 Vaccination

- 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®.
- 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 1.6/million).
- 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 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).
- There may be circumstances where a person who has received a first dose of Vaxzevria® does not wish to get a second dose. For those who have already had a first dose of Vaxzevria® and who did not complete the vaccination schedule as recommended, an mRNA vaccine should be offered.
- Those who have received 1 dose of Vaxzevria® should be informed that a course of 2 doses of Vaxzevria® is:
  - approved and licensed by regulators as being safe and effective by the European Medicines Agency (EMA)
  - proven to be safe and very effective at preventing COVID-19 and preventing serious illness from COVID-19 because it has been tested with thousands of people as part of clinical trials
  - shown to be very effective at reducing the risk of serious illness from COVID-19 including from the Delta variant since it has been used
- Those who have received 1 dose of Vaxzevria® and are considering an mRNA vaccine as their second dose should be informed that:
  - This option is not approved and licensed by the European Medicines Agency (EMA) and is “Off-Label”
  - There is limited evidence about the safety of mixing the two different COVID-19 vaccines although there have not been safety concerns identified so far
  - The rate of mild and moderate side effects following the administration of a heterologous vaccination schedule may be higher. These include pain and induration at the injection site, myalgia, fatigue, headache, chills and feverishness and fever.
11.5 COVID-19 Vaccine Janssen® and Vaxzevria® and very rare cases of Guillain-Barré Syndrome

Information for vaccinated people
Guillain-Barré syndrome (GBS) has occurred very rarely in people who have had COVID-19 Vaccine Janssen® and Vaxzevria®

GBS is a rare neurological disorder in which the body's immune system mistakenly attacks nerves located outside the brain and spinal cord. Symptoms of GBS range from mild weakness to more severe paralysis. Most people eventually fully recover even from the most severe symptoms, while some may continue to have some degree of weakness.

People receiving COVID-19 Vaccine Janssen or Vaxzevria® should seek immediate medical attention if they develop the following:

- double vision or difficulty moving eyes
- difficulty swallowing, speaking, or chewing
- coordination problems and unsteadiness
- difficulty walking
- tingling sensations in the hands and feet
- weakness in the limbs, chest or face
- problems with bladder control and bowel function

Healthcare professionals should be alert to signs and symptoms of GBS to ensure correct diagnosis, to initiate adequate supportive care and treatment and to rule out other causes.

11.6 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.

11.7 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/

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.
12. 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.
13. **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 Spikevax® (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 9 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?**
The day that the first dose of vaccine is given is day 0
Comirnaty® (Pfizer BioNTech)
- If the second dose is given at an interval of less than 17 days, this is not considered a valid dose. A third dose should be given 28 days after the second (invalid) vaccine.
- If a dose is given between 17 and 27 days, this is considered a valid dose.

Spikevax® (COVID-19 Vaccine Moderna)
- If a dose is given at an interval of less than 24 days, it is not considered a valid dose. A third dose should be given 28 days after the second (invalid) vaccine.
- If a dose is given between 24 and 27 days, this is considered a valid dose.

Vaxzevria® (AstraZeneca)
- If a dose is given at an interval of less than 24 days, it is not considered a valid dose. A third dose should be given 28 days after the second (invalid) vaccine.
- 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.

In CVC where doses may be prepared in advance, if eight doses have been obtained from a vial, each of the syringes must be examined by another person to identify the syringe with less than 0.3ml. If all syringes contain 0.3ml then more than 1.8ml must have been added and the vial has been over-diluted.
15.10 What if a person under 12 years is given Comirnaty® (Pfizer BioNTech) or Spikevax® (Moderna) vaccine inadvertently?
The vaccine is currently licensed by the EMA from age 12 years and above only. The young person and their parent/guardians should be informed. A HSE incident form should be completed and the incident reported to the HPRA. The young person and their parents/guardians should be advised regarding the common adverse events expected after vaccination. They should also be informed of the very rare adverse event of myocarditis and pericarditis, the symptoms to be aware of, and to seek medical attention if they develop.

15.11 What if a person under 18 years is given 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. They should be advised of Thrombosis with Thrombocytopenia syndrome (TTS) reported very rarely after vaccination, and of the symptoms to be aware of, and to seek urgent medical attention should these appear. They should also be advised of the very rare reported adverse event of capillary leak syndrome and of the symptoms to be aware of. If they received COVID-19 vaccine Janssen®, they should also be advised of the very rare adverse event of Guillain-Barré syndrome and of the symptoms to be aware of.

15.12 Will a booster dose of COVID-19 vaccines be needed?
The only groups recommended to receive a booster dose of a COVID-19 vaccine are people aged 65 years and older living in long-term care facilities, and people aged 80 years and older living in the community. The need and timing for booster doses for any other groups has not been established. See Section 8. For more details.

15.13 What if a woman becomes pregnant between the first and second dose of a COVID-19 vaccine?
The woman should have had an individual benefit/risk discussion with their obstetric care prior to vaccination.

Women who are receiving a second dose of an mRNA vaccine may receive the vaccine at any stage of pregnancy.

If the woman received a 1st dose of Vaxzevria®, she may receive a second dose between 14 and 36.
If the woman choses to receive an mRNA vaccine as a second dose, the vaccine can be given at any stage of pregnancy.

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, the second dose can be given at any stage of pregnancy, following an individual benefit/risk discussion with their obstetric care giver.
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.


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 to vaccination are detailed in section 6; these are as per the recommendations of the National Immunisation Advisory Committee.

If someone has had a reaction to the first dose of a vaccine but it is not a contraindication to vaccination, it is not currently recommended to give a vaccine from a different platform (i.e., mRNA or viral vector) as a second dose. However, a person who has received a 1st dose of Vaxzevria® but has chosen not to receive a second dose may receive an mRNA vaccine at least 28 days after the 1st Vaxzevria® dose.

Please refer to Question 15.30 for more details and to the Immunisation Guidelines for Ireland Chapter 5a.

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 Spikevax® (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 15.19 and 15.20 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 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

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
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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/2020/12/09/bishops-conference-statement-welcoming-vaccines-for-the-common-good/

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\textsuperscript{12} or are on blood thinning treatments. 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 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

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.

\textsuperscript{12} The only exception to this is if they developed TTS after a previous dose of Vaxzevria® (AstraZeneca) or COVID-19 Vaccine Janssen®
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) as scheduled. 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 1.6/million). If a person has received a 1st dose of Vaxzevria and has decided not to receive a 2nd dose, they can receive an mRNA vaccine as a second dose at least 28 days after the 1st dose of Vaxzevria (see question 14.30 for details).

15.29 Should a person who has already received a first dose of Vaxzevria® (AstraZeneca) be offered a different vaccine for their second dose?

The National Immunisation Advisory Committee have recently revised their recommendations regarding heterologous (different vaccine) COVID-19 vaccination schedules. NIAC have advised that homologous (the same vaccine) vaccination schedules are recommended for all age groups and preferred especially for those aged under 50 years. This is recommended because of the proven effectiveness and safety of two Vaxzevria® doses against COVID-19. Therefore, Vaxzevria® should be used for both doses unless contraindicated. However, in the event where a person who has received a first dose of Vaxzevria® does not wish to get a second dose they can choose to get an mRNA vaccine as their second dose. Those who choose to receive an mRNA vaccine as their second dose must be informed that:

- This option is not approved or licensed by the EMA and is “off-label”
- While there is evidence of increased immunogenicity for this schedule compared to two doses of Vaxzevria®, there is no evidence that this results in increased protection against COVID-19.
- There is no evidence that this schedule has efficacy against COVID-19.
- There is limited evidence about the safety of mixing two different COVID-19 vaccines although there have not been safety concerns identified so far.
- The rate of side effects following the administration of a heterologous vaccination schedule may be higher.

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 indifferent limbs.
15.32 What is the advice if someone has received a COVID-19 vaccine outside Ireland?

Those who have documentary evidence of a complete COVID-19 vaccination course with a COVID-19 vaccine authorised by the FDA, MHRA or recommended by WHO should be considered fully vaccinated.

Those who have partially completed a COVID-19 vaccine course with a vaccine authorised by the FDA, MHRA or recommended by WHO should be offered an EMA authorised COVID-19 vaccine to complete the series, and then should be considered fully vaccinated. The minimum interval between the last vaccine dose and an EMA authorised COVID-19 vaccine is 28 days.

Those who have received a partial or complete course of COVID-19 vaccine not authorised by the FDA, MHRA or recommended by WHO should be offered a complete course of an EMA authorised COVID-19 vaccine. The minimum interval between the last dose and an EMA authorised COVID-19 vaccine is 28 days.

WHO: https://www.who.int/groups/strategic-advisory-group-of-experts-on-immunization/covid-19-materials
16. Useful links

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

Immunisation Guidelines for Ireland: Chapter 5a COVID-19.

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

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

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

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

Health Products Regulatory Authority. Human Medicines Adverse Reaction Report

HPSC COVID-19 guidance www.hpsc.ie